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FACTORS INFLUENCING GLYCAEMIC CONTROL IN DIABETICS AT THREE COMMUNITY HEALTH CENTRES IN JOHANNESBURG

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Community Health

Johannesburg, 2010

DECLARATION

I, Geraldine Antoinette Timothy, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Community Health, to the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.



Geraldine Antoinette Timothy

On the 28th day of October 2010

DEDICATION

This research project is dedicated to my husband, Mervin, and my family. Your support, motivation and encouragement were truly an inspiration.

ABSTRACT

Introduction:

The complications associated with diabetes usually occur over a long period of time and are mainly influenced by poor glycaemic control. Diabetic complications impact on the individual, the healthcare delivery system, and also have high cost implications. A number of studies have shown the management of diabetes to be sub-optimal in primary health care settings. Barriers that impair a patients' ability to achieve good glycaemic control can be looked at from a patient, health facility and health professional perspectives. Good glycaemic control will not only benefit the individual patient but will also have a positive financial impact on South Africa's already overstretched healthcare budget.

Methods:

In this cross sectional analytical study set in three Community Health Centres (CHCs) in the Johannesburg Metropolitan Health District, 418 diabetic patients were selected. An HbA_{1c} test was conducted for every patient and was used to classify patients into a well controlled glycaemic group ($HbA_{1c} < 7\%$) or a poorly controlled group ($HbA_{1c} \geq 7\%$). Differences between the two groups in terms of their risk factors for poor glycaemic control were investigated. Patient related risk factors studied included, basic demographic, treatment related, clinical, behavioural and lifestyle characteristics. Healthcare professionals and facility managers were interviewed and patient records were reviewed to describe health system challenges to providing optimal care. Univariate and multivariate logistic regression models were used to determine patient related factors influencing glycaemic control.

Results:

Of 394 patients with a measurable outcome (HbA_{1c}), only 62 (15.7%) had well controlled diabetes. The mean HbA_{1c} was similar across the three CHCs studied (p=0.464). Good glycaemic control was significantly associated with unemployment, shorter duration since diabetes diagnosis, treatment with oral medication alone and normal LDL-cholesterol levels (p<0.05). On multivariate analysis significant predictors of good glycaemic control were found to be a shorter duration since diabetes diagnosis, treatment with oral medication alone, being male, and those who were unemployed.

Numerous challenges to providing optimal diabetes care were reported by health professionals including high patient to staff ratios, lack of working equipment as well as a need to improve diabetes management skills. Record review revealed that only a limited number of patients (16%) had ever had HbA_{1c} testing.

Conclusions:

The majority (84.2%) of patients attending the selected facilities for diabetes care had poor glycaemic control. Management of diabetes in these CHCs is suboptimal. Patients with a shorter duration of diabetes, those who were male, Black African, unemployed and treated with oral medication alone were more likely to have good glycaemic control. Although the study concludes that patient related factors are at the forefront in terms of factors influencing glycaemic control, improved strategies in all spheres can only improve diabetes management at the CHCs.

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CHAPTER ONE

1.0 INTRODUCTION

The purpose of this study was to describe and determine factors that influence glycaemic control in diabetic patients attending community health centres in the Johannesburg district. This chapter gives an introduction and background to the topic, as well as a review of relevant literature.

1.1 Background

Diabetes is a complex chronic disease which accounted for 5% of all deaths globally in the year 2000.[1] In 2006, The World Health Organisation (WHO) estimated that more than 180 million people worldwide had diabetes and this number was predicted to double by the year 2030.[2] These predictions of a global increase in the burden of diabetes places the onus on world healthcare leaders to ensure that they implement effective management strategies to address this burden.

Diabetes complications such as stroke, diabetic neuropathy, amputations, coronary artery and peripheral vascular disease, renal failure and blindness have resulted in an increase in disability and have frequently been the cause of death in people with diabetes.[3] Diabetes is known to be the most common cause of non-traumatic amputations and is a leading cause of blindness worldwide.[1] Diabetes can also cause end stage renal disease, which often requires dialysis or even transplantation.[1] In comparison to the general population, persons with type 1

diabetes and type 2 diabetes have a 4 - 7 and 2 – 3 times higher death rates respectively.[4] The WHO has estimated that 80% of all diabetes related deaths occur in low and middle income countries.[2] The burden of complications and premature mortality associated with diabetes constitutes a major public health problem for most countries and creates an enormous financial burden on the healthcare system.

In Africa, it is predicted that the prevalence of type 2 diabetes will increase by 80% by 2025, as opposed to 55% globally.[3] In South Africa the prevalence rates of diabetes, already being between 4% - 6% of adults, are higher than the African average, especially in urban areas.[5] In 2000 it was estimated that 2 to 3 million people in South Africa were affected with diabetes mellitus, of which more than 1 million were undiagnosed.[6] The 2000 Burden of Disease study estimated the prevalence of diabetes among South Africans over 30 years of age to be 5.5% in the year 2000.[1] The revised estimates from the Burden of Disease 2000 report, highlighted that diabetes contributed to 3.5% of all female deaths and 1.8% of male deaths.[7] In 2004, diabetes was the sixth most common cause of death in South Africa and seventh in Gauteng.[8] The expanding burden of this disease is shown by a rise in morbidity; including a high prevalence of end-stage renal diseases, and a rapid increase in diabetes related mortality among South Africans.[9]

Studies show that risk factors associated with the development and prevalence of diabetes include age, sex, family history, high body mass index, sedentary lifestyles, unhealthy diets, ethnicity, race as well as urbanisation.[2,4] The burden of diabetes

however is mainly related to its complications, both microvascular and macrovascular. The risk factors for the development and progression of diabetic complications include hyperglycaemia, the impact of hypertension, high lipids, age, sex and genes.[2,4,10-12]

Evidence shows that good glycaemic control, as measured by glycated haemoglobin (HbA_{1c}), reduces the risk of developing diabetic complications.[1,13-17] The United Kingdom Prospective Diabetes Study (UKPDS) showed that in type 2 diabetes, each 1% reduction in mean HbA1c was associated with reductions in risk of 21% for deaths related to diabetes ,14% for myocardial infarction and 37% for microvascular complications .[18]

Diabetes and its complications, not only cause human suffering but also have a significant impact on the economy of a country and its healthcare system.[2] It has been estimated that the life time medical costs for patients with diabetes are more than double those without the disease.[19] In addition the occurrence of diabetes co-morbidities in type 2 diabetics are reported to be associated with an increase in average annual medical costs.[20] Strategies aimed at preventing the onset of diabetes complications are likely to reduce medical costs in the long term, whilst improving patients' health. In developed countries most people with diabetes are above the age of retirement, whereas in developing countries those most frequently affected are aged between 35 and 64, which is their most economically productive years.[24]

Beaglehole and Yach[21] indicated in 2003 that the improvement in terms of non-communicable disease prevention and control was occurring very slowly. The quality of care of patients with diabetes varies throughout the world.[25] They highlighted that in order to make progress in prevention and control efforts numerous bodies (including governments, relevant international agencies, non-governmental agencies, and the general population) would all need to acknowledge that public health efforts must refocus and include non-communicable diseases and their risk factors as a priority target for intervention.[33]

In Africa, health systems are geared mainly for the treatment of acute conditions rather than chronic conditions and Tavis et al[22] and Whiting et al[23] have highlighted some failings of the health systems in Africa with regards to diabetes care. These challenges include: short consultation times due to heavy patient volume, leaving little or no time for quality care or patient education; inequitable access to services; poor patient compliance to medication as well as appointment keeping; lack of physical infrastructure and equipment; deficiencies in human resources – need for more training, better utilisation of existing resources, and better supervision; inadequate drug supplies; poor service management; complications are not monitored or evaluated in a systematic manner; poor control of blood glucose; inadequate referral systems; lack of communication; poor organisation of services and poor record keeping.[22-23] Also less developed countries have less money for diabetes care therefore the care offered is likely to be inadequate.[24]

Africa is also experiencing one of the most rapid demographic transitions, a phenomenon that can be linked to the global trends of an increased prevalence of diabetes in African populations. The urbanisation of South Africa's Black population is rapidly increasing with an estimated 56% of the country's population now living in urban areas.[28] This rapid urbanisation has resulted in changes in the epidemiology of diseases in South Africa, including diabetes. Urbanisation, known to be a major risk factor for chronic disease development is associated with dietary changes which are considered more westernised. This includes the higher intake of animal protein fats and sugars.[29] Lifestyle changes associated with urbanisation include cigarette smoking, alcohol consumption and lower physical activity levels. All these factors increase the risk of developing chronic diseases, including diabetes and some may even contribute to the development of chronic disease complications.

Most chronic disease conditions are managed at the primary level of care. In South Africa chronic disease management is offered at both private and public primary health care facilities.

1.2 Statement of the Problem

Studies conducted in South Africa, mainly in the Western Cape Province; show that many diabetic patients in the public sector remain poorly controlled.[9,15,26,30-35] Diabetes management has been shown to be suboptimal with a high prevalence of unrecorded diabetic complications.[9,12,15,30-32,36-37]

The quality of diabetes patient care and glycaemic control can be influenced by patient factors, health professional factors or organisational factors[17] and numerous studies worldwide have already highlighted the various factors that hinder optimal management of this disease.[12,14-17,25,30,38] To improve quality of care, a better understanding of the various factors that are possibly associated with good glycaemic control, is essential.

Beattie et al[26] highlighted some of the obstacles to achieving good glycaemic control, in his evaluation of diabetes care at primary level facilities in SA from the 1990's, which included costs to patients, transport difficulties, lack of health education and shortcomings in clinical expertise.[26]

In 2004, The National Department of Health in South Africa issued guidelines for the management of diabetes at the primary level.[27] On the basis of evidence, these guidelines in place at the time of this study, aimed for optimal control of glycaemia as well as modifying risk factors for future diabetic complications. However, despite increasing recommendations regarding diabetes management and glycaemic control, many individuals with diabetes are not managed according to these guidelines.[2,13,15,39-41]

The complications associated with diabetes are patient specific, dependent on time of diagnosis as well as level of glycaemic control, and may occur over a long period of time. The need for the comprehensive management of diabetes is critical.

Diabetes management in South Africa has to be targeted at prevention of this disease, as well as early treatment in order to prevent complications.[27] Knowledge of factors that influence quality of care in diabetes in the Johannesburg area may therefore be helpful in implementing quality improvement programmes.

1.3 Justification for the study

Although studies have been conducted in South Africa on the management of diabetes, as well as on factors influencing glycaemic control, little has been done in Gauteng. Gauteng is the smallest province in surface area; it is regarded as the country's economic heartland and is the most densely populated province in South Africa. Despite being mainly an urban province, there is also a significant peri-urban population and high proportion of migrant workers.

This study will attempt to describe the patient, health care professional as well as health facility related factors that influence glycaemic control in the Johannesburg Metropolitan Health District. The findings of this study may enable the Gauteng Department of Health (GDoH) to develop and implement targeted interventions that could contribute to decreasing the burden of diabetes.

1.4 Literature Review

Good glycaemic control has become an important goal of diabetes care. Studies have shown that intensive diabetes management with good glycaemic control reduces microvascular as well as macrovascular complications.[18,42] Glycaemic

control is a measure / indication of whether blood glucose is maintained within a normal range in diabetic patients. Glycaemia refers to the presence of glucose in the blood. This level of blood glucose can fluctuate constantly.

Measuring glycaemic control

Glycaemic control is measured by a blood test, HbA_{1c}. The current acceptable HbA_{1c} levels are <7%, according to the American Diabetes association (ADA).[44] HbA_{1c} is used as a marker of the level of glycation (previously referred to as glycosylation) of haemoglobin. It was first used 25 years ago and has since played a role in the prediction and prevention of diabetic complications.[43] Glycation refers to the process whereby chemical linkage of glucose onto proteins, through amino groups, occurs.[43] The extent of glycation depends on the level of exposure to glucose and is expressed as a percentage of the total HbA_{1c}. It has been shown that the level of HbA_{1c} is a reflection of the level of glycaemia over the past 3 to 4 months.[43]

Recommended practice in South Africa's public sector follows the ADA guidelines[44] whilst some private sector recommendations follow the International Federation of Diabetes (IFD) guidelines. According to the national guidelines* for control and management of diabetes type 2 at primary level,[27] in South Africa, HbA_{1c} levels are

* At the time of the study, primary care facilities were guided by the National Guidelines [27] issued in 2004. The revised version was being finalised when this study was undertaken.

divided into three categories: optimal (normal HbA_{1c}); acceptable (< 2% points above normal); compromised (> 2% points above normal). These guidelines recommend that all diabetic patients have an annual HbA_{1c} test.

Influences on glycaemic control

Efforts to improve the quality of management of diabetic patients should be informed by knowledge of factors that influence glycaemic control and how these factors act as barriers or facilitators. Describing and determining factors that may influence glycaemic control enables planning and ensures better intervention programmes for diabetic patients with poor glycaemic control, in the future.

The Wagner Chronic Care Model, developed by the MacColl Institute for Healthcare Innovation more than a decade ago,[37,45] served as a basis for identifying factors to be investigated in this study. The model is a widely adopted approach to improving chronic care that has guided clinical quality initiatives in the United States of America and around the world. The basis of the model is to encourage better interactions between the patient and his/her healthcare team. The elements of the model are: clinical information systems; decision support; self-management support; delivery system design; the community and organisational leadership. The model describes how these elements work together to create a patient-centred, health care team and summarises the basic elements for improving chronic care in health systems at the community, organisation, practice and patient levels.[37] Based on this model, in this study, barriers that impair patients' ability to achieve good glycaemic control were

described from a patient, health facility and health professional perspectives (Figure 1.1).

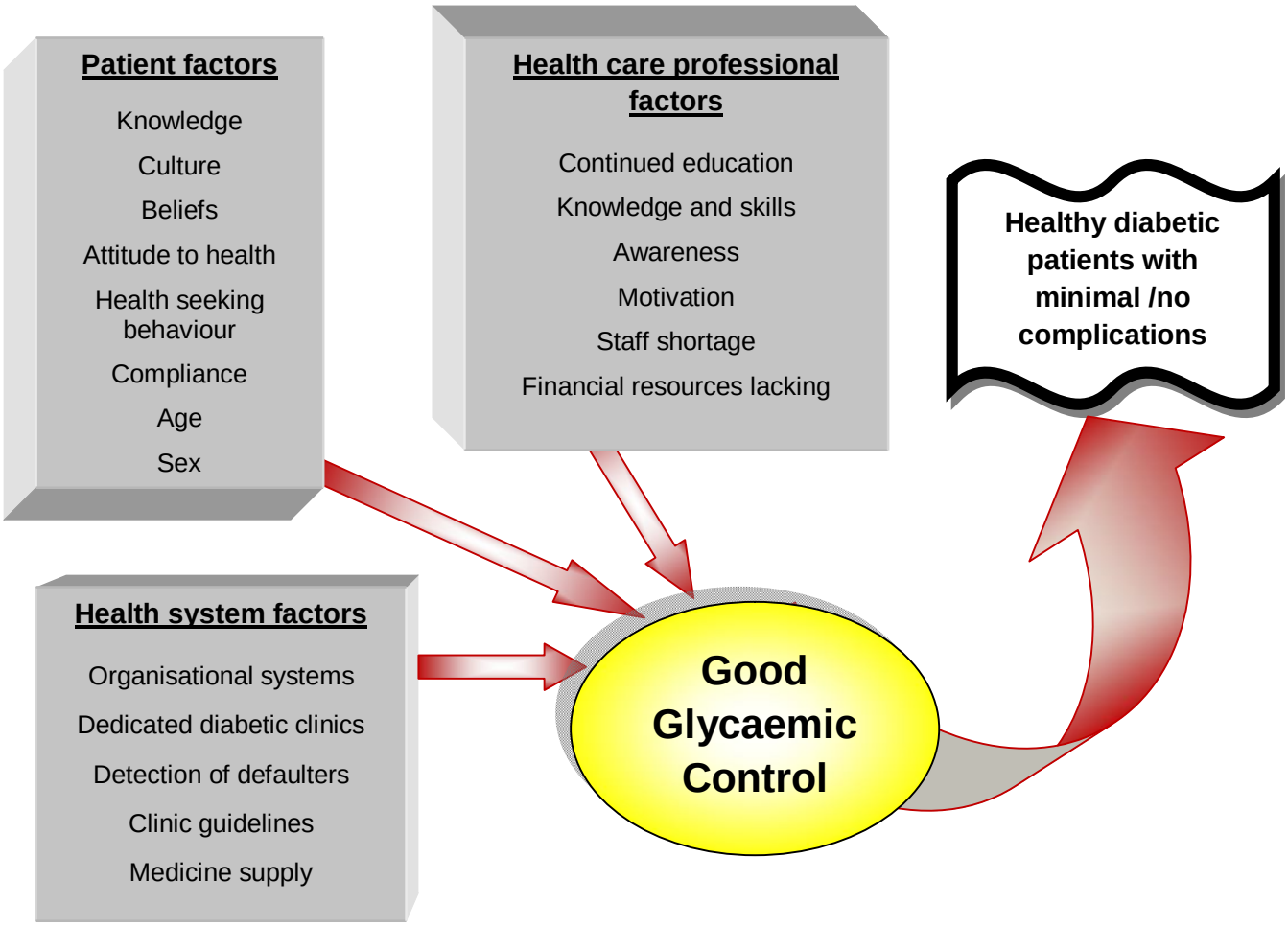


Figure 1.1 Illustration of factors investigated in this study as influences on glycaemic control

2.1.1 Patient related factors

Recognised predictors of good glycaemic control in diabetic patients include compliance with medication,[46] physical activity levels,[47] compliance with dietary advice,[38] clinic attendance,[25] diabetes education,[25] existing co-morbidities as well as

age and sex.[25] Factors such as a person's attitude to health, as well as their health seeking behaviour may be influenced by one's knowledge, culture and beliefs.[48]

Studies have shown that diabetic patients, who have an adequate knowledge about their disease and who receive regular counselling are most likely to have better glycaemic control.[49] Poor health literacy (a patient's ability to read, comprehend and act on medical instructions) is common among patients who have attained lower levels of education.[50] A study in San Francisco found that most patients with chronic medical conditions such as type 2 diabetes, asthma and hypertension had inadequate health literacy. This was independently associated with poor glycaemic control in diabetics and was found to disproportionately add to the burden of diabetes among the lower socio-economic populations.[50] A South African study showed that patients are not sufficiently educated about diabetes and thus are unable to manage their own disease well.[33] A study that researched dietary compliance in South African type 2 diabetics found that patients with low health literacy were unable to follow nutrition advice, especially when this advice was presented in ways that did not relate to the patient's cultural environment and in ways that were not easy to comprehend.[38]

Compliance with medication is a key component of self management of diabetic patients and increased compliance is associated with substantial improvements in glycaemic control.[51-52] Plausible patient challenges in adhering to diabetes medication include, poor patient education, therapy with multiple drugs, believing

one has diabetes only when one's sugar is high, worrying about side-effects of diabetes medication, lack of self-confidence in controlling diabetes and feeling medicines are hard to take (difficulty reading prescription labels).[53] Some of these challenges are potentially modifiable and should be targeted for educational interventions to improve diabetes outcomes.

