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Processes of care, lifestyle advice, treatment and glycaemic control amongst patients with Type 2 diabetes attending the Johan Heyns Community Health Centre in Sedibeng District

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PROCESSES OF CARE, LIFESTYLE ADVICE, TREATMENT AND GLYCAEMIC CONTROL AMONGST PATIENTS WITH TYPE 2 DIABETES ATTENDING THE JOHAN HEYNS COMMUNITY HEALTH CENTRE IN SEDIBENG DISTRICT

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfillment of the requirements for the degree

of

Master of Family Medicine

Johannesburg, 2014

DECLARATION

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

_____

Aswin Kalain

……day of……., 2014

DEDICATION

In memory of my mother

Sarita Kalain

1927-2001

ABSTRACT

Background

The combined influence of processes of care, lifestyle advice and drug treatment on glycaemic control in Type 2 diabetes in primary care settings is not well documented.

Aim

To describe the provision of lifestyle advice, selected processes of care and drug treatment to, and assess the influence of these factors on glycaemic control in, a sample of adults with type 2 diabetes mellitus attending the Johan Heyns Community Health Centre in Sedibeng District, Gauteng.

Methods

A cross-sectional design was used. Participants consisted of 200, consecutively chosen, adult volunteers with type 2 diabetes. Information on demographics, reported receipt of lifestyle advice and anthropomorphic measurements was collected through questionnaire-based interviews. This was followed by a record review of all participants' clinic files for information on current drug management, co-morbid medical conditions and documentation of processes of care, in the preceding 12 months, in respect of HbA1c, blood pressure (BP), weight, waist circumference (WC) and body mass index (BMI) monitoring. HbA1c values were used to ascertain glycaemic control. Performance of processes of care was assessed in accordance with Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) guidelines. Parsimonious models for glycaemic control were constructed through multivariate logistic regression.

Results

Mean age of the sample was 58 years with 58% in the 50-64 year age group. Blacks (88%) and females (63%) were in the majority.

Over two-thirds had diabetes for under 10 years and 98% had at least one co-morbid condition, mainly hypertension (92%). Obesity was noted in 65%, while 95% of females and 83% of males had a WC that conferred substantial cardio-metabolic risk.

Receipt of advice on any of diet, exercise or weight control from a health professional in the preceding 12 months was reported by 79%, with 67% reporting receipt of advice on all three.

Under 2% of patient records met the SEMDSA standard for processes of care for HbA1c, weight, WC and BMI monitoring, while 93% achieved the standard for BP monitoring.

Exclusive oral treatment was prescribed in 62%, and the majority of these were on combined metformin and sulphonylurea; 5% were on insulin monotherapy.

Optimal glycaemic control (HbA1c < 7%) was noted in only 25% of the sample.

On multivariate analyses, the presence of CCF conferred higher odds of controlled glycaemia (OR = 3.17, P = 0.035). Compared with insulin monotherapy, treatment with either combined metformin and insulin (OR = 0.216, P = 0.02), or with the combination of all 3 drug classes (metformin, sulphonylurea and insulin) (OR = 0.185, P = 0.027), conferred lower odds of glycaemic control.

Conclusions

This study highlights substantial shortcomings in the compliance with key processes of care and the achievement of optimal glycaemic control for type 2 diabetes mellitus in the current research setting. An inverse association was noted between glycaemic control and the use of combined oral and insulin drug therapy. Measured processes of care and reported receipt of lifestyle advice showed no association with glycaemic control. CCF co-morbidity conferred improved odds of controlled glycaemia.

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TABLE OF CONTENTS

		Page
DECLARATION		ii
DEDICATION		iii
ABSTRACT		iv
ACKNOWLEDGEMENTS		vi
TABLE OF CONTENTS		vii
LIST OF TABLES		xii
ABBREVIATIONS		xiv
CHAPTER 1: INTRODUCTION		1
1.1	**Background**	1
1.2	**Motivation and Rationale**	2
1.3	**Aim and Objectives**	3
1.3.1	Aim	3
1.3.2	Objectives	4
CHAPTER 2: LITERATURE REVIEW		5
2.1	**Literature search and structure of the chapter**	5
2.2	**Pathophysiology of type 2 diabetes mellitus**	5
2.3	**Epidemiology**	7
2.4	**The Importance of glycaemic control**	8
2.5	**Prevalence of glycaemic control**	11
2.6	**The processes of care in type 2 diabetes**	12
2.6.1	Compliance with process of care standards	15
2.6.2	Processes of care and glycaemic control	16

2.7 Weight, diet and exercise 18

2.7.1 Exercise, diet and weight loss advice by healthcare professionals 21

2.7.2 Lifestyle advice and glycaemic control 23

2.8 Diabetic medications 24

2.8.1 The need for pharmacological agents 24

2.8.2 Diabetic medication and glycaemic control 25

2.8.2.1 The effectiveness of oral agents as mono-therapy 25

2.8.2.2 The need for additional drugs 25

2.8.2.3 Adjunctive insulin therapy 27

2.9 Conclusions 29

CHAPTER 3: METHODOLOGY 31

3.1 Study design 31

3.