According to the American Diabetes Association, home blood glucose monitoring is a component of effective therapy to achieve good glycaemic control in insulin dependent diabetics. Self monitoring of blood glucose allows patients to evaluate their individual responses to therapy and to assess whether they are achieving their glycaemic targets.[58]

Socio-economic factors play a role in diabetes outcomes including glycaemic control, morbidity and mortality.[56] Two population based studies from Sweden showed that diabetic patients who had poor glycaemic control showed characteristics of a lower social class position.[54,55] A hypothesis on the relationship between social status and health is highlighted in an article by Wray et al.[57] The authors argue that increased education levels would improve occupational prospects, resulting in higher incomes, which would result in improved health outcomes through safer and less stressful workplaces, greater access to health literacy and information and better social networking. One of these studies showed that lower social class, which was defined by economic groups according to employment, correlated with poorer glycaemic control irrespective of the person being foreign or Swedish national. These studies

highlighted that socio-economic class may have an influence on the onset or course of diabetes and may also impact on compliance to medication. Socioeconomic status has also been identified as an important factor influencing physical activity levels.[58] Lower socio–economic status was found to be related to poorly controlled diabetes but also to higher rates of obesity and hyperlipidaemia.[11]

Obesity has been considered a major risk factor for the development of type 2 diabetes. The basic metabolic abnormality of both diabetes and obesity is resistance of peripheral tissues to the action of insulin. Increasing levels of obesity and insulin resistance have been associated with poorer glycaemic control.[61-62] Cultural beliefs may play a role in obesity. This is particularly of significance in South Africa, where HIV/AIDS is associated with being underweight. Obesity on the other hand is associated with a feeling of authority, affluence and well-being.[63]

Regular physical activity is associated with a reduced risk of numerous chronic conditions and premature mortality.[64] The results of a meta-analysis by Boulé et al[65] showed a 0.66% reduction in HbA_{1c} in a group that exercised and this finding supported the theory that exercise improves glycaemic control in patients with diabetes. This study showed that exercise does not need to reduce body weight to have a beneficial impact on glycaemic control. In a study presented at the European Congress of Endocrinology in Germany 2007, looking at women with type 2 diabetes, it was found that systematic exercise combining both aerobic and strength training significantly improved oxygen consumption, power and muscle strength and

thus had benefits on glycaemic control.[66] Exercise training decreases hepatic and muscle insulin resistance and increases glucose disposal through mechanisms that are not associated with weight changes. A primary benefit of exercise for non-insulin-dependent diabetes mellitus (NIDDM) is the effect it has on reducing blood cholesterol, triglyceride levels, and body fat.[64]

A study in SA found that poorly controlled black diabetic patients were also hypertensive, obese and with dyslipidaemia.[38] Although no direct relationship between co-morbidity and poor glycaemic control has yet been established, it is important to bear in mind the possibility that co-morbidity may contribute to glycaemic control indirectly. Dyslipidaemia (which comprises hypertriglyceridaemia and reduced HDL cholesterol) cannot be attributed to being an influence on glycaemic control, but it is associated with poor control in diabetics.[67] A study in 2001 by El-Kebbi et al[68] showed that co-morbidity did not appear to limit achievement of good glycaemic control in patients with type 2 diabetes. However, a study by Odegard et al[53] in 2008, showed that good glycaemic control was considered more difficult to achieve in diabetic patients with co-morbid diseases, as a result of poorer adherence.

The reasons behind the relationship between age and glycaemic control remain unclear. A Tunisian study, with 94% of its study population having type 2 diabetes, found that younger patients are generally better at managing their glycaemic control.[25] However a study conducted amongst 15 Native American Indian tribes, the

Strong Heart Study, which investigated both type 1 and type 2 diabetes, found that younger individuals had the worst glycaemic control.[69] Although the finding of poorer control amongst younger patients was suggested to be due to the poor compliance noted in this age group, the possibility of survival bias, in that patients with higher HbA_{1C} levels may die at a younger age, could not be ruled out.[69] Other studies[52,68] however, have shown that older patients tend to keep their follow-up appointments more regularly than younger patients, and those who keep their appointments are able to achieve better glycaemic control.

Another finding from the Strong Heart Study was that women had worse glycaemic control than men.[69] Misra and Lager also mention numerous studies in the US which have found that diabetes related complications are more common in women and minority populations.[70]

A study undertaken in the UK showed that monotherapy (insulin or sulfonylurea or metformin) increased the proportion of patients who had good glycaemic control when compared to diet modifications alone.[62] However it was found that after three years, at least 50% of patients on monotherapy would have a deteriorating level of glycaemic control and by nine years, only 25% of patients on monotherapy are still controlled. The majority of diabetic patients are thought to need multiple therapies to attain good glycaemic control over time in keeping with the theory that β-cell function progressively deteriorates with time.[18]

2.1.2 Health care professional related factors

Caring for patients with diabetes is a complex process and this is reflected in the multiple potential factors that can affect the quality of care highlighted in previous studies.[14,17,25,31,71-73] Health care professionals can play a very important role in managing diabetic patients. In order to improve the care of diabetic patients, it is essential to determine the obstacles that these providers face.

Whilst some studies have identified issues such as the sex of health care professionals as well as their motivation levels as possible influences on their management of diabetes[17,25,73-74] a study by Steyn et al[30] identified that one of the main factors affecting doctors and nurses ability to provide optimal diabetes management, was staff shortage and the fact that the resultant high patient load prevented quality of care.

Reinforcement of the need for comprehensive care of diabetes patients, awareness of complications, adequate training, guideline implementation and good supervision are all essential in managing diabetic patients.[33] As part of comprehensive care, healthcare professionals need to offer counselling on diet and lifestyle modification as well as ensure that patients are well educated about their disease. It is important that these personnel are adequately trained to perform these tasks. The study that researched dietary compliance in South African type 2 diabetics also showed that although some health care professionals offered dietary counselling, these professionals had little training in nutrition and knowledge of foods that are

traditionally eaten.[38] This study highlighted that inadequate and inaccurate dietary counselling given by healthcare professionals can influence glycaemic control.[38] The quality of diabetes education received from healthcare professionals has been shown to influence glycaemic control.[15] Studies in the Western Cape, looking at the quality of care received by patients at the primary care level, showed that clinical examinations to detect treatable diabetic complications were inadequately done by health care providers.[30,32]

Healthcare staff training has been identified in numerous studies as a factor that may influence glycaemic control.[17,25,73-74] Nurses play an important care giver role in the primary care setting in South Africa. However despite this important role that they undertake, chronic diseases are not extensively covered in their training.[36] As a result South Africa nurses often lack skills to intensively deal with chronic diseases.[36,41,75-76] In addition to basic training continued education and a need for regular assessment of these health care providers' knowledge and skills regarding diabetes is essential.[33]

Steyn et al[30] also highlighted that health professionals felt that they were restricted in performing special investigations due to a lack of financial resources at primary care facilities.

The implementation of simple protocols as well as in-service training was shown to be likely to improve glycaemic control and diabetic outcomes at primary care sites.[32]

The use of guidelines ensures standardisation of care and improves patient outcomes.[72] In South Africa, studies have highlighted that although National Department of Health's guidelines for hypertension and diabetes care exist, guideline implementation remains a significant problem[39,41] In addition healthcare staff referred to the guidelines infrequently.

Barriers identified, locally and internationally,[39,41,72] to guideline adherence are:

- Need for education on the disease
- Need for education on guideline usage
- Lack of time
- Lack of confidence in clinical skills
- Complexity of the disease
- Scepticism about the guidelines
- Conflict with known practice
- Conflict with patient beliefs

2.1.3 Health facility related factors

The 2003 South African Health Review[29] showed that more patients attended public rather than private health care facilities for chronic disease management. Even though the public and private sectors in South Africa are of comparative size in terms of overall expenditure they cater for significantly varying population sizes. The public health care system is overburdened and under-resourced, often leading to overcrowded clinics, inadequate number of staff, high patient loads, short

consultation time and poor record keeping. A huge burden is placed on these public health facilities and may contribute to the quality of care delivered to chronic disease patients.

The effective management of chronic diseases is dependent on well managed health facilities. Some goals of a well managed facility include controlling cost, improving access and assuring high levels of quality of care provided to those attending the facility.

South African studies have shown deficiencies in health care delivery to people who attend public primary care facilities for chronic disease management.[12,26] One of these studies, in 1998, showed that only a third of patients with diabetes managed at the primary care level were in fact well managed.[26]

Health facility related factors found to influence diabetes care include the presence of a dedicated diabetic clinic, a recall system or system to detect defaulters, reminder systems, availability of clinic guidelines, an uninterrupted supply of medication, insulin and the syringes needed as well as education programs.[25] Dedicated chronic disease clinics were introduced following a study in Tunisia, and were found to be a major success in improving the quality of care of diabetes.[25] The absence of organisational systems to support diabetes management can be a leading influence in glycaemic control.[72]

1.5 Purpose of the study

Aim

To determine factors that influence glycaemic control in diabetic patients attending three selected Community Health Centres (CHCs) in the Johannesburg metropolitan health district (JMHD), in Gauteng, with the view to enabling health care managers improve the quality of services and management of diabetic patients.

Objectives

1. To determine the proportion of diabetics attending at the CHCs who are well controlled as measured by an HbA_{1c} test.
2. To describe the factors that influence glycaemic control in diabetic patients -:
   2.1 Patient related factors
   2.2 Health care professional related factors
   2.3 Health facility related factors
3. To determine patient related factors that influence glycaemic control in diabetic patients.

CHAPTER TWO

2.0 METHODS

This chapter describes the methods used to conduct this study. The study design, setting, and the sampling strategy are described. Descriptions of data collection as well as the methods of data analysis are included.

2.1 Study Design

A cross sectional analytical study design was used for patient related factors. Primary data collection involved patient interviews and well as anthropometric measurements and blood tests. A six month retrospective review of these patients' records was also undertaken. Health care professionals and facility managers were interviewed. Health care professional and health facility factors were described only.

2.2 Study Setting

Three Community Health Centres[†] (CHCs) from the Johannesburg Metropolitan Health District (JMHD) were selected for the setting of this study. The Gauteng Provincial Health Department (GDoH) has chosen, for management purposes, to

[†] Community Health Centres (CHCs) are primary care facilities that provide comprehensive services including promotive, preventive, rehabilitative and curative care. Casualty and maternity services are available as 24-hour services. Community health services are part of a coordinated District Health System.

divide the province into districts which are co-terminus with the local government areas. JMHD is a large urban metropolitan district with a population of approximately 3.2 million people.[12] This District is subdivided into 7 administrative sub-districts (regions), referred to as A-G (Figure 2.1).



Figure 2.1 Map of the Johannesburg Metropolitan Health District showing sub-districts A to G[75]

The JMHD has approximately 107 primary health care facilities of which ten 10 are CHCs. All of the CHCs are administered by the Provincial Health Department with the exception of Alexandra CHC which is managed by a non-Governmental Organisation (NGO).

District Health Information System (DHIS) data shows that 40% of all diabetes patient visits between April 2007 and March 2008, to primary care facilities in the public sector, were to CHCs in Gauteng for the period.[78] In view of the high proportion of patients seen in such a limited number of facilities, CHCs were chosen as the study setting.

Historically, the population groups in South Africa lived in racially defined areas. Clinics that served the various areas were managed differently and these divisions persist. Because of these underlying divisions, selecting one CHC from each of the sub-districts would ensure demographic representation. All CHCs in the JMHD were ranked according to the number of diabetic patient visits during the period April 2007 - March 2008 (DHIS data) and the provincially run CHCs with the highest number of diabetic patients seen in each region were selected (Table 2.1).

Table 2.1 Data for provincially run Community Health Centres in the Johannesburg Metro Health District, summarised from District Health Information System for period April 2007- March 2008[76]

Region	CHCs	Total number of diabetic patient visits to CHC April 07-Mar 08	Rank
Region C	Discoverers	8210	6
Region D	Zola	19148	1
	Chiawelo	17970	2
	Itireleng	12259	3
	Mofolo	12048	4
	Lilian Ngoyi	4364	7
Region F	Hillbrow	10886	5
Region G	Lenasia South	3729	8
	Stretford	1042	9

* There are no CHCs in regions A , B or E.

Two CHCs were excluded from the selection process as they were considered to be potential sources of bias.

- Zola CHC (Region D) was excluded because an intervention study, looking at improving diabetic care had already been undertaken at this clinic. A Chronic Disease Outreach Program (CDOP) based on the chronic care model involved follow up of patients with diabetes mellitus and hypertension and provided support to primary health care nurses, to improve health systems for management in Soweto.[9] The program has had an impact on the knowledge of healthcare staff involved in the program as well as improved the early detection and referral of high risk, poorly controlled diabetic patients.
- Hillbrow CHC (Region F) was excluded because most of the attending diabetic patients had been down referred from Johannesburg Hospital during 2007, when the restructuring of tertiary services came into effect. The care provided at this tertiary institution was assumed to be optimal and including these patients would not reflect the management of diabetes at a primary care facility.

The selected CHCs were therefore -:

A. Chiawelo Community Health Centre (Region D)
B. Discoverers Community Health Centre (Region C)
C. Lenasia South Community Health Centre (Region G)

2.3 Study Period

Data collection took place between the 18 November and 11 December 2008. There were no public holidays during this period. The CHCs had specific days on which diabetic patients were seen and each CHC was visited four times (Table 2.2).

Table 2.2 Diabetes clinic days at Community Health Centres

CHC	Diabetic Clinic Days	Dates visited during 2008
Chiawelo	Tues, Wed	18/11, 19/11, 25/11, 09/12
Discoverers	Thurs	20/11, 27/11, 04/12, 11/12
Lenasia South	Tues, Wed	26/11, 02/12, 03/12, 10/12

2.4 Study Population

Objective 1 and 2.1

For objectives 1 and 2.1 the study population included all diabetic patients (Type I/Type 2), 18 years of age and older, who attended one of the three clinics, for diabetes care during the study period.

Exclusion criteria:

- Patients less than 18 years of age
- Those with dementia or severe psychiatric illness.
- Those who were diagnosed as having diabetes less than 6 months prior to their clinic visit during the study period. Six months was considered to be too short a period to draw conclusions regarding glycaemic control.

- Those patients who had attended the CHCs in which they were seen for less than six months. These patients would not have attended at the CHC long enough for conclusions to be made about health facility factors that may influence their care.

Objective 2.2

The study population for objective 2.2 was all nursing staff and doctors who provided care to patients with chronic diseases, including diabetes, in the selected CHCs during the study period.

Exclusion criteria:

One of the factors that may have an impact on glycaemic control is clinical practice, therefore the following staff were excluded as they would not have been in the system long enough to comment on staff related factors that could influence the glycaemic control of patients:

- Health professions employed at the CHC for less than 6 months
- Agency/locum (temporary) staff

Objective 2.3

The CHC managers were interviewed. Data were also collected by reviewing patient records.

2.5 Sampling

A sample size of 385 was calculated for this study based on the following assumptions:

- 50% of patients would have controlled glycaemia,[29]
- the true proportion of patients who have controlled glycaemia would be estimated to within 5%, and
- the proportion of patients who have controlled glycaemia would be estimated with 95% confidence.

This sample size was calculated to have sufficient observants to fit a logistic regression model accommodating 25[‡] independent factors (explanatory variables).

The aim was to sample approximately 420 patients (this was approximately a 10% overestimation of the required sample size of 385). Patients were systematically sampled. Patients were excluded if any of the exclusion criteria were fulfilled. Analysis was only conducted on those records that had a measureable outcome (i.e. HbA_{1c} result).

[‡] It is recommended that approximately 10-15 subjects per variable is necessary when performing logistic regression[59].

The number of patients that needed to be interviewed per day in each clinic was estimated. As Chiawelo had twice as many patient visits than the other two CHCs (Table 2.1) 50% of the study population was taken from this CHC. Therefore 210 patients (approximately 55 patients per day) were to be selected at Chiawelo CHC. Chiawelo CHC sees between 150-180 diabetic patients per day and every third patient was sampled starting from a random number between one and three.

The aim was to sample 100 patients each from Lenasia South and Discoverers CHC as they both indicated that they saw between 40 to 50 patients per diabetic clinic. At Lenasia South and Discoverers CHC a sample size of 25 to 30 per day was required. As both CHCs see between 40 and 50 patients per day, every second patient was sampled.

In all three clinics, if a patient did not give their consent to participate the next person was selected.

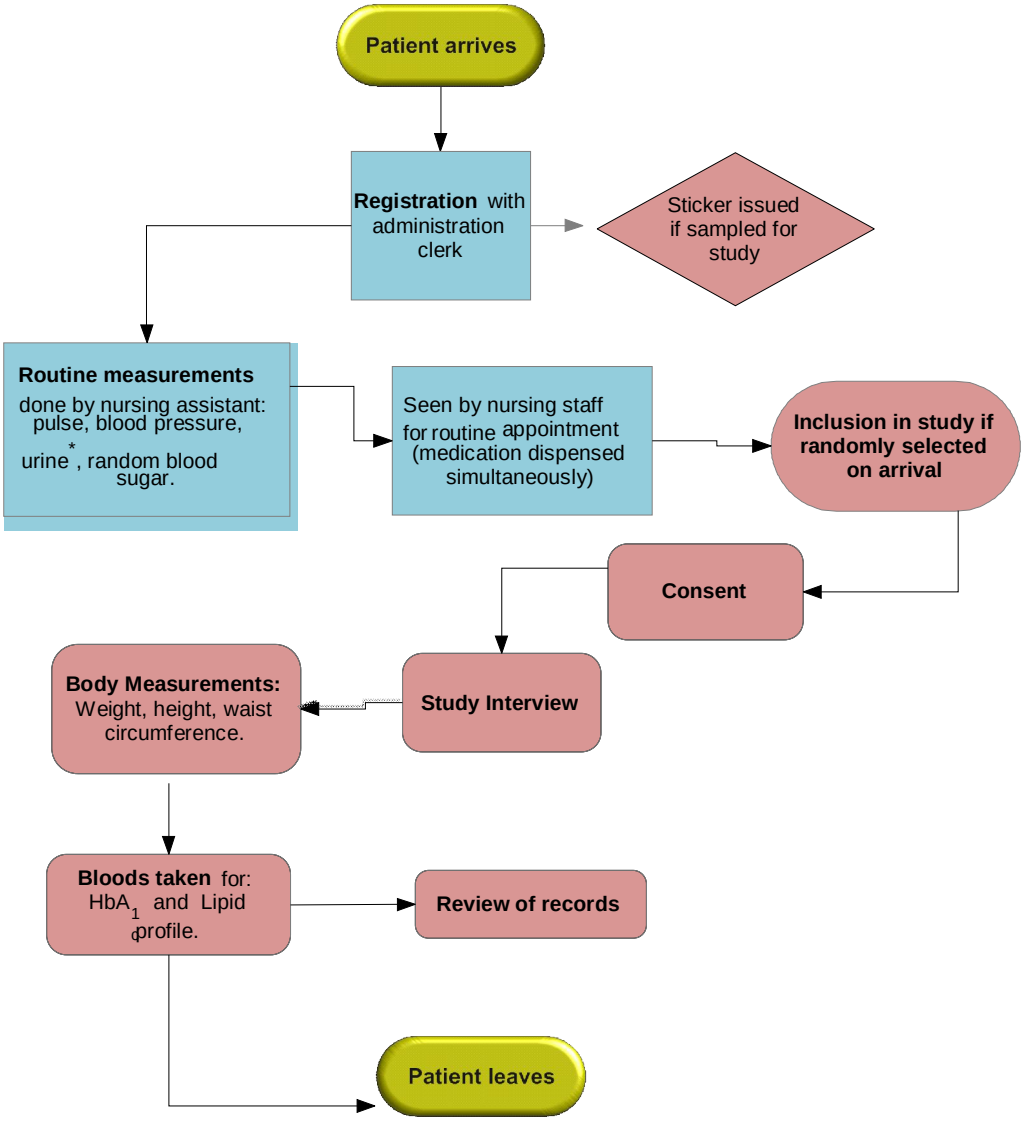
2.6 Data collection

Primary data were collected by the principal investigator and two research assistants (interviewers), which included a registered professional nurse. Research assistants were trained by the principal investigator during a half day workshop to ensure that questions were well understood and minimal inter observer variability occurred. The research assistants were fluent in local languages and conducted all interviews on patients who did not speak English. The principal investigator conducted all facility manager and healthcare staff interviews.

Data collection tools were developed for this data collection (Appendices D-G). All research tools used in this study were developed by reviewing the literature on factors influencing the care of diabetics and factors influencing glycaemic control.[17,25,30,38,46-48,57,66,70] This literature search focussed on primary care and was conducted using Pubmed and included years from 1990 onwards. Studies reviewed were restricted to those involving humans and published in English. The literature review identified many articles that reported similar factors relating to achieving good glycaemic control and only relevant articles have been referenced for this study.

2.6.1 Patient related data

The movement of diabetic patients through the diabetes clinic is illustrated in Figure 2.2 below.



*** Urine dipsticks were used to test for both glycosuria as well as proteinuria**

Figure 2.2 Flow diagram of patient movement through diabetes clinic during study period

Patient information was obtained by interviewing the patients and by reviewing the patients' medical records to look at their management over the past year as recorded in their notes. The patient interview contained questions about socio-demographic factors, disease related factors, co-morbidity related factors, and some behavioural factors. A standardised questionnaire was used for the interview process (Appendix D)

and a data collection tool (Appendix G) was used to collect data from reviewing the records. Each patient also underwent blood testing and body measurements.

Clinical Measurements

Some of the measurements, blood pressure, random blood glucose and urine dipsticks, form part of the routine management for patients with diabetes and were conducted by nursing staff at the selected CHCs. The remainder of the measurements, height, weight and waist circumference, were conducted by the principal investigator.

Weight, height, and waist circumferences were measured while the patient was wearing light clothes, having removed heavy jackets. Weight was taken to the nearest 0.5 kg, and height and waist circumference was taken to the nearest 0.5 cm.

Blood pressures were measured by nursing staff with a sphygmomanometer. The measurement was done while the patient was in a sitting position with the arm at the level of the heart after 5 minutes of rest.

Random blood glucose, a fingerprick sample, was measured using the Accu-Chek[§] glucometer at all study sites.

Blood tests

Blood samples were collected from each patient with their permission by either the principal investigator or a phlebotomist. The National Health Laboratory Services (NHLS) are contracted by the GDoH. The samples taken during this study were sent to and analysed by the NHLS laboratories that serviced the respective CHCs. All of the above tests were measured according to the same reference ranges by the different NHLS laboratories. Whilst diabetic patients at all three CHCs are asked to arrive for their routine appointments in a fasting state, it was difficult to verify if this was true for all patients. The tests conducted during this study, taken on the day of the interview, are highlighted in Table 2.3.

Table 2.3 Blood tests conducted during this study

Test	Rationale
HbA_{1c}	As a measure of glycaemic control
Lipids (total cholesterol and lipid profiles)	To assess presence of hypercholesterolemia

[§] Accu-chek is the brand of blood glucose-testing devices (glucometers) manufactured by Roche Diagnostics. Kits consist of an electronic monitor which measures blood glucose via inserted one-time-use "strips" and a lancet device which fires a sharp needle marginally through the epidermis of the finger in order to allow a small amount of blood to be squeezed onto the strip in the monitor.

Details of laboratories and methods utilised for blood testing are provided in Appendix C.

The NHLS Thusano Database was reviewed to determine if patients included in the study had previously had a blood test for HbA_{1c}.

2.6.2 Health Professional Data

Health care professional interviews were conducted face to face, using the health care professional questionnaire (Appendix E). Questions related to the number of years since qualifying, time employed at the CHC, knowledge about basic diabetes care, knowledge of normal ranges of blood tests relevant to diabetes care, continued diabetes education, challenges experienced whilst working in the diabetes clinic, and their perception of their skills were posed. These questions were a combination of both closed and opened ended types.

2.6.3 Facility Related Data

Information on each health facility and the possible factors that might influence glycaemic control were collected by:

- Face to face interviews with clinic managers using the 'Health Facility Review' data sheet (Appendix F). As part of the health facility manager interview, enquiries were made about whether the facility had a dedicated diabetic clinic, whether an appointment system and a system to detect defaulters existed at the facility for diabetes clinics. The interview also involved collecting information on the systems that existed for ensuring good quality diabetes care.

- The availability of equipment needed for comprehensive diabetes care at each facility was assessed with a separate data collection sheet (Appendix H).

  The following equipment was looked at in terms of the total number present at each clinic, as well as total number in working condition:

  - Weighing scales
  - Glucometers
  - Sphymanometers (Blood pressure machines)
  - ECG Machines and the availability of ECG paper
  - Snellens Charts
  - Height Scales
  - Fundoscopes - battery availability and functioning light
  - Tape Measures

Data from patient interviews from closed questions on patient satisfaction with overall care received at the facility and accessibility were also used in describing health facility related factors.

2.6.4 Study Variables

Table 2.4 A list of objectives and variables utilised in the study

OBJECTIVE	VARIABLES
1. To determine the level of glycaemic control of diabetes at the selected CHCs	HbA_{1c} <7 = Good glycaemic control HbA_{1c} ≥7 = Poor glycaemic control

2.1 To determine patient factors influencing glycaemic control	**Demographic Characteristics:** Gender Race Age Employment status Education level Socio-economic score **Disease related characteristics:** Type of diabetic treatment Time since diagnosis Length of time attending CHC Self reported compliance with medication **Co-morbid conditions:** Hypercholesterolaemia Dyslipidaemia Hypertension Obesity **Behavioural/lifestyle Characteristics** Alcohol consumption Physical activity levels Fruit and vegetable consumption
2.2 To determine health care professional factors influencing glycaemic control	Demographic information of health care professional Level of qualifications and training specific to diabetes Perceived work load Attitudes to diabetes management Challenges faced by staff in working in chronic disease clinics Patient perceptions about education on diabetes received Patient perceived satisfaction with diabetes care National diabetic guideline adherence Perceived level of own diabetic management skills
2.3 To determine health facility related factors that influence glycaemic control	Patient satisfaction with service delivery Presence of dedicated chronic diseases clinics Staff complement overall and in diabetic clinic Total number of patients seen at clinic – overall and in diabetic clinic Total number of patients seen in the chronic disease clinic

	Total number of new diabetics
	Total number of diabetic follow ups per month
	Presence or absence of system to detect defaulters
	Availability of diabetes guidelines
	Availability of diabetic drugs at the facility
	Method used to diagnose diabetes
	Good record keeping at routine visits
	Prior assessment of glycaemic control via HbA_{1c}
	Referrals for -Health promotion
	-Dietician review

2.7 Data management

Data were coded and captured using Epi-info version 3.5.1 and stored in a Microsoft Access database. To protect the integrity of the database, the Microsoft Access database was write-protected and stored, whilst copies of the database were used for analysis. For the purposes of descriptive analysis this data were exported to Microsoft Excel as well as STATA version 10. STATA version 10 was utilised for all other analysis. Data were verified with the original interview scripts to exclude duplicate records and errors. Data cleaning for all fields was conducted by looking at data ranges as well as outliers.

Managing variables

Some variables needed to be defined or calculated before they could be analysed. These were as follows:

- **Demographic characteristics:** Age was measured as a continuous variable. Patients were categorised as Black African, Coloured, Indian, or White. For purposes of data analysis the variable for level of education attained was classified into three main groups: “no formal education”, “completed secondary

education" and "did not complete secondary education." As the number of patients with tertiary education was relatively small, they were combined with those that had completed secondary education.

- **Disease related characteristics:** To determine the variable length of time as a diabetic, the difference between the dates of the patients study interview and date of diabetes diagnosis was used. Attendance at the study CHC was determined by the difference between the year the study was conducted and the year the patient reported having started diabetes clinic attendance at the CHC. Patients were classified as 'compliant' if they reported that they did not miss their medications more than once in a month and "non-compliant" if they missed their medications more than once in a month.
- **Co-morbid conditions**

  For descriptive purposes co-morbid disease variables were categorised according to the National Department of Health guidelines (2004) in South Africa, which were in effect at the time of the study.[27] In the univariate analysis these variables were used as continuous variables. Table 2.5 shows the co-morbid variables and their categories.

Table 2.5 Categorisation of variables used to describe co-morbid factors

Variable	Categories
Blood pressure	Optimal < 140/90
	Acceptable ≥ 140/90 and < 160/95
	Compromised (high risk) ≥ 160/95
Lipid Profile:	
Total Cholesterol	Optimal (< 5.2 mmol/L)
	Suboptimal (≥ 5.2 mmol/L < 6.5 mmol/L)
	Compromised (≥ 6.5 mmol/L)
HDL-Cholesterol	Optimal (≥ 1.1 mmol/L)
	Suboptimal (≥ 0.9 mmol/L < 1.1 mmol/L)
	Compromised (< 0.9 mmol/L)
LDL-Cholesterol	Optimal (< 2.6 mmol/L)
	Suboptimal (≥ 2.6 mmol/L < 3.4 mmol/L)
	Compromised (≥ 3.4 mmol/L)
BMI (kg/m^2)	Optimal > 18.5 < 25
	Suboptimal 25-27
	Compromised > 27

Hypertension was considered to be present if the patient was being treated with anti-hypertensive drugs and/or self reported that he/she was a known hypertensive. Patients were considered to have dyslipidaemia if they were receiving lipid lowering drugs. Body mass index (BMI), used to determine control of body weight, was calculated as weight in kilograms divided by height in meters squared. BMI greater than or equal to 30kg/m^2 was considered obese. Internationally BMI is categorized as normal if BMI was <25 kg/m^2, overweight if BMI was 25–29.9 kg/m^2, and obese if BMI was ≥30 kg/m^2 (World Health Organization, 1995).

- **Socio- economic Indicator Score**

  A score was used to reflect the socio-economic status of participants. This score was formulated from nine assets (electricity, television, fridge, radio, microwave, video machine/DVD player, washing machine, telephone, motor vehicle). Each asset contributed one point towards the score and the study socio-economic indicator score thus ranged from 0 - 9 (poorest-richest). Factors contributing to the socio-economic indicator score were adapted from a study[80] which identified assets as significant contributors to the socio-economic score through a factor analysis.

- **Behavioural Factors**

  -A patient was considered to be an alcohol consumer if a minimum of one unit of alcohol was consumed at least once a week by the participant.

  - Physical activity was estimated by considering all physical activity undertaken by the patient in a one week period. The physical activity section of the study questionnaire was based on the International Physical Activity Questionnaire (IPAQ) short form. The IPAQ short form is an instrument designed primarily for population surveillance of physical activity among adults and has been tested and validated for use in adults' aged 15 - 69 years.[79] Patients were asked about the amount of vigorous activity, amount of moderate activity, waking and sitting undertaken by them in the week preceding the study interview. Patients were asked to report the duration in minutes per day that each of these activities

were performed as well as the total number of days per week that they would undertake such activity.

Physical activity was scored using a metabolic physical activity score by weighting the intensity (multiples of basal metabolic rate (METS)) by the duration (h/wk) of each of the activities that data had been collected for. The selected MET values[**] were derived from the IPAQ Reliability Study undertaken in 2000 - 2001 as indicated in the guidelines for data processing and analysis of the IPAQ.[79]

These scores were divided into three categories[81]:

- Category 1: Low. Lowest level of physical activity for all individuals who do not meet criteria for the other two categories.
- Category 2: Moderate. Five or more days of any combination of walking, moderate or vigorous activity achieving a total physical activity of at least 600 MET- minutes/week or three or more days of vigorous-intensity activity of at least 20 minutes per day or five or more days of moderate-intensity and/or walking of at least 30 minutes/day

[**] Walking MET-minutes/week = 3.3 * walking minutes* walking days
Moderate MET-minutes/week = 4.0 * moderate-intensity activity minutes * moderate days
Vigorous MET-minutes/week = 8.0 * vigorous-intensity activity minutes*vigorous intensity days
Total physical activity MET minutes/week= sum of Walking +Moderate + Vigorous MET-minutes/week scores.

- Category 3: High. Vigorous-intensity activity on at least 3 days achieving a minimum of total physical activity of at least 1500 MET minutes/week or 7 or more days of a combination of walking, moderate-intensity or vigorous-intensity activities achieving a minimum total physical activity of at least 3000 MET-minutes/week.

2.8 Data analysis

For descriptive purposes, means (together with standard deviation (SD)) were reported for continuous variables while proportions (percentages) were reported for categorical variables. The number and proportion of patients were recorded for each variable within the demographical, disease related characteristics, co-morbid conditions and behavioural factor groups. These proportions were described per clinic. The outcome factor was dichotomised glycaemic levels (HbA_{1c} <7% and ≥7%). The means and proportions of these variables were then compared for well controlled and poorly controlled glycaemic groups. Health care professional factors and health facility factors were described only. Means and proportions were used where appropriate. Responses to open-ended questions were listed according to common lists.

Chi squared tests, t-tests, or one-way ANOVA were used to assess significant differences between means and proportions appropriately. Pearson's/Spearman's correlation coefficients were used to examine the relationship between numerical variables. All inferential analyses were done at an alpha level of 0.05: a value of

$p<0.05$ was regarded as being significant. 95% confidence intervals were reported for all estimates.

Univariate and multivariate logistic regression models were used to determine patient related factors influencing glycaemic control. To build each model, the crude associations between potential factors and good glycaemic control were assessed using univariate logistic regression, reporting the unadjusted odds ratios. For adjusted analysis, multivariate logistic regression was undertaken, reporting the adjusted odds ratios. An initial variable selection (from all the independent variables in the study) was carried out to determine which variables could potentially be important in the final model. Three methods were used for variable selection to ensure that no potentially important variable was left out. These include: a) a plausible relationship with the outcome variable b) significant univariate relationship as well as c) exploratory automatic variable selection techniques, with probability of entry $p<0.1$ and probability of removal $p<0.15$.

Variables that were selected from these three selection techniques were used for modelling. Those that were significant ($p<0.05$) in the model as well as those that improved the model fit were retained in the final models.

During modelling, the final model was selected from a family of models on the basis of parsimony and model fit, using the likelihood ratio test, the area under the receiver operating curve (ROC) and the Hosmer-Lemeshow (HL) test of fit.[81] The area under

the ROC curve lies between zero and one and provides a measure of the ability of the model to discriminate between those with good glycaemic control and those with poor glycaemic control. A value of 0.5 suggests no discrimination, such that the model is no better than random, while values between 0.7 and 0.8 are considered acceptable, between 0.8 and 0.9 as excellent and over 0.9 are rare and considered outstanding.[81] The Hosmer-Lemeshow test is used to determine the ability of the model to accurately predict the outcome. The null hypothesis for the test says that there is no significant difference between the outcome predicted by the model and the data. If the p-value for the HL test is greater than 0.05, that means that we cannot reject the null hypothesis, indicating that the model is fit and able to well predict the outcome.

2.9 Ethical considerations

Ethics approval has been obtained for this project (Ethics clearance number: M081138) from the University of Witwatersrand Committee for Research on Human Subjects (Appendix A).

Information sheets were given to all participants (Appendix I). These information sheets were in English only, and the research assistants were able to translate to local languages. All participants provided informed consent. An attempt was made to obtain written consent from all patients. Patients who could not read were verbally told about the study and placed an X on the consent form.

The identity of all participants was kept completely confidential. Patient names were only recorded on the consent forms and were never reflected on any of the data collection forms. The unique study number allocated to each patient was also recorded on the consent forms and was the only method of identifying the patients. Only the principal investigator had access to the consent forms which link the study numbers to patient names. Blood test results were received with patient names and patient health facility numbers. Consent forms were used to link these names and numbers to the study number. This process was conducted by the principal investigator only. Once the blood results were entered in the Microsoft Access database no further identifiers could link the results to patient names. Only the study number was used for identification purposes thereafter. Data was stored in a Microsoft Access database and only the principal investigator had access to this data.

CHAPTER THREE

3.0 RESULTS

In this chapter, the study findings are presented. A description of the study population and factors influencing glycaemic control, by the three study sites, is presented. This is followed by regression analysis of these factors. Thereafter findings related to health facility and healthcare professionals are highlighted.

3.1 Introduction

A total of 418 patients fulfilled the study criteria and were included in the study. Those patients that did not have a measurable outcome for the study i.e. an HbA_{1c} result was unobtainable (either due to the sample being lost or not done) were excluded from data analysis. The final study sample consisted of 394 patients (Figure 3.1)

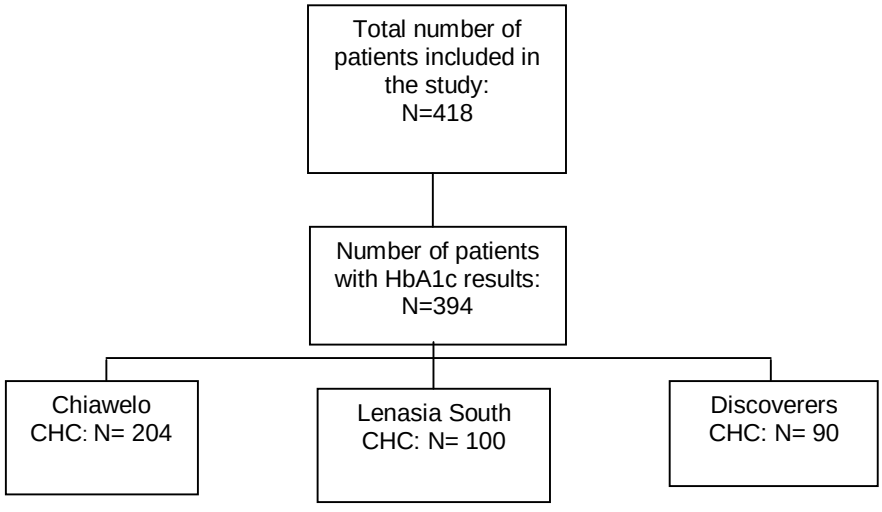


Figure 3.1 Flow diagram of number of cases forming the sample size for this study, Nov-Dec 2008

3.2 Descriptive Analysis of Patient Related Factors

3.2.1 Glycaemic Control

Of the 394 participants in this study, only 62 (15.7%) were found to have good glycaemic control (HbA_{1c} <7). The median HbA_{1c} (%) was 8.9 (mean ± SD: 9.4 ± 2.4) ranging from 4.8%-18.4%. Although the proportion of patients with good glycaemic control was low in all three CHCs, Figure 3.2 shows that Chiawelo CHC had a higher proportion of diabetics with good glycaemic control than Discoverers CHC or Lenasia South CHC (21.6% vs. 7.8% vs. 11.0%; *p*= 0.007).

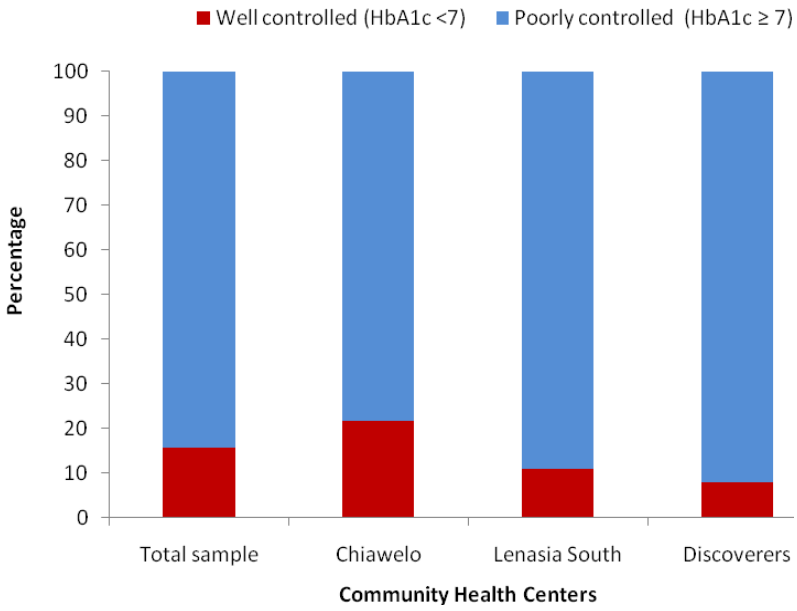


Figure 3.2 Glycaemic control per CHC, Nov-Dec 2008

Almost 20% of the total population fall into the National Department of Health (NDoH) category “not within the target range but at the same time, not requiring

additional action" (Table 3.1). Using this classification 64.5% of the study population had an HbA_{1c} level that definitely required intervention.

Table 3.1 Glycaemic control at the three CHCs as per NDoH guidelines

	Chiawelo CHC (N=204)	Discoverers CHC (N=90)	Lenasia South CHC (N=100)	Total cohort: all clinics (N=394)	*P* value
HbA_{1c} (%) (Mean ± std dev)	9.0±2.3	9.8±2.4	9.7±2.5	9.4±2.4	0.464
Good glycaemic control (%)					
. HbA_{1c}<7%	21.6	7.8	11.0	15.7	**0.004**
Poor glycaemic control (%)					
not requiring action:					
m (HbA_{1c}≥7 %< 8%)	21.6	17.8	18.0	19.8	
Requiring action:					**0.007**
n (HbA_{1c} ≥ 8%)	56.9	74.4	71.0	64.5	

The frequency of HbA_{1c} levels among diabetic clinic attendees is shown in Figure 3.3. The distribution is uneven.

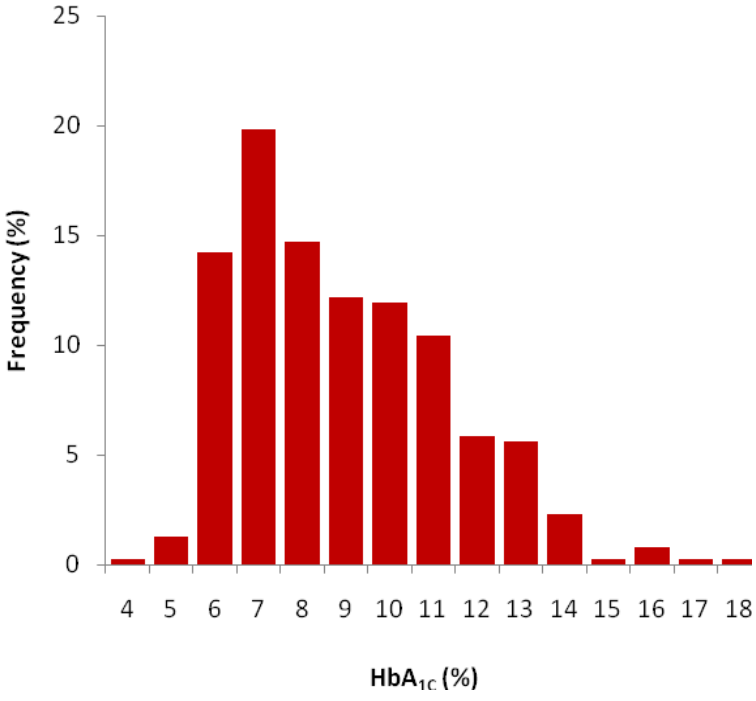


Figure 3.3 Frequency of HbA_{1c} levels among diabetic Community Health Centre attendees

3.2.2 Basic demographic characteristics of the study population

The study population was comprised of 276 females (70%) and 118 males (30%). The average age was 58.5 (SD: 11.3) and ranged from 25 years to 88 years. The mean age of females was 58.1 years (SD: 11.6) and that of males was 59.5 years (SD: 10.5) No significant difference was found between the average age of males and females. (p=0.281). Almost one third (30%) of the population was over 65 years old (Figure 3.4).

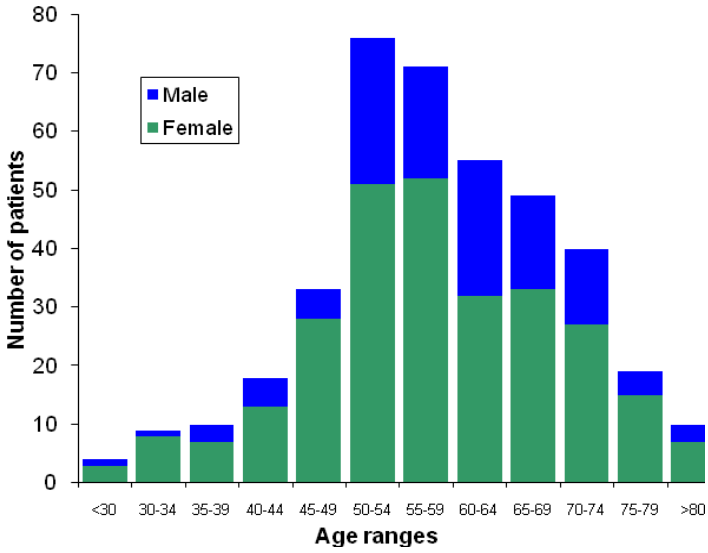


Figure 3.24 Age and sex distribution of study population, Nov-Dec 2008

Most patients in this study had not completed secondary schooling (86.3%). Only 9.4% of participants had completed their final year of school and an additional 4.1% had a tertiary education (Figure 3.5).

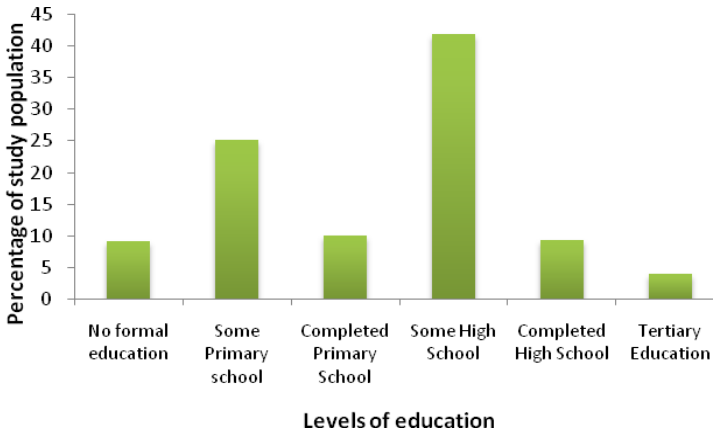


Figure 3.25 Showing levels of education in the overall study sample

Demographic characteristics of the study population in the three study sites are shown in Table 3.2.

Table 3.2 Basic demographic characteristics of participants by the Community Health Centres

	Chiawelo CHC (N=204)	**Discoverers CHC (N=90)**	**Lenasia South CHC (N=100)**	**Total cohort : all clinics (N=394)**	***P* value**
Gender n (%)					
Male	57 (27.9)	28 (31.1)	33 (33.0)	118 (30.0)	0.640
Female	147 (72.1)	62 (68.9)	67 (67.0)	276 (70.1)	
Race n(%)					
Black	204 (100)	74 (82.2)	39 (39.4)	317 (80.7)	
Indian	0	5 (5.6)	44 (44.4)	49 (12.5)	**<0.001**
White	0	2 (2.2)	1 (1.0)	3 (0.8)	
Coloured	0	9 (10.0)	15 (15.1)	24 (6.1)	
Age at time of study interview (yrs) mean±SD	60.5±10.9 (n=202)	55.7±10.2 (n=89)	56.9±12.2 (n=100)	58.5±22.3 (n=392)	**0.001**
Employment: Employed n (%)	48 (23.5)	47 (52.2)	24 (24.0)	119 (30.2)	**0.000**
Education:					
None	20 (9.8)	7 (7.8)	9 (9.0)	36 (9.1)	
Some schooling	161 (78.93)	73 (81.1)	71 (71.0)	305 (77.4)	0.675
Completed School	23 (11.27)	10 (11.11)	20 (20.0)	53 (13.5)	
Socio-economic indicator score	5.9±2.0	5.8±2.5	6.8±2.4	6.1±2.3	**0.005**

The predominant race was Black African (80.7%). Chiawelo CHCs study population was entirely Black African (100%). There was a statistically significant difference in the age of participants (p=0.001), distribution of race groups (p<0.001), proportion employed (p<0.001) and socio-economic score attained (p=0.005), between the three sites. There were no differences between the three sites in terms of gender distribution or level of education.

Lenasia South CHC had the highest proportion of participants with higher education; the highest socio-economic score as well as a low proportion of patients at this CHC were employed.

The mean socio-economic score was 6 (median 7) (Table 3.2). The components of this score are illustrated in Figure 3.6 below.

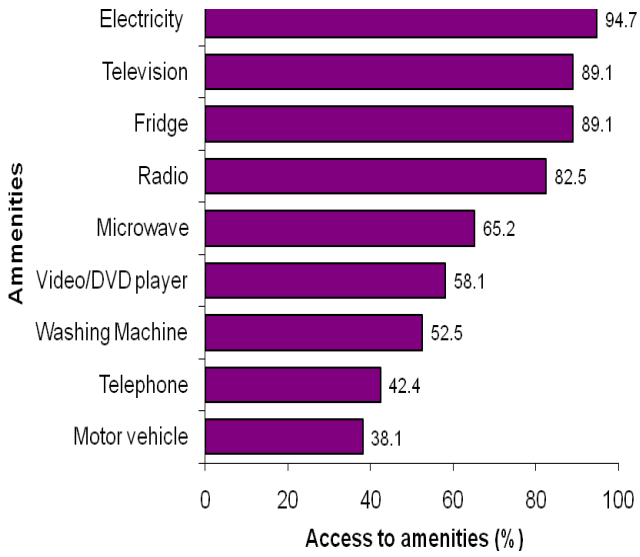


Figure 3.26 Percentages of study participants with access to amenities contributing to socio-economic indicator score

A small proportion (13.2%) scored 9 points (highest possible score) in this asset indicator score, with 2.5% and 2.8% scoring just 0 and 1 (lowest possible scores) point respectively.

3.2.3 Characteristics related to diabetes.

Relevant diabetes related characteristics are shown in Table 3.3. The mean length of time that participants had been diabetic was 9.2 years, ranging from 10 months to 42 years.

Table 3.3 Diabetes related characteristics of study participants by the various clinics

	Chiawelo CHC (N=204)	Discoverers CHC (N=90)	Lenasia South CHC (N=100)	Total cohort : all clinics (N=394)	*P* value
Time since diagnosis (years)					
<5	76 (38)	21 (24.74)	24 (24.49)	121 (31.43)	**0.028**
5-10	54 (27)	22 (25.29)	33 (33.67)	109 (28.31)	
>10	70 (35)	44 (50.57)	41 (41.84)	155 (40.26)	
Time attending current CHC for diabetes care (years) mean ± SD	7.5±.2	7.3±5.0	7.4±6.8	7.4±6.1	0.959
Type of diabetes treatment (%)					
Combined therapy	22 (10.1)	15 (16.7)	28 (28.3)	65 (16.6)	
Injectable	31 (15.3)	24 (26.7)	14 (14.1)	69 (17.6)	<**0.001**
Oral	150 (73.9)	51 (56.7)	57 (57.6)	258 (65.8)	
Medication compliance n (%)					
Reported compliance	159 (78.3)	73 (81.1)	75 (75.0)	307 (78.1)	0.732

Overall 65.8%, (N=394) of patients were on oral medication only, with significant variation between the clinics.

The majority of patients reported that they never forgot to take their medication. The response to the question was found to be similar across all three CHCs (*p*=0.732)

3.2.4 Clinical characteristics

Table 3.4 gives the clinical characteristics of the study population. Known hypertension was noted in 80.8% of patients. Whilst 57.7% (n=394) of participants had a blood pressure measurement that was within the recommended target range, 20.5% (N=394) were considered to require immediate intervention for blood pressure control according to the guidelines issued by the National Department of Health.[27]
Mean total cholesterol was 5mmol/L with 62.7% having an optimal level. A much lower proportion of participants (33.8%) however, had LDL cholesterol results in the optimal range.

The mean BMI was 31.3 (SD: 7.1) and ranged from 17.5 - 52 kg/m^2. According to the international BMI classification, 16% of patients were within the normal BMI range, a further 28% were considered to be overweight and 55% of patients were obese.
The mean waist measurement was 104.6cm (SD: 14.4) (range 69-166cm).

Table 3.4 Clinical characteristics of participants by the clinics

	Chiawelo CHC (N=204)	Discoverers CHC (N=90)	Lenasia South CHC (N=100)	Complete sample: all clinics (N=394)	*P* value
Known to have hypertension n (%)	176 (86.7)	71 (80.7)	69 (69.0)	316 (80.8)	0.001
Blood Pressure Measurement	138±16.4/85±15	143±20.3/85±15	143±23.7/80±14	140±19.5/84±12	
Optimal	67 (32.8)	30 (33.3)	38 (38.0)	135 (34.3)	0.028
Acceptable	113 (55.4)	52 (57.8)	46 (46.0)	211 (53.6)	
Compromised	24 (11.8)	8 (8.9)	16 (16.0)	48 (12.2)	
Total Cholesterol (mmol/L)	4.9 ± 1.1	4.9 ± 1.1	5.1 ± 1.4	5.0 ± 1.2	
Optimal (<5.2)	132 (64.7)	56 (62.2)	59 (59.0)	247 (62.7)	
Suboptimal (≥5.2 <6.5)	51 (25.0)	27 (30.0)	29 (29.0)	107 (27.2)	0.229
Compromised (≥ 6.5)	21 (10.3)	7 (7.8)	12 (12.0)	40 (10.2)	
HDL-cholesterol (mmol/L)	1.2 ± 0.3	1.2 ± 0.4	1.1 ± 0.3	1.2 ± 0.4	
Optimal (≥ 1.1)	130 (63.7)	51 (56.7)	63 (63.0)	244 (61.9)	
Suboptimal (≥0.9 <1.1)	61 (29.9)	26 (28.9)	25 (25.0)	112 (28.4)	0.008
Compromised (<0.9)	12 (6.4)	13 (14.4)	12 (12.0)	38 (9.6)	
LDL cholesterol (mmol/L)	2.9 ± 1.0	3.1 ± 0.8	3.0 ±1.3	2.9 ± 1.0	
Optimal (<2.6)	72 (35.3)	27 (30.0)	34 (34.0)	133 (33.8)	
Suboptimal (≥2.6 <3.4)	68 (33.3)	26 (28.9)	26 (26.0)	120 (30.5)	0.223
Compromised (≥ 3.4)	64 (31.4)	37 (41.1)	40 (40.0)	141 (35.8)	
BMI mean±SD	32.3 ± 7.3	31.0 ± 6.8	29.3 ± 6.5	31.3 ± 7.1	
Optimal >18.5 <25	22 (10.9)	20 (22.2)	22 (22.5)	64 (16.4)	
Suboptimal 25-27	13 (6.4)	10 (11.1)	16 (16.3)	39 (10.0)	0.003
Compromised >27	167 (82.7)	60 (66.7)	60 (61.2)	287 (73.6)	

3.2.5 Behavioural / lifestyle risk factors

There was no difference between the three CHCs in the proportion of participants who consumed alcohol (p=0.345). Overall, 21.6% of participants (Table 3.5) reported that they did consume alcohol with 5.6% reporting that they consumed alcohol at least once a week.

The distribution of physical activity levels was found to be similar in the three CHCs, with the overall majority of patients reporting medium physical activity levels (*p*=0.937).

Fifty percent of the study population consumed fruit less than 3 days in a week whilst 40% indicated that they ate vegetables less than 3 days a week.

Table 3.5 Presence of lifestyle risk factors

	Chiawelo CHC (N=204)	Discoverers CHC (N=90)	Lenasia South CHC (N=100)	Total sample (N=394)	*P* value
% Alcohol Consumption	39 (19.1)	24 (26.7)	22 (22.2)	85 (21.6)	0.345
Physical activity levels (%)					
Low	58 (32.7)	25 (29.4)	29 (30.9)	112 (31.5)	
Moderate	78 (44.1)	42 (49.4)	42 (44.7)	162 (45.5)	0.937
High	41 (23.2)	18 (21.2)	23 (24.5)	82 (23.0)	

3.2.6 Markers of glycaemic control

Forty five percent of the participants (n=178) were found to have glucose in their urine (glucosuria) on urine dipstix testing (Table 3.6).

Of these 178 patients with glucosuria, 94.4% also had an HbA_{1c} result greater than 7%, and were classified as poorly controlled diabetics (*p*< 0.001).

A statistically significant difference between the three CHCs was noted in terms of random blood glucose fingerprick results (*p*=0.032). Only 23.4% of the total study sample had optimal random blood glucose finger prick results (Table 3.6).

Table 3.6 Markers of glycaemic control at the three CHCs

	Chiawelo CHC (N=204)	Discoverers CHC (N=90)	Lenasia South CHC (N=100)	Total sample (N=394)	P value
Presence of glucosuria (%)	42%	58%	40%	45%	*P*<0.001
Random Glucose (mmol/l)	9.9±4.0	11.1±4.1	9.7±4.4	10.1±4.2	
Optimal (<7)	55 (21.0)	10 (11.1)	27 (27.0)	92 (23.4)	0.032
Suboptimal (7-10)	56 (27.5)	32 (35.6)	34 (34.0)	122 (31.0)	
Compromised (>10)	93 (45.6)	48 (53.3)	39 (39.0)	180 (45.7)	

As shown in Figure 3.7, there was a good correlation between HbA_{1c} and random blood glucose concentrations (Spearman's r =0.51; *p*<0.001)

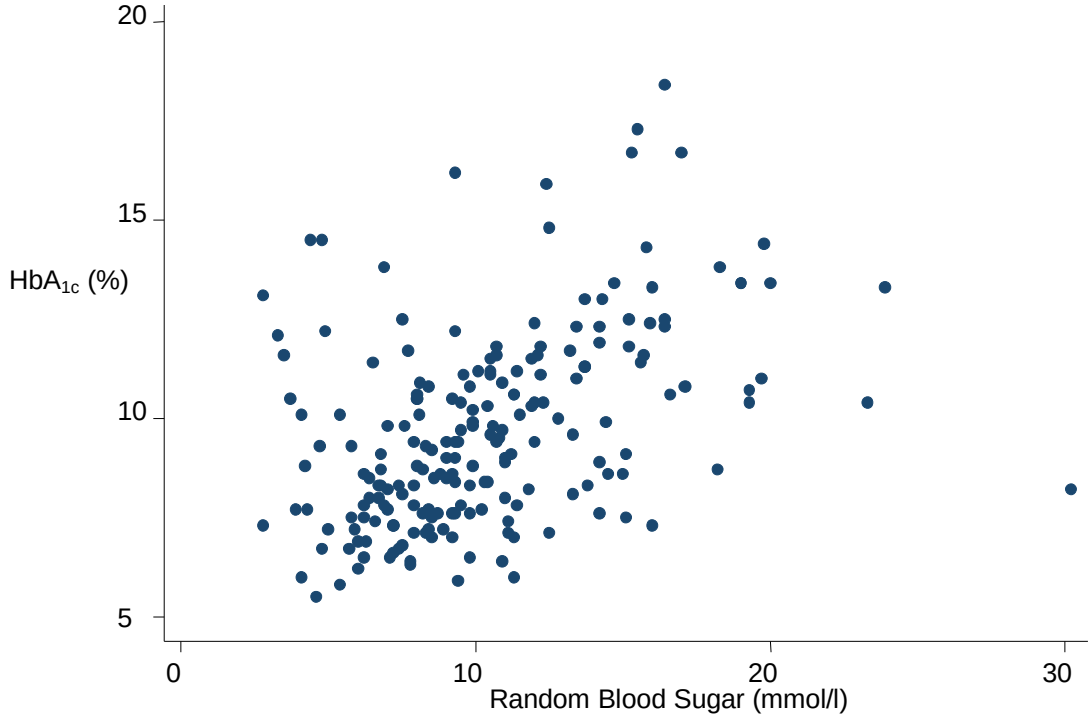


Figure 3.27 Relationship between Haemoglobin A_{1c} (%) and random blood glucose (mmol/L)

3.3 Risk factors for glycaemic control

Table 3.7 characterises glycaemic control according to demographic, clinical, disease related and behavioural characteristics.

Table 3.7 Proportion of patients with good and poor glycaemic control according to demographic, clinical, co-morbid and behavioural characteristics

Risk Factors	Good Glycaemic control (HbA_{1c} <7) n (%)	Poor Glycaemic control (HbA_{1c} >=7) n (%)	*P* value
DEMOGRAPHIC CHARACTERISTICS			
Gender n (%)			
Male	24 (38.7)	94 (28.3)	
Female	38 (61.3)	238 (71.7)	0.101
Race n (%)			
Black	53 (84.5)	264 (79.8)	
Indian	8 (12.7)	41 (12.4)	
Coloured	1 (1.6)	23 (7.0)	0.394
White	0	3 (0.9)	
Age (yrs)	59.4 ± 11.0	58.3 ± 11.3	0.496
Employment:			
Employed	10 (16.1)	109 (32.8)	
Unemployed	52 (83.9)	223 (67.2)	**0.009**
Education:			
None	4 (6.5)	32 (9.7)	
Some schooling	48 (77.4)	256 (77.3)	0.629
Completed School	10 (16.3)	43 (13.0)	
Socio economic score	5.9 ± 2.5	6.2 ± 2.2	0.418
DISEASE RELATED CHARACTERISTICS			
Time since diagnosis of diabetes (years)			
<5	27 (44.26)	94 (29.01)	
5-10	17 (27.87)	92 (28.4)	**0.037**
>10	17 (27.87)	138 (42.59)	
Length of time attending at the CHC	6.9 ± 5.8	7.5 ± 6.2	0.458
Type of diabetes treatment (%)			
Combined therapy	1 (1.6)	64 (19.3)	
Injectable	9 (14.8)	60 (18.1)	**<0.001**
Oral	51 (83.6)	207 (62.5)	

Risk Factors	Good Glycaemic control (HbA_{1c} <7) n (%)	Poor Glycaemic control (HbA_{1c} >=7) n (%)	*P* value
Compliance with medication			
Yes	48 (77.4)	259 (78.3)	0.895
No	14 (22.6)	71 (21.5)	
CLINICAL CHARACTERISTICS			
Blood Pressure			
Optimal	21 (60.0)	114 (57.3)	0.866
Acceptable	8 (22.9)	43 (21.6)	
Compromised	6 (17.1)	42 (21.1)	
Known Hypertensive			
Yes	54 (88.5)	262 (79.4)	0.096
No	7 (11.5)	68 (20.8)	
Total Cholesterol (mmol/L)	4.8 ± 1.2	5.0 ± 1.2	0.296
HDL-cholesterol (mmol/L)	1.2 ± 0.3	1.2 ± 0.4	0.373
LDL cholesterol (mmol/L)	2.7 ± 1.0	3.0 ± 1.0	**0.050**
BMI mean±SD	31.9 ± 6.1	31.1 ± 7.3	0.457
Random fingerprick Glucose (mmol/l)	7.1 ± 2.5	10.7 ± 4.1	**<0.001**
BEHAVIOURAL FACTORS			
Alcohol Consumption			
No	45 (72.6)	263 (79.5)	0.228
Yes	17 (27.4)	68 (20.5)	
Physical Activity			
Low	13 (24.5)	99 (32.7)	0.212
Medium	30 (56.6)	132 (43.6)	
High	10 (18.9)	72 (23.8)	

Participants who were well-controlled had a shorter duration of disease (44.26% <5 years, p=0.037), were more likely to be unemployed (83.9% vs. 67.2%, p=0.009), were on oral medication only (83.6% vs. 62.5%, p<0.00), had lower LDL-cholesterol levels (2.7 vs. 3.0mmol/L, p=0.050) and had lower random glucose levels (7.1 vs. 10.8 mmol/L, p<0.00) than those who were poorly controlled.

There was no differences between the well and poorly controlled diabetics (p>0.05) in terms of gender, race, age, level of education, socio-economic score, length of time attending the CHC, compliance with medication, blood pressure measurement, being a known hypertensive, total cholesterol levels, HDL-cholesterol levels, BMI, alcohol consumption, or physical activity levels.

3.4 Predictors of Glycaemic control

Table 3.8 presents the crude odds ratios and 95% confidence intervals of glycaemic control for basic demographic factors, behavioural/lifestyle factors, body measurements and adherence to guidelines.

Glycaemic control was significantly associated with unemployment, length of time since diabetes diagnosis, treatment with oral medication only or injectable therapy alone and LDL cholesterol levels (p<0.05).

Random blood glucose was related to glycaemic control in univariate analysis (p<0.001). However, it was not included in the multivariate analysis because of its correlation with glycaemic control.

Table 3.8 Univariate analysis of patient factors known in the literature to predict glycaemic control

Risk Factors	Crude Odds ratio 95% Confidence Interval)	P value
DEMOGRAPHIC CHARACTERISTICS		
Gender		
Male	1	
Female	0.63 (0.36-1.10)	0.103
Race		
Black	1	
Indian	0.97 (0.43-2.19)	0.945
Coloured	0.22 (0.03-1.64)	0.138
Age (yrs)	1.01 (0.98-1.03)	0.495
Employment:		
Employed	1	
Unemployed	2.54 (1.24-5.19)	**0.010**
Education:		
None	1	
Some schooling	1.50 (0.51-4.44)	0.464
Completed School	1.86 (0.53-6.47)	0.329
Socio economic classification	0.95 (0.85-1..07)	0.418
DISEASE RELATED CHARACTERISTICS		
Time since diagnosis of diabetes (years)		
<5	1	
5-10	0.64(0.33-1.26)	0.198
>10	0.43 (0.22-0.83)	**0.012**
Length of time attending the CHC	0.98 (0.94-1.03)	0.457
Type of diabetes treatment (%)		
Combined Therapy	1	
Injectable	9.6 (1.18-78.06)	**0.034**
Oral	15.77 (2.14-116.37)	**0.007**
Compliance with medication		
Yes	1	
No	1.06 (0.56-2.04)	0.852
Received education about diabetes at the Clinic	1	
No	0.96 (0.51-1.81)	0.894
Yes		
CLINICAL CHARACTERISTICS		
Blood Pressure		
Optimal	1	
Acceptable	1.01 (0.42-2.45)	0.983
Compromised	0.78 (0.29-2.05)	0.609

Risk Factors	Crude Odds ratio 95% Confidence Interval)	P value
Known Hypertensive		
No	1	
Yes	2.0 (0.87-4.60)	0.102
Total Cholesterol (mmol/L)	0.88 (0.69-1.12)	0.295
HDL-cholesterol (mmol/L)	1.39 (0.67-2.90)	0.373
LDL cholesterol (mmol/L)	0.74 (0.55-1.0)	**0.050**
BMI mean±SD	1.01 (0.97-1.05)	0.455
Random fingerprick Glucose (mmol/l)	0.72 (0.64-0.80)	**0.000**
BEHAVIOURAL FACTORS		
Alcohol Consumption		
No	1	0.229
Yes	1.46 (0.79-2.71)	
Physical Activity		
Low	1	
Medium	1.73 (0.86-3.49)	0.125
High	1.06 (0.44-2.55)	0.900

Of the 19 potential factors selected from the review of literature, four variables (employment, time since diagnosis LDL cholesterol levels and type of diabetes treatment), using univariate regression, were significantly associated with the outcome (Table 3.8). Using automatic variable selection, six variables (gender, race, type of diabetes treatment, physical activity levels, employment and levels of education attained) were found to be significantly associated with good glycaemic control. Two variables (employment and type of diabetes treatment) were common to both of these selection approaches.

Variables included in the final model are shown in Table 3.9. Gender, type of diabetes treatment, time since diagnosis of diabetes and employment were all

significantly associated with good glycaemic control (p<0.05). The inclusion of the variable race, although marginally significant, into the model gave a final model that had the best overall fit. Females were less likely than men to have good glycaemic control while Coloureds had poorer glycaemic control than Black. Patients who used oral or injectable treatment had better control than those who used combined therapy. Unemployment was associated with better glycaemic control with unemployed patient about 4 times more likely to have better control than employed patients.

The final model had a good fit (p= 0.36) and the area under the ROC of 0.74 was good, implying this model could well predict good glycaemic control for this study population.

Table 3.9 Multivariate analysis of patient factors known in the literature to predict glycaemic control

Risk Factors	Adjusted Odds ratio (95% Confidence Interval)	*P* value
Gender n (%)		
Male	1	
Female	0.49 (0.26-0.92)	0.026
Type of diabetes treatment (%)		
Combined Therapy	1	
Injectable	11.06 (1.34-91.30)	0.022
Oral	15.44 (2.07-115.46)	0.012
Time since diagnosis of diabetes (years)		
<5	1	
5-10	0.68 (0.33-1.40)	0.293
>10	0.49 (0.24-1.01)	0.052
Race n (%)		
Black	1	
Coloured	0.14 (0.02-1.16)	0.060
Indian	0.92 (.036-2.34)	0.849
Employment		
Yes	1	
No	3.65 (1.67-8.01)	0.001

3.5 Health facility related factors

3.5.1 Facility description

All three of the CHCs have dedicated days and clinics for diabetes care.

- **Chiawelo CHC**

Chiawelo CHC serves a predominantly Black African population. There is no booking system for appointments and all patients arrive at once. Chris Hani Baragwanath Hospital is the referral hospital for Chiawelo CHC and is in very close proximity to the CHC (about 9km). There is a committee for quality assurance at this CHC and they meet monthly to discuss issues at the CHC generally. Medicine is dispensed on site from the pharmacy. There has not been an interruption of medicine stock at this CHC in the one year prior to this study being conducted.

- **Discoverers**

Discoverers CHC has a dedicated diabetic clinic with a semi structured method of appointments. Patients are advised to arrive at intervals. Helen Joseph Hospital is the referral hospital and is approximately 7 kilometres away. There is no system in place for detecting or tracing defaulting patients as it is felt that many patients at this clinic give false addresses. There has been no interruption in the medication stock supply in the past year prior to this study.

- **Lenasia South CHC**

Lenasia South CHC refers diabetes patients with complications to Chris Hani Baragwanath Hospital which is 45 kilometres away. There is no booking system that allows the staggered arrival of patients. There are no systems in place for tracing defaulting patients. Quality of care gets discussed in the general primary health care nurses meetings, but no forum exists to discuss diabetic patient management specifically. Medicines are dispensed directly from the CHCs pharmacy. In the six months prior to this study, the supply of Metformin ran out once. Stock was borrowed from another CHC, Lillian Ngoyi CHC in Soweto.

Table 3.10 below describes the patient load of the CHCs in the six month period prior to this study. The table also highlights the staff complement at each CHC.

None of the clinics had access to a chiropodist and only one clinic (Discoverers CHC) had a registered dietician. From the total number of patients seen in the six month period it appears that all three CHCs have a similar number of doctors and professional nurses despite different patient loads. Although Lenasia South CHC has far fewer patients, they have more new diabetic patients than Chiawelo CHC and a higher number of visits for diabetes than Discoverers CHC.

Table 3.10 Staff complement and patient load at the three CHCs for the six month period, May-Oct 2008

	Chiawelo CHC	Discoverers CHC	Lenasia South CHC
Total number of patients (facility count)	93031	89028	36114
Total number of patients seen at the chronic diseases clinics	39247	38407	15671
Total number of new diabetics	15	51	35
Total number of diabetic follow up visits	5964	4006	4566
Average number of overall patients seen per month	15 505	14 838	6019
Total number of doctors	4	4	4
Ratio of doctor: patient per month (NOT diabetes specific)	1: 3976	1:3709	1:1504
Number of dieticians at the CHC	0	1	0
Professional nurses Staff nurses Nursing assistants	43 16 12	42 7 18	40 15 9
Health promoters	3	4	1

3.5.2 Access to CHCs

A high percentage, 88.9% (n=394), of the participants were noted to be attending their nearest primary health care clinic. The highest proportion of patients attending at a facility that was not considered their closest health facility was at Discoverers CHC (26.1%). There was no significant difference in glycaemic control between those who attended their nearest clinic and those who did not (p=0.219).

Whilst 30% of the study population walked to the CHC, the majority (38.6%) used a taxi. Twenty three percent % travelled by car and the remainder used a combination of train (7.4%) or bus (0.7%).

An overwhelming proportion of participants found that staff at all the CHCs was friendly and helpful and a high proportion were generally satisfied with the care they received at these CHCs for diabetes (Table 3.11).

Table 3.11 Patient perception of staff and overall services at the three CHCs

	Chiawelo CHC (n=204)	Discoverers CHC (n=90)	Lenasia South CHC (n=100)	Complete sample: all clinics (n=394)
% Attending their nearest clinic	97.4	73.9	85.7	88.9
Perception of staff (%):				
Friendly	95.6	98.9	91	95.2
Helpful	93.6	98.9	94	94.9
% satisfied with overall clinic care	90.69	100	88.89	92.4

3.5.3 Equipment

Table 3.12 below highlights the equipment available at the CHCs for diabetes care. Chiawelo CHC appears to have a shortage of equipment despite having the busiest diabetic clinic.

Table 3.12 Functional equipment available at the three CHCs for the diabetic clinics

	Chiawelo CHC	Discoverers CHC	Lenasia South CHC
Weighing scales(n)	2 *	2	1
Glucometers	1#	7	2
Sphygmanometers	3*	7	5
ECG machines	0	0	0
Snellens charts	1	0	4
Height scale	0	2	1
Fundoscopes	0	0	4
Tape measure (for waist measurement)	0	1	0

*One of each of these was NOT in working order
Although only one exists; there have been times when this has **NOT** been in working order

Healthcare staff indicated that some patients were able to purchase their own glucometers for self monitoring of their blood glucose levels, but the CHCs were unable to supply the glucose sticks required for testing.

3.6 Healthcare professional related factors

3.6.1 Healthcare Professional interview findings

Fourteen healthcare professionals, 11 nurses and 3 doctors, were interviewed. The average number of years of experience was 20 years (SD: 9.3) and ranged from 4 years to 36 years. Most respondents were women (93%). The median time working at the CHC being studied was 9 years, ranging from 5 to 24 years.

Capacity to manage diabetes

Only one healthcare professional was not aware that National Guidelines for Diabetes Management existed. Almost a third (29%) admitted to not strictly adhering to these guidelines. Four of the healthcare staff interviewed did not have a copy of the guidelines or know where to access a copy.

As an example of guideline adherence, Table 3.13 below indicates the blood glucose values used by healthcare professionals when diagnosing diabetes.

Table 3.13 Target values used by healthcare professionals to diagnose diabetes in symptomatic individuals

Upper limit of random blood sugar level used to diagnose diabetes in symptomatic patients (mmol/l)	N (%)
7	2 (14.3)
9	2 (14.3)
10	1 (7.1)
11	3 (21.4)
15	5 (35.7)
17	1 (7.1)

Three health care professionals did not provide any answer at all as to the upper limits of normal of the HbA_{1c} test. A further three healthcare professionals chose 6% as the upper limit of normal, four others chose 7%, two chose 8% and one healthcare professional chose 10%. When asked how often the HbA_{1c} test should be done, 42% indicated six monthly and 33% said yearly. One responded that the HbA_{1c} test should be done whenever a patient is found to have poorly controlled random blood sugar levels. Two offered no response at all to how often the HbA_{1c} should be conducted and lastly one respondent indicated that testing should be conducted every three months.

Thirty six percent of healthcare professionals agreed that glucosuria can be used as a diagnostic tool for diabetes and that a fasting glucose tolerance test would be deemed unnecessary if glucose was present in the urine.

Healthcare professionals were asked to comment on whether they were comfortable performing the following tests. The percentages reflected in Table 3.14 indicate the proportion of those that were comfortable performing the test.

Table 3.14 Proportion of healthcare staff comfortable performing diabetes care related procedures/tests

Test	% comfortable n=14
1. Visual acuity	12 (86%)
2. Fundoscopy	1 (7%)
3. Urine dipstix	14 (100%)
4. Complete foot exam	9 (64%)
5. Neurological exam for nerve damage	2 (14%)

The consensus (12/14) was that the quality of care provided is considered better in dedicated diabetic clinics versus general chronic disease clinics and general primary care clinics.

Patient workload

Nurses stated that they saw on average approximately 30-40 patients during each diabetic clinic. Staff at Chiawelo clinic however indicated that they saw between 80-120 patients as a norm during each diabetic clinic.

3.6.2 Patient Education

The majority of patients reported receiving education about diet, exercise and footcare from either a doctor or a nurse whilst being managed at the respective

CHCs (Table 3.15). Approximately 76% of the patients indicated that they had received general information about diabetes.

Of those who were well controlled; 75% (n=62) indicated that they had received diabetes education and 25% had not. Of those poorly controlled 76% (n=332) indicated they had received education. There was no difference between those with good glycaemic control and those with poor control, in terms of the reported diabetes education received (*p*=0.894).

Table 3.15 Indication of education received at the CHCs

	Chiawelo CHC (n=204)	Discoverers CHC (n=90)	Lenasia South CHC (n=100)	Total sample (n=394)	P value
Reported diabetes education received					
. General diabetes education	144 (70.6)	78 (86.7)	77 (77.8)	299 (76.1)	
Diet education	155 (76.0)	86 (86.9)	86 (86.7)	319 (81.2)	**0.011**
Exercise education	151 (74.0)	78 (86.7)	84 (84)	313 (79.4)	
Footcare education	122 (60.4)	75 (83.3)	75 (75)	272 (69.2)	

3.6.3 Challenges to providing comprehensive care

Healthcare professionals interviewed highlighted a number of challenges they faced in providing adequate diabetic care-:

- Most believe that 15-20 minutes is the minimal required consultation time per patient if adequate care is to be provided. Due to current staff shortages, it is not possible to dedicate this amount of time.
- Necessary patient measurements are not always done:

a) Nursing assistants employed to assist at the clinics with routine measurements are often reluctant to conduct urine tests and weigh patients when patient volumes are high.

b) Lack of working equipment was often an obstacle to staff that are required to conduct routine measurements, including weight measurements and random fingerprick glucose measurements Glucometers, weight scales and height scales were in short supply (refer Table 3.12 for working equipment).

- Health promotion talks are supposed to be given during the clinics and this is not always done due to insufficient support staff.
- Health talks are sometimes given in a language that does not benefit all patients present. For example in diverse population groups like those at Lenasia South Clinic, patients have a variety of home languages. Talks are often given in one chosen ethnic language and many of the English speaking patients do not comprehend.
- Dieticians are not available during the clinic times. There is no avenue to refer patients who required a dietician consult. Only 3% of participants had ever been counselled by a dietician.
- Diabetic diaries were not always available and teaching materials were inadequate. The numbers of diabetic diaries supplied by the Department of Health were never enough.
- Lipid lowering drugs were unavailable at the three CHCs studied. Patients need to be referred to secondary and tertiary institutes and opt to avoid this scenario due to perceived long waiting times at these facilities

- Most CHCs have a poor booking system whereby all patients to be seen for the day arrive all at once, usually in the mornings. Patients get impatient with the prolonged waiting times and are content with a rushed consultation so that they can get home sooner.
- Blood test results are often unavailable. This is usually due to a poor system of attaining blood results or organisation of results. As a result both patients and staff do not put much emphasis on taking blood tests. Only a small percentage of the participants (16%) have had an HbA_{1c} test done previously. Of those classified with poor glycaemic control, only 5.7% (n=332) had records of previous total cholesterol testing being conducted in the past one year. 10.2% (n=332) were noted to have compromised total cholesterol levels from blood testing conducted as part of this study with just 2.52% of participants noted to be on lipid lowering medication.
- Not enough attention is dedicated to encouraging patient compliance. There is a tendency for the nurses to increase the dosage if insulin when in fact lifestyle modification or importance of medication compliance deserves more attention.

CHAPTER FOUR

4.0 DISCUSSION

4.1 Discussion

In this chapter, the results obtained from the analysis of the study data are discussed and interpreted in light of other published studies.

This study showed that patients who had diabetes for a shorter period of time, used oral therapy alone or injectable therapy alone, who were male, and those unemployed, were more likely to have good glycaemic control. In terms of race being Coloured had the least likely odds of being well controlled as compared to being Indian or Black African.

The aim of this study was to determine factors that influence glycaemic control in patients at selected community health centres in Johannesburg. Factors that influence glycaemic control are vast and difficult to investigate extensively in one study, thus factors that were mainly considered to be modifiable in the Gauteng context were included in this study. This study focused on demographic features, disease severity, clinical characteristics, access/quality of care, and behavioural factors. Studies do suggest that personal characteristics of patients alone may not explain the reasons for glycaemic control among patients with type 2 diabetes.[83-84] This study did not attempt to explore psychological, some biological factors or the self care skills needed for good glycaemic control.

Diabetes is not only a problem in the developed world; it has become an increasing health problem in less developed countries as well. By 2015, it is estimated that in Africa mortality from non-communicable diseases will exceed that from communicable diseases.[63]

4.1.1 Glycaemic Control

Good glycaemic control was only described in 15.7% of the study population. This proportion was slightly lower than other studies that have investigated / measured glycaemic control in South Africa. In a study carried out in a rural district in KwaZulu-Natal, acceptable glycaemic control (defined as HbA_{1c}< 2% above normal population range) was found in only 16% of patients.[34] Similarly a study looking at patients attending a peri-urban community clinic with predominantly black patients, found that good glycaemic control (HbA_{1c} < 7%) was achieved in only 20% of patients.[35] In Black African patients at the primary care level in the public sector in the Western Cape, acceptable glycaemic control (defined as HbA_{1c} < 2% above normal population range) was found in 49% of patients.[31] Studies from other countries also showed poor levels of glycaemic control. A study in Jordan estimated that the proportion of Type 2 diabetic patients who did not achieve good glycaemic control was 65.1%.[85] In Kuwait, 66.7% of the studied population had an HbA_{1c} ≥8%.[86] In Trinidad 85% of patients had HbA_{1c} >7%[87] and in the UK, 69% had HbA_{1c} >7.5%.[88] Glycaemic control appears to be a worldwide problem.

4.1.2 Patient related factors influencing glycaemic control

Gender

More women (70%) than men participated in this study. This might be that more men were in employment and thus unable to attend at primary health care facilities during working hours. The high proportion of women in the study population is comparable to previous studies on glycaemic control in SA,[12,15,89] showing that the gender of patients attending primary care facilities for chronic disease care in South Africa is predominantly female.

This study found that diabetic women were less likely, when compared to men, to have good glycaemic control. A study looking at type 1 diabetic patients, suggested that a possible reason that women may have poorer glycaemic control is that women have reported greater difficulty in adhering to the diabetes regimen than men.[90] Wexler et al[10] showed that diabetic women were also noted to be less likely to have well controlled blood pressures or LDL-cholesterol levels compared to men. Clarity is required in understanding the reason that women are less likely to be well controlled.

Previous South African studies have also re-enforced the findings of a high prevalence of obesity, (BMI≥25 kg/m^2 for females and BMI≥27 kg/m^2 for males) which was present in 79% of diabetic patients in one study.[35] The prevalence of obesity (BMI >30 kg/m^2) in South Africa is high, with more than 29% of men and 56% of women being classified as overweight or obese.[91] Increasing levels of obesity and

insulin resistance has been associated with poorer glycaemic control.[61-62] Perhaps the fact that women in South Africa are more obese than men contributes to their poorer glycaemic control and warrants further investigation.

Being overweight had no significant association with glycaemic control in this particular study, and findings were similar to another international cross-sectional study in primary care.[92] The United Kingdom Prospective Diabetes Study (UKPDS trial)[18] has explained that good glycaemic control can cause weight gain of between 2 and 5kg.[18] However this may not be relevant to this study population in light of the already high mean BMI of 31.3kg/m^2. The adverse effect of weight gain on glycaemic control may worsen other physiological parameters such as hypertension and hypercholesterolemia, which are important risk factors for cardiovascular disease.[93]

Employment

Employment was found to be a significant predictor of glycaemic control in our multivariate model with unemployed people having a higher probability of being well controlled than those in employment. It may be that patients with employment have less time for clinic attendance or self care. There is little supporting literature for this association between unemployment and better glycaemic control. This finding contradicts a theory highlighted by Wray et al[57] that better education levels result in better occupational prospects and higher incomes, which would result in improved health outcomes through safer and less stressful workplaces, greater access to health literacy and information as well as better social networking.

Length of time since diagnosis of diabetes

Although no studies have formally been conducted in SA on the effects of length of time of diabetes and glycaemic control, international study findings have differed on the association between glycaemic control and disease duration.[31,84,92] This study found that the longer the duration of diabetes the harder it was to maintain glycaemic control. These findings were similar to Blaum et al[92] and contradictory to Nichols et al.[84] In 1997 Curtin et al[94] reported that conformity to medical care improved with age. Although this improvement was expected with longer duration of disease, resistance to medication and the need for higher doses or additional medications also increased over time.[95-96] Longer duration of diabetes is often associated with poor control, possibly because of progressive impairment of insulin secretion with time due to β-cell failure, which makes the response to diet alone or oral agents insufficient.[18]

Type of treatment

Participants in this study on oral medication alone or injectable therapy alone were found to have much greater odds of having good glycaemic control than patients on combination therapy. The association between treatment with a combination of oral and injectable medication and poor glycaemic control is consistent with other studies.[85,97-98] Insulin, which is used as a first line of therapy in type 1 diabetics is also recommended in addition to oral medication as second or third-line therapy, when glycaemic targets in type 2 diabetes mellitus are unmet.[27] The use of insulin often reflects disease severity and some studies[83,95-96] have used it as a predictor of

poorer glycaemic control. Only 17.6% of this study population were on injectable therapy alone, of which 89% were poorly controlled. Diabetes does deteriorate over time and perhaps those on combination therapy in our study population had a more progressive form of the disease which required more aggressive second and third line therapy.

Race

A prior study has demonstrated race/ethnicity as a predictor of glycaemic control showing higher proportions of poorly controlled patients among black women and Mexican-American men.[95] Utilising multivariate analysis, this study found that patients of Coloured race were least likely to have good glycaemic control when compared to Black African and Indian race groups. This finding of patients from the Coloured race being least likely to be well controlled, is in keeping with the South African Institute for Race Relations' "South Africa Survey 2008/9",[99] which reported that people who were Coloured were most likely to have had diabetes as one of their three leading causes of death. The white race was poorly represented in this study sample with only three participants noted overall and they were therefore not included in the multivariate analysis.

Urbanisation is a major risk factor for the development of chronic diseases[100] and as populations migrate from rural to urban areas in South Africa the proportion of race groups affected by chronic diseases may change.

Socio-economic status

Although it is known that the distribution of non-communicable diseases has disparities in terms of socio-economic status[100-101] this study found no association between an asset indicator score, utilised to reflect socio-economic status, and glycaemic control. There was also no difference between the means of the asset indicator scores for those with good and poor glycaemic control. These findings, were similar to a US study by Harris et al,[83] the Michigan community study,[92] Benoit et al[95] and a study of blacks and whites in South Carolina,[102] with all finding no association between glycaemic control and socioeconomic status. One study however in the USA found that patients from higher socioeconomic levels were more likely to achieve better glycaemic control.[16] It should be noted that although the asset indicator score used in this study was adapted from an asset indicator score used in other studies to asses socio-economic status, this adapted score was not validated in this study population.

Age

Similar to a study by Benoit et al,[95] age was also found not to be a significant predictor of glycaemic control in this study. Some previous studies have reported that younger aged diabetics are more likely to be poorly controlled.[42,84] Early-onset type 2 diabetes is generally more associated with poorer glycaemic control outcome,[42] and possibilities for this outcome include behavioural reasons and the suggestion that glycaemic control may be much more difficult to achieve for some younger patients with a shorter duration of disease.[84] Currently there are no known

studies that have evaluated whether individuals developing type 2 diabetes at an earlier age require more aggressive interventions to achieve glycaemic control.

Co-morbid conditions

Blood pressure measurements conducted during this study revealed that 20.5% of patients had blood pressures that were considered to be in the compromised category according to the NDoH guideline. In this study 80.8% of the population reported that they were known hypertensives and this high proportion may have contributed to the lack of finding a significant relation between being hypertensive and glycaemic control. Previous studies in South Africa have shown that poorly controlled diabetics are also often found to be hypertensive and obese,[38,40] with up to 76% of black diabetic women having coexisting hypertension and being obese in one study.[40] Having a multitude of diseases can often lead to or enhance difficulties in treatment compliance and lifestyle modification. Persons with co-morbid chronic diseases experience a wide range of barriers to self-care, often leading to poor overall control.[53,68] So whilst the existence of a co-morbid factor may not directly predict glycaemic control, it may influence areas of compliance and lifestyle modification.

Diabetes and hypertension are not only increasing in urban African settings but in rural settings as well. Harris et al[83] found that blood pressure was elevated (greater than or equal to 140/90mm Hg) in 55% to 65% of the diabetic population. A SA study found hypertension (blood pressure ≥ 160/95mmHg and/or prescribed anti-

hypertensive medication) was present in 65% of patients, and severe obesity (BMI > 33 kg/m2) in 37% of patients[34] with poorly controlled diabetes. Levitt et al[31] found a high prevalence of suboptimal glycaemic and blood pressure control with hypertension (blood pressure ≥160/95mmHg and/or prescribed antihypertensive medication) present in 52% of diabetic patients.[31]

Benoit *et al*,[95] found in their study that high total cholesterol was associated with poorer glycaemic control. In another study it was also found that the total cholesterol was greater than or equal to 200 mg/dl in 62% to 69% of the diabetic patients investigated.[83] Diabetic patients are already at high risk for cardiovascular disease, thus elevated cholesterol levels need to be treated. Despite this known fact, only 2.5% of this study population were on lipid lowering drugs, whilst 10.2% were noted to have elevated total cholesterol levels. Although hypercholesterolaemia should be routinely screened for in diabetics, according to NDoH diabetes guidelines, only 5.3% of this study sample has previously had their total cholesterol levels tested. The use of lipid lowering drugs is recommended in the national guidelines, however due to limited resources, the implementation of this therapy is very low.

Behavioural / lifestyle factors influencing glycaemic control

A study on dietary intake and barriers to dietary compliance in Black African type 2 diabetic patients suggests that healthcare professionals be re-trained in concepts of optimal diabetic diet which is culturally and economically acceptable to Black African

patients.[38] Factors that were identified as possible contributors to poor glycaemic control from this study included: lack of knowledge regarding the disease; inadequate and inaccurate dietary counselling; and poor compliance with the dietary advice given. This study was only able to determine the number of days in a week that diabetic patients from the study ate fresh fruit and vegetables, as it was never an intention to extensively investigate dietary habits of the study population.

The highest proportion of patients at all three CHCs were classified as undertaking moderate physical activity. Although previous studies[64-65] have shown that improved physical activity levels can result in better glycaemic control, no significant association with glycaemic control was found in this study, either on univariate or multivariate analysis.

Compliance

Surprisingly compliance was not found to be a significant predictor of glycaemic control in this study. One study found that poor glycaemic control was more common among patients who were not adherent to their treatment.[87] There is some difficulty in assessing patient compliance to diabetic medication and diabetic lifestyle modification. The nature of the question phrased in this study questionnaire, i.e. a closed question, may have left patients with the tendency to say “yes” when asked about their compliance to diabetes medication or perhaps they gave false information in fear of reprimand. Often many patients are found to be on injectable therapy due to poor compliance rather than a failure of oral medication.

4.1.3 Health facility related factors influencing glycaemic control

A key strength in interviewing health care professionals and facility managers is that these personnel are responsible for delivering care and thus allows for a more personalised insight into the delivery of services and the difficulties experienced with delivering good quality care.

Previous international studies have indicated that smaller clinics achieve better glycaemic control and might be influenced by better interpersonal skills related to lower workloads.[16] Contrary to this, it was found in this study, despite the fact that all three CHCs had dedicated diabetes clinics, patients attending the clinic with the higher number of diabetics seen, displayed a higher proportion of glycaemic control.

Although the mean HbA_{1c} level was similar for all three CHCs, the proportion of patients who achieved good glycaemic control was significantly different. The CHC with the highest proportion of good glycaemic control had the highest patient volume, a predominantly black population, the oldest average age of patients, the highest proportion of patients that were employed, the lowest proportion of patients who were diabetic for more than 10 years and the highest proportion of patients on oral therapy alone. Except for these predominantly patient characteristics, this study did not identify any key organisational findings that differentiated this clinic from the other two. Thus an overall effort to improve diabetes care at all clinics is logical from a management perspective. The study did not allow for a comparison between patient, health professional and facility factors.

Patients expressed some concerns in terms of facility management. The main frustration was the poor flow of patients through the clinic. All patients with appointments for clinic attendance on that particular day were expected to arrive at the same time, early in the morning. In view of it being impossible to see all these patients on arrival, the majority of patients spent many hours waiting in queues. Patients are often disillusioned with the long waiting times and accept rushed consultations as a norm. Annual physical examinations are not routine in health facilities, and the public are not well informed about the need for routine physical examination to detect disease early and initiate appropriate care.[103]

A study has shown that the existence of defaulter detection systems can be associated with overall improved glycaemic control.[25] All three CHCs lacked a system to detect defaulters.

Although the study concludes that patient related factors are at the forefront, improved strategies in all spheres, including facility management can also improve the level of glycaemic control in patients attending the CHCs.

4.1.4 Health care professional factors influencing glycaemic control

The health care professional can play an important role in achieving good glycaemic control. Characteristics such as good communication skills, enthusiasm and care may determine whether a health care professional will influence glycaemic control but these cannot be easily measured as these characteristics are difficult to test for.

Other studies have shown that healthcare professionals have minimal direct impact on glycaemic control,[104-106] but that these professionals do influence patient behaviour and thus diabetes outcomes.

Healthcare professionals reported that they did not feel they are adequately trained in diabetes care. This could be a possible reason why healthcare professionals were not comfortable performing certain essential diabetes related examinations as well their lack of knowledge when asked simple basic diabetes related questions. A previous South African study by Levitt et al[36] highlighted the limited training of health personnel in a comprehensive approach to chronic diseases stating that both medical and nursing curricula in 2005 focused on curative care, rather than a comprehensive approach that incorporates prevention, promotive and rehabilitative aspects. The skill to manage chronic diseases was lacking in many health care workers. A European study in primary care which looked at 288 poorly controlled diabetic patients, found that after supporting health professionals with flow-charts and treatment protocols, a 17% reduction in HbA_{1c} levels was noted, suggesting an element of under-performance prior to this intervention.[97]

Despite the existence of national guidelines for the management of diabetes in South Africa, the implementation of these guidelines appears to be poor in view of the low proportion of patients who have previously had their HbA_{1c} levels tested, the low proportion of patients who have had examinations specific to identifying diabetes complications; the low proportion of patients that have been referred for specialist

care, e.g. dieticians, ophthalmologists; as well as a very low proportion of patients that were found to have good glycaemic control. It appears that healthcare professionals are not adhering to protocols.

Good glycaemic control does depend on diabetes education that patients receive from health care professionals.[37] In this study patient perceptions about the diabetes education that they received did not feature as a predictor of glycaemic control. A high percentage of diabetic patients indicated that they were satisfied with the care as well as the education about diabetes received at the CHCs. This overwhelming positive response might be attributable to the nature of the question asked, i.e. closed questions. The scope of this study did not accommodate for determining the actual extent or quality of patient education given by healthcare professionals as the questions asked were not sufficient to know exactly how much knowledge patients had about their disease, how much information they received and from whom. In considering the amount or quality of education that diabetic patients receive, it is important to be cognisant of the high patient volume and the fact that any one nurse can see up to 90 diabetic patients within a working day. This high patient to staff ratio is a potential contributor to poor glycaemic control as it may limit the time available for quality patient education.

A moderate inverse relationship was observed between educational level and glycaemic control. In this population almost 86.5% of the patients had not completed formal schooling. Diabetes is a ‘complex’ disease; as such providers of diabetes care

need to be aware of the potential influence of educational level on the patients' receptiveness to the education and information made available to them. Authors have emphasised the significance of health literacy in diabetes care.[50,107] In particular it is recognised that diabetes information needs to be adjusted to a patient's literacy levels, cultural beliefs, environment influences and economic status.[38,50,108] Health literacy is a measure of a patient's ability to read, comprehend and act on medical instructions. Poor health literacy is common among patients who have achieved lower levels of educational attainment and among patients with chronic medical conditions, such as type 2 diabetes.[108]

This study found that the random blood glucose measurement appeared to be associated with glycaemic control. This association of high random blood glucose with poor glycaemic control may highlight the usefulness of this simple and cheap test which can be utilised by primary care clinics in daily diabetes care. Following persistently high random glucose readings, a patient should have an HbA_{1c} test. This study highlighted that only 16% of the study population had ever had an HbA_{1c} test according to their patient records. Although random blood glucose testing may be useful in the primary care setting, a caution of relying solely on random blood glucose measurement comes from a study by Bouma et al[109] in non-insulin-using patients, which highlighted a risk for under-treatment in view of the overestimation of HbA_{1c} from good fasting plasma glucose levels (<7.8 mmol/l) especially in patients on oral diabetic therapy.[109] Although random blood glucose should be tested at all clinic visits, healthcare professionals do not appear to be using this test as an

indicator that a patient may be poorly controlled and require further investigation with an HBA1C test.

4.2 Limitations

The findings of this study must be interpreted taking into cognisance the limitations of the study. The factors identified in the literature review were investigated in this study as independent variables only.

Due to the cross-sectional design of the study, temporality between the factors influencing glycaemic control could not be assessed and therefore causality could not be measured.

It is possible that some variables, for example self-reported alcohol use and compliance to treatment, may have suffered from social desirability bias as patients may consider some practice socially sanctioned. It would be interesting to investigate the validity of these measures in a future study. The usefulness of these measures is also limited due to the closed nature of the questions asked.

The size of this study population was adequate, but the diversity of the population both in terms of race and socioeconomic status were not fully represented. In South Africa higher socio-economic groups usually seek healthcare within the private sector. Only three participants were white, and a high proportion of patients were unemployed. On multivariate analysis those unemployed were more likely to be well

controlled. The possibility that the study sample had an element of selection bias, in that more people who were unemployed were selected, cannot be ruled out. This bias would be due to the fact that more people who are unemployed tend to use health services at the selected CHCs.

Some patients sampled did not wait for the study interview perhaps for reasons of time constraints, other commitments such as being in employment or scepticism. We were unable to determine the number of people who did not wait around for an interview. Those who left may have less interest in the control of their diabetes; may have been men and perhaps were worse controlled. Potentially these same patients could have been from a better socio-economic background and thus perhaps had better glycaemic control.

Health professional and health facility factors that may influence glycaemic control could not be entered into the logistic regression model due to lack of variation as well as difficulty in assigning the responses of individual health care providers to specific patients.

4.3 Conclusion

The majority of patients in this study had poor glycaemic control. The determinants of the quality of glycaemic control and diabetes care are multiple and complex with inputs and interactions at the patient, health care provider and the health facility level.

Several patient characteristics were found to be associated with good glycaemic control. Patients with a shorter duration of diabetes, those who were male Black African, unemployed and treated with oral medication alone were more likely to have good glycaemic control.

Healthcare professionals self reported that some of their diabetes management skills were lacking. This study showed there were health professionals who were unable to answer simple questions related to the management of diabetes which may be related to the training of healthcare professionals in the area of chronic disease management, suggesting a need to improve health professional diabetes education.

There appears to be poor adherence to NDoH diabetes guidelines, as evidenced by the vast majority of patients having never had an HbA_{1c} test. Several challenges to providing comprehensive care were reported by healthcare professionals, including high volumes of patients encountered with minimal consultation time to ensure quality of care, lack of working equipment, no access to dieticians during clinic times, shortage of diabetic diaries and difficulties in obtaining blood test results. Some of the challenges reported suggest that there is a need to improve the management of the healthcare facilities.

Addressing these findings with a comprehensive plan of action is needed to help reduce the increasing epidemic of diabetes and its complications among diabetic patients in the JMHD.

4.4 Recommendations

There is a definite need to improve glycaemic control in the Gauteng province. The findings of this study will contribute to the strategic plans of the GDoH in addressing the growing diabetes epidemic in the province by ensuring that the:

- Current clinical management guidelines be adapted such that people who have been diabetic for longer periods of time be targeted for intensive management. These patients must undergo closer monitoring (regular recommended HbA_{1c} testing, higher vigilance for the possibility of complications), have more detailed healthcare professional consultations, be referred timeously if and when complications arise, and healthcare professionals must have a lower threshold for increasing therapy with these patients.
- Current guidelines and policies be reinforced, such that all diabetic patients receive at least one annual physical examination as well as six monthly HbA_{1c} blood tests.
- There is a growing need for monitoring and evaluation of the implementation of current policies and guidelines. A potential value add to assist in the monitoring and evaluation process is the conducting of more regular clinical audits at facilities, scrutinising patient records to identify inconsistencies with current guideline adherence and ensuring that essential management practices like diabetic foot care, dietary advice and six monthly HbA_{1c} testing are being conducted as prescribed.
- Further implementation of mechanisms, programmes and processes that assist health staff attain confidence in terms of the referral pathways and in

becoming more vigilant of potential diabetic complications are critical in enhancing better glycaemic control.

The primary health care professional plays a pivotal role in the patient's chances of achieving good glycaemic control. It is this important role that necessitates prudent investment in the continuous education and training of the health care professional to enable them to optimally ensure the glycaemic control of their diabetic patients. Many health care professionals interviewed in this study expressed interest in a refresher course which could improve the quality of care provided to diabetics at the primary care level and reduce the number of referrals to the secondary and tertiary level with long and short term complications of diabetes. Experts in the field of diabetes must be approached in helping refresh the nursing staffs' knowledge and practices regarding diabetic patients. This could have a very positive impact on the lives of many diabetics in the Johannesburg region.

The health facilities should aim to ensure that all patients under their care are empowered to practice self management, are educated about the importance of compliance and are well motivated. Patients should be well educated with regards to the possible risk factors associated with poor glycaemic control and how to control them as well as possible complications and how to identify them. The promotion of self care is vital in sustaining good glycaemic control. Dieticians and nursing staff specialising in this field of study would contribute immensely in cultivating an environment conducive to better self management.

Strengthening of Public Private Partnerships (PPP's) e.g. partnerships with private pharmaceutical companies, medical aid companies, and non-government organisations should be encouraged. PPP's can be benchmarked to offer expertise in how to improve the management of facilities, communication strategies to improve compliance amongst patients and motivating healthcare professionals to improve adherence to clinical guidelines. An example of this would be the Discovery Health Vitality programme which is a preventative programme for diseases of lifestyle. These PPP's could also prove vital in conducting further research that identifies barriers that need to be overcome in order to achieve good glycaemic control.

The HbA_{1c} test is valuable and greater awareness of this should be created. This test can be used as a monitoring tool, as a tool for predicting diabetes complications and to a much lesser degree, a diagnostic tool.[110] Healthcare professionals should be encouraged to utilise this blood test according to recommendations in national guidelines.

However it is important that the research gaps identified be adequately addressed. Intervention studies aimed at motivating patients to self monitor as well as aim for good glycaemic control are of vital importance. Further studies should also focus on knowledge, attitude and practices of healthcare professionals in terms of diabetes management.

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APPENDICES

Appendix A: Ethics clearance certificate

Appendix B: Study Permission letters

Appendix C: Methods utilised by different laboratories for blood testing

Appendix D: Patient questionnaire

Appendix E: Healthcare professional questionnaire

Appendix F: Facility manager questionnaire

Appendix G: Data collection tool for review of records

Appendix H: Equipment verification form

Appendix I: Consent forms and information sheets

Appendix A:

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Timothy

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M081138**
PROJECT	Factos Influencing Glycaemic Control in Diabetics in Three Community Health Centre in the City of Johannesburg
INVESTIGATORS	Dr GA Timothy
DEPARTMENT	School of Community Health
DATE CONSIDERED	08.11.28
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 09.02.16 **CHAIRPERSON** .....
(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr J Moolman

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

APPENDIX B:

Department of Health
Lefapha la Maphelo
Departement van Gesondheid
Umnyango wezeMpilo
JHB METRO DISTRICT
Office of the Director
JHB/WEST RAND REGION
FAMILY MEDICINE & PHC

MEMORANDUM:

TO: Dr GA Timothy
Wits Public Health Medicine Registrar

CC: Dr. Masilela
Assistant Directors:
Ms. Gasa
Ms. G. Dlamini
Ms. M. Thokoane

The relevant Facility Managers

DATE: 21/10/2008

SUBJECT: PERMISSION ALLOWING DR GA TIMOTHY TO CONDUCT THE DIABETES STUDY IN THE RELEVANT HEALTH FACILITIES IN JOHANNESBURG MERTO.

Dear Dr G A Timothy

I have received your research proposal entitled, "Determining factors that influence glycaemic control at Community Health Centers in the Johannesburg Metro District in Gauteng Province, South Africa:

I will grant you permission to conduct this research within the Health Facilities stated below (Table 1).

Please ensure that allowance is made for feedback to be communicated to my office to ensure that the District and patients benefit from this study.

109 – 1st Floor Hillbrow CHC Admin Block, Corner Klein & Smith Street, Hillbrow
Private Bag X21, Johannesburg, 2001
Tel: 011 694 3713 Fax: 011 694 3825

Table 1: Health Facilities specified by Researcher

Health Facility	Assistant Director	Facility Managers
Chiawelo CHC	D – Ms. Gasa	Mrs. Joyce Phume
Discoverers CHC	C – Ms. G. Dlamini	Mrs. Van Schuyf
Lenasia South CHC	G – Ms. M. Thokoane	Mrs. Mzolo

Thank you

.....

11/11/08

MS C. KULA
ACTING DIRECTOR
JOHANNESBURG METRO DISTRICT

109 – 1st Floor Hillbrow CHC Admin Block, Corner Klein & Smith Street, Hillbrow
Private Bag X21, Johannesburg, 2001
Tel: 011 694 3713 Fax: 011 694 3825

TO: Dr GA Timothy
Wits Public Health Medicine Registrar

DATE: 12/12/2008

SUBJECT: PERMISSION ALLOWING DR GA TIMOTHY TO CONDUCT THE DIABETES STUDY AT DISCOVERERS COMMUNITY HEALTH CENTRE.

Dear Dr G A Timothy

Following our discussion regarding your research proposal entitled, "Determining factors that influence glycaemic control at Community Health Centers in the Johannesburg Metro District in Gauteng Province, South Africa:

I will grant you permission to conduct this research within the above mentioned facility.

Please ensure that allowance is made for feedback to be communicated to my staff such that the facility, staff and patients benefit from this study.

Thank you

MRS J. V. DER SCHYFF
CLINIC CO-ORDINATOR

....

Facility Managers Name **Signature**

TO: Dr GA Timothy
Wits Public Health Medicine Registrar

DATE: 12/12/2008

SUBJECT: PERMISSION ALLOWING DR GA TIMOTHY TO CONDUCT THE DIABETES STUDY AT CHIAWELO COMMUNITY HEALTH CENTRE.

Dear Dr G A Timothy

Following our discussion regarding your research proposal entitled, "Determining factors that influence glycaemic control at Community Health Centers in the Johannesburg Metro District in Gauteng Province, South Africa:

I will grant you permission to conduct this research within the above mentioned facility.

Please ensure that allowance is made for feedback to be communicated to my staff such that the facility, staff and patients benefit from this study.

Thank you

17, 12, 2008

Facility Managers Name **Signature**

Department of Heal
Lefapha la Maphe
Departement van Gesondhe
Umnyango wezeMpi

JHB-WEST RAND REGIC
LENASIA SOUTH C.H.C.

Enq:011 855 -4648
Fax: 011 855 – 1518

To whom it may concern

Dear Sir/Madam

This letter serves to confirm that Dr GA Timothy has discussed her proposal to conduct a study entitled "Determining factors that influence glycaemic control at CHC's in the JHB Metro District" .
I am happy to give her the permission to do her study at our facility. Permission has also already been permitted by Mrs C Kula (Acting Regional Health Director)

Yours sincerely

.....
MS. T. P. MZOLO
FACILITY MANAGER

DATE : 30/1/09

APPENDIX C:

Methods utilised by different laboratories for blood testing

Two of the CHCs utilized the same NHLS laboratory for all blood testing whereas the third CHC used a different NHLS laboratory. (Table 16)

Table 16: Laboratories used for blood testing by each CHC

	Lenasia South CHC	**Chiawelo CHC**	**Discovery's CHC**
HbA_{1c}	CHBH* NHLS	CHBH* NHLS	Johannesburg Hospital NHLS
Lipids	CHBH* NHLS	CHBH* NHLS	Krugersdorp NHLS

*Chris Hani Baragwanath Hospital (CHBH)

Comparing the methods used for measurement between the various laboratories for the 3 tests, the following were noted:-

HbA_{1c}

Both the Johannesburg Hospital and the CHBH laboratories utilize the Tin1-quant Hemoglobin A_{1c} II machine to measure HbA_{1c} based on turbidimetric inhibition for haemolysed whole blood. The method had been standardized against the approved International Federation of Clinical Chemistry (IFCC) reference method for the measurement of HbA_{1c} in human blood.

Lipids

Cholesterol and triglycerides are all analysed at both the laboratories using the ADVIA Chemistry Systems and the Bayer Clinical Method for ADVIA 1200.

APPENDIX D:

PATIENT QUESTIONNAIRE

Interviewer I.D.: ☐ Study number: ☐

Clinic name: ----------
Date of Interview: YY | MM | DD

1. Socio Demography:

1.1 Sex: M ☐ F ☐

1.2 Date of Birth: YY | MM | DD

1.2.1 Verified with I.D book/passport/clinic card? Y ☐ N ☐

1.3 Ethnicity:

White ☐ Black ☐ Indian ☐ Coloured ☐ Other ☐

1.4 How much schooling have you completed?

None ☐ Less than Primary school ☐
Primary school completed ☐ Some high school ☐
High school completed ☐ Tertiary education ☐

1.5 Which of the following best describes your work status over the past 1 year?

Unemployed (but able to work) ☐ Unemployed (unable to work) ☐
Retired/pensioner ☐ Homemaker ☐
Self employed ☐ Student ☐
Government employee ☐ Non government employee ☐
Voluntary work (unpaid) ☐

Other: Please specify----------

1.6 Which of the following do you have in your household at the present time?

Electricity	Yes=1	No=0	
Television	Yes=1	No=0	
Radio	Yes=1	No=0	
Motor vehicle	Yes=1	No=0	
Fridge	Yes=1	No=0	
Washing machine	Yes=1	No=0	
Telephone	Yes=1	No=0	
Video machine	Yes=1	No=0	
Microwave	Yes=1	No=0	

2. General Diabetes Information

2.1 When were you diagnosed with diabetes? | YY | MM | DD |

2.2 Where was the diagnosis made? ----------

2.3 How long have you been attending this CHC? ----------

2.4 What type of treatment are you currently on?

Oral ☐ Injectable ☐ Combination of both ☐

3. Clinic accessibility

3.1 What transport do you use to get here?

Walk ☐ Car ☐ Taxi ☐ Bus ☐

Other: Please specify----------

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? Y N

If not, why do they come here? ----------

4. Service satisfaction

4.1 On a scale of 1-5 how friendly and helpful would you say the clinic staff are?
1 being very unfriendly and very unhelpful and 5 being very friendly and very helpful.

1	2	3	4	5

4.2 On a scale of 1-5 how satisfied are you with the care you receive at this clinic?
1 being very dissatisfied and 5 being very satisfied.

1	2	3	4	5

5. Treatment Compliance

5.1 Do you ever forget to take your medication?

☐ Yes ☐ No ☐ Unsure

5.1.1 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

5.1.2 Have you taken your medication today? ☐ Y ☐ N

5.2 Have you ever been hospitalised for diabetes problems? e.g. For high or low glucose levels.

Specify? ---------- ☐ Y ☐ N

---

6. Perception of Diabetes Education

6.1 Have you ever received education from this clinic on how to care for yourself with regards to diabetes? ☐ Y ☐ N

6.2 Do healthcare staff inform of you of your glucose level after you are tested at this clinic?

☐ Y ☐ N

What is your reading today? ----------

6.3 Has your nurse or doctor at this clinic ever advised you to take special care of your feet?

☐ Y ☐ N

6.4 Has your nurse or doctor at this clinic ever told you to follow an exercise program?

☐ Y ☐ N

6.5 Has your nurse or doctor at this clinic ever asked you to follow a special diet?

☐ Y ☐ N

7. RISK FACTOR ANALYSIS

7.1 Alcohol Consumption

Have you consumed alcohol within the past 1 year? ☐ Y ☐ N

If yes, how often do you drink?

☐ Daily ☐ 5-6 times a week ☐ 1-4 times a week

☐ 1-3 times a month ☐ Less than once a month

When you **do** drink, how many standard drinks do you have at one go? i.e. on one day?--------

---

7.2 Diet

In a typical week, how many days do you eat fruit? ----------

In a typical week how many days do you eat vegetables? ----------

7.3 Raised BP

Are you a known Hypertensive? Y N

Are you currently receiving treatment for hypertension? Y N

When last was your BP checked? ----------

During the past 1 year have you ever been told that your BP is high? Y N

During the past 1 year have you been to a traditional healer or alternate healer who has said that your BP is high? Y N

Are you on any herbal medication, traditional medicines or homeopathic treatment for high BP? Y N

7.4 Physical Activity

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **day/s per week**

☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **hour/s per day** _____ **minute/s per day**

☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **day/s per week**

☐ No moderate physical activities → ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hour/s per day** _____ **minute/s per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **day/s per week**

☐ No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **hour/s per day** _____ **minute/s per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hour/s per day** _____ **minute/s per day**

☐ Don't know/Not sure

PATIENT MEASUREMENTS

1. Random blood glucose (Mmol) ☐

2. Height (cm) ☐

3. Weight (kg) ☐

4. Waist circumference (cm) ☐

5. Blood Pressure (mm/hg) ----------/----------

7. Pulse (beats/min) ☐

8. Urine Analysis

---

9. Bloods taken for:

	Y	N
HBA1C		
Creatinine		
Lipids (total cholesterol + lipid profiles)		
Has the patient been fasting when these samples were taken?		

APPENDIX E:

HEALTHCARE PROFESSIONAL QUESTIONNAIRE

Interviewer I.D. [ ] Participant study number [ ]

Date of Interview: [YY] [MM] [DD]

1.1 Do you have a diploma or higher training in chronic diseases or Diabetes specifically? [Y] [N]

If yes, specify what and from where? ----------

1.2 Where do you believe that diabetes treatment at primary health care (PHC) level is most effectively dealt with?

A) in a specific dedicated Diabetes Clinic in PHC [ ]

B) in a generalised Primary Health care setting [ ]

1.3 On average how many patients do you see in a diabetes clinic in a day? --

1.4 How much time do you believe is sufficient on average to ensure each patient is managed adequately? ----------

Comments----------

1.5 List some of the challenges you face whilst working in the chronic disease clinics, especially diabetic patient care.

---

2 Guideline Adherences:

2.1 Are you aware that National guidelines for diabetes care at the primary level exist? [Y] [N]

2.2 Do you follow strictly the guidelines issued by the Department of Health for Diabetes Treatment? [Y] [N]

2.3 Do you have a copy of the diabetes guidelines readily available? [Y] [N]

2.4 According to the guidelines:

2.4.1 What random glucose level do you use to treat diabetes together with symptoms of diabetes? ----------

2.4.1.2 What fasting glucose level do you use to treat diabetes together with symptoms of diabetes? ----------

2.4.2 Can glucose in the urine (glucosuria) be used as a diagnostic tool for diabetes?

Y N

2.4.3 What is the preferred treatment of choice for obese or overweight patients with diabetes?

☐ Glibenclamide ☐ Gliclazide ☐ Metformin

2.4.4 How often should urinanalysis be done at clinics? ----------

2.4.5 What are the values used to diagnose an impaired glucose tolerance test?

2.4.6 What is the cut off value for HBA1C? ----------

2.4.7 How often should the HBA1C be done? ----------

3 Skills perception

Are you comfortable performing the following tests?

	Y/N
1. Visual acuity	
2. Fundoscopy	
3. Urine dipstix	
4. Complete foot exam	
5. Neurological exam for nerve damage	

APPENDIX F:

HEALTH FACILITY MANAGER INTERVIEW

1. Does this clinic have set days for seeing patients with chronic diseases? Y N

If Yes, Please specify the days----------

2. Does this clinic have set days dedicated for Diabetic patients only? Y N

If yes, please specify the days----------

3. Does your clinic run on an appointment system or are patients expected to arrive all at once? -------

---

4. How long has it been now that you are in the position of Clinic manager? ----------

5. STAFF COMPLEMENT				
	Total	**NCD**	**Diabetes**	**If unavailable at this clinic, where do patients get referred to see them**
Professional nurses				
Staff Nurses				
Nursing Assistants				
Social Workers				
Dieticians				
Doctors				
Health Promoters				
Podiatrist				
Nurses with special Diabetes training				

6. PATIENT DATA 2008							
	Mar	**Apr**	**May**	**June**	**July**	**Aug**	**Total**
Total number of patients seen at clinic							
Total number of Patients seen in the Chronic Disease clinic							
Total number of new diabetics							
Total number of diabetic follow ups							
Number of patients referred to higher level of care							

7. Which hospital do you refer to complicated cases to?

How far is it? (Distance)----------

8. Are course readily available for healthcare staff if higher learning in diabetes is required? Specify ----------

---

---

9. Does the clinic have a system to detect defaulting diabetic patients?

If yes, please explain Y N

---

10. Does this clinic have a system for following up defaulting patients? N Y N

If yes, please explain

---

11. What systems do you have in place to ensure good quality of care of Diabetic patients?

---

12. Are copies of the following available at the clinic and how many?

	Y/N	(n)
National guidelines on treatment of Diabetes		
Management protocols on Type II diabetes at primary health care level		
Patient educational material related to diabetes		

13. Is there a pharmacy on site at this clinic? Y N

14. Has there ever been in interruption in the availability of medication (insulin) in the past 6/12? Y N

If yes, specify when ----------

Specify why? ----------

15. Has there ever been an interruption in the availability of insulin syringes or pens?

If yes, specify when. ---------- Y N

APPENDIX G:

RECORD REVIEW DATA COLLECTION SHEET

Date of diabetes diagnosis/ date of start of attendance at the clinic?

YY	MM	DD

How many clinic visits for diabetes has occurred in the last 6 months? ----------

Indicate recorded values for the following at all clinic visits during the past 6 months?

	Dates												
Laboratory measurements													
Random Glucose level	Mmol/l												
HBA1C	%												
T Chol	Mmol/l												
Creatinine													
Fasting Glucose	Mmol/l												
Non Laboratory Measurements													
Weight	kg												
Height	m												
BMI	Kg/m^2												
BP	Mm/hg												
Health promotion done													
Dietician referral?													
Date seen by dietician													
Alcohol history recorded													
Advised on reducing intake?													
Advised to stop smoking.													

HBA1C last recorded result ever? ----------

Number of HBA1C recorded on NHLS system for same record reviewed? ----------

Does the patient have the following co-morbid conditions noted in the patient records?

Condition	Y/N	Diagnosed >6/12 ago	Diagnosed <6/12 ago	Additional comments
Hypertension				
Hypercholesterolemia				
Obesity				

Is there a prescription in the patient records for any of the following?

	Y/N	SPECIFY
Diabetes		
Hypertension		
Lipid lowering		
Other chronic disease:		

Were the following examinations ever recorded in the notes?

EXAM	Y/N	LAST RECORDED DATE
CVS exam		
ECG		
Visual acuity		
Fundoscopy		
Foot exam by nurse		
Examination by Podiatrist		

APPENDIX H:

EQUIPMENT VERIFICATION

EQUIPMENT	(n)	NUMBER WORKING	If applicable indicate if manual or electronic
1.Weighting scales			
2.Urine Glucose sticks			
3.Blood Glucometer			
4.Sphygmomanometers			
5.Stethoscopes			
6.ECG Machines			
7.Snellens Charts			
8.Fundoscopes			
9.Tape Measure			
10.Height Scale			

Measurements done for verification									
	1	2	3	4	5	6	7	8	9
BP machines									
Weighting scales									
Glucometers									

APPENDIX I:

PARTICIPANT INFORMATION SHEET FOR PATIENT INTERVIEWS:

FACTORS INFLUENCING GLYCAEMIC CONROL IN DIABETICS AT THREE COMMUNITY HEALTH CENTRES IN JOHANNESBURG

Good day. My name is Dr Geraldine Timothy and I am a Registrar at the WITS School of Public Health. You are being invited to participate in a research study to determine factors that influence glycaemic control in the Johannesburg Metro District, Gauteng Province. This form is to help you decide whether you wish to participate in the study or not.

What is the Purpose of the Study?
The research project, to be conducted from January 2009 will involve interviews with patients and doctors to determine what influences the control of glucose levels in the blood. I am hoping to find out from service providers what factors we can target to improve the way you as a patient with diabetes is managed.

Why have you been chosen?
You have been chosen to participate in this study because we are interested in determining how well patient's blood glucose levels are controlled. I would like to conduct an interview with you requiring about 10-15 minutes of your time, answering various questions about yourself and diabetes. We also would like your permission to do a blood test to determine how well controlled your blood glucose level is. Lastly we wish to do a few measurements for you, i.e. height, weight, and waist.

Participation is voluntary: I would like to stress that this is voluntary, and you may choose not to participate or to discontinue participation at any time.

Risks: There are no foreseeable risks to your participating. Very minor discomfort might be experienced whilst taking your blood for testing. Drawing blood is part of your routine medical examination as a patient with diabetes. This will be exactly the same amount of discomfort you are already accustomed to as a diabetic patient.

Benefits: The benefits of taking part in this study include having a role in improving the control of diabetes in the district.

Confidentiality
Your identity will not be revealed and your confidentiality will be protected in any reviews and reports of this study which may be published.

Contact details
If you have any questions or concerns or would like more information about this study please contact: Geraldine Timothy, Principal Investigator on the study, at 076 646 2369 or e-mail geraldine.timothy@wits.ac.za

If you are unhappy with the way this research is conducted, you are welcome to contact the Chair of the Wits Human Ethics Committee Prof P Cleaton Jones through his secretary Ms Anisa Keshav on 011-717-1234

Thank you for taking time to read this sheet.
Dr Geraldine Timothy

PARTICIPANT INFORMATION SHEET FOR HEALTH CARE PROFESSIONAL INTERVIEWS

FACTORS INFLUENCING GLYCAEMIC CONROL IN DIABETICS AT THREE COMMUNITY HEALTH CENTRES IN JOHANNESBURG

Good day. My name is Dr Geraldine Timothy and I am a Registrar at the WITS School of Public Health. You are being invited to participate in a research study to determine factors that influence glycaemic control in the Johannesburg Metro District, Gauteng Province. This form is to help you decide whether you wish to participate in the study or not.

What is the Purpose of the Study?
The research project, to be conducted from January 2009 will involve interviews with health care professionals working with diabetic patients at primary clinics to determine what influences the control of glucose in the blood. I am hoping to find out from service providers what factors we can target to improve the burden of disease caused by diabetes.

Why have you been chosen?
You have been chosen to participate in this study because we are interested in determining health care professional factors that influence blood glucose levels. I would like to conduct an interview with you requiring about 10-15 minutes of your time, answering various questions about how you perceive diabetes management. I would like to stress that this is voluntary, and you may choose not to participate or to discontinue participation at any time.

Confidentiality
Your identity will not be revealed and your confidentiality will be protected in any reviews and reports of this study which may be published.

Are there any disadvantages or benefits to taking part?
There are no foreseeable risks to your participating. The benefits of taking part in this study include having a role in improving the control of diabetes in the district.
The Gauteng Department of Health has approved this project. Feedback of our findings will be offered to them. You can be assured of your anonymity as well as your Facilities anonymity in the feedback thereby NOT exposing any healthcare professional to any form of victimisation or repercussions from the study.

Contact details
If you have any questions or concerns or would like more information about this study please contact: Geraldine Timothy, Principal Investigator on the study, at 076 646 2369 or e-mail geraldine.timothy@wits.ac.za

If you are unhappy with the way this research is conducted, you are welcome to contact the Chair of the Wits Human Ethics Committee Prof P Cleaton Jones through his secretary Ms Anisa Keshav on 011-717-1234

Thank you for taking time to read this sheet.
Dr Geraldine Timothy

Informed Consent

Adult Patient Participant

FACTORS INFLUENCING GLYCAEMIC CONROL IN THREE COMMUNITY HEALTH CENTRES IN THE CITY OF JOHANNESBURG

The research project- *Factors influencing glycaemic control in three community health centres in the City of Johannesburg*:

1. Has been explained to me. I understand that it involves a face to face questionnaire administered by a research assistant. I do not mind giving information about myself, my general health.

2. I understand that a blood test is required. I do not mind having this test done on me.

3. I understand that while the study may not have any direct benefits for me, it will help researchers to understand how diabetes management can be improved in the Gauteng province.

4. I understand that my name, address, and other personnel information will not be recorded on the questionnaire forms and thus ensuring my confidentiality.

5. I understand that I do not have to take part in this project. If I choose not to take part or decide not to answer a question, this will not affect the way, in which I will be treated at the health facility. Similarly, if I choose to withdraw from this project at any stage, this will not prejudice me in anyway in the future.

Name of Patient participant: _____

Name of Research Assistant: _____

Signature of Patient-participant _____

Signature of Research assistant _____

Date	d	d	m	m	2	0			**Study No**	f	f	d	d	p	p

GT number										

Informed Consent

Health Care Professionals

FACTORS INFLUENCING GLYCAEMIC CONROL IN THREE COMMUNITY HEALTH CENTRES IN THE CITY OF JOHANNESBURG

The research project- *Factors influencing glycaemic control in three community health centres in the City of Johannesburg*:

1. Has been explained to me. I understand that it involves a face to face questionnaire administered by a research assistant. I do not mind giving information about my clinical practices.

2. I understand that while the study may not have any direct benefits for me, it will help researchers to understand how diabetes management can be improved in the Gauteng province.

3. I understand that my name, address, and other personnel information will not be recorded on the questionnaire forms and thus ensuring my confidentiality.

4. I understand that I do not have to take part in this project. If I choose not to take part or decide not to answer a question, this will not affect the way, in which I will be treated at the health facility. Similarly, if I choose to withdraw from this project at any stage, this will not prejudice me in anyway in the future.

Name of participant: _____

Name of Research Assistant: _____

Signature of participant _____

Signature of Research assistant _____

Date	d	d	m	m	2	0			**Study No**	f	f	d	d	p	p

INFORMATION SHEET FOR FACILITY MANAGERS

FACTORS INFLUENCING GLYCAEMIC CONROL IN THREE COMMUNITY HEALTH CENTRES IN THE CITY OF JOHANNESBURG

Dear Facility manager. My name is Dr Geraldine Timothy and I am a Registrar at the WITS School of Public Health. You and your facility are being invited to participate in a research study to determine factors that influence glycaemic control in the Johannesburg Metro District, Gauteng Province. This form is to help you decide whether you wish to participate in the study or not.

What is the Purpose of the Study?
The research project, to be conducted from January 2009 will be conducted at three Community Health Centres already randomly selected in the Johannesburg Metro District.
The study will consist of a few components.
It will involve interviews with diabetic patients attending at the CHC's, interviews with health care professionals at the CHC's as well as an interview with you the facility manager.
Records of the same patients to be interviewed will also be reviewed.
Interviews will be conducted by myself as well as a research assistant. Confidentiality of all participants will be maintained.
We are hoping to find out from these facilities what factors we can target to improve the burden of disease caused by diabetes.

Why have you been chosen?
Your facility was randomly chosen for this study from all the CHC's in the JHB metro district.
I would like to stress that this is voluntary, and you may choose not to participate or to discontinue participation at any time.

Confidentiality
Your identity as well as your facilities identity will not be revealed and your confidentiality will be protected in any reviews and reports of this study which may be published.

Are there any disadvantages or benefits to taking part?
There are no foreseeable risks to your participating. The benefits of taking part in this study include having a role in improving the control of diabetes in the district. Feedback will be offered to your facility and reflection on the findings will obviously benefit your institute.
The Gauteng Department of Health has approved this project. Feedback of our findings will be offered to them. You can be assured that there will be no repercussions from the study and no form of victimisation will occur. Names of healthcare professionals will be kept confidential in the report.
Please also note that researchers and research assistants will be well trained in their responsibilities and professionalism will be guaranteed at all times.

Contact details
If you have any questions or concerns or would like more information about this study please contact: Geraldine Timothy, Principal Investigator on the study, at 076 646 2369 or e-mail geraldine.timothy@wits.ac.za

If you are unhappy with the way this research is conducted, you are welcome to contact the Chair of the Wits Human Ethics Committee Prof P Cleaton Jones through his secretary Ms Anisa Keshav on 011-717-1234

Thank you for taking time to read this sheet.

Dr Geraldine Timothy

INFORMED CONSENT: FACILITY MANAGER

FACTORS INFLUENCING GLYCAEMIC CONROL IN THREE COMMUNITY HEALTH CENTRES IN THE CITY OF JOHANNESBURG

The research project- *Factors influencing glycaemic control in three community health centres in the City of Johannesburg*:

1. Has been explained to me. I understand that it involves a face to face questionnaire administered by the principal investigator. I do not mind giving information about my clinical practices.

2. I understand that while the study may not have any direct benefits for me, it will help researchers to understand how diabetes management can be improved in the Gauteng province.

3. I understand that my name, address, and other personnel information will not be recorded on the questionnaire forms and thus ensuring my confidentiality.

4. I understand that I do not have to take part in this project. If I choose not to take part or decide not to answer a question, this will not affect the way, in which I will be treated at the health facility. Similarly, if I choose to withdraw from this project at any stage, this will not prejudice me in any way in the future.

Name of participant: _____

Name of Researcher: _____

Signature of participant _____

Signature of Researcher _____

Date	d	d	m	m	2	0			**Study No**	f	f	d	d	p	p

Facility Name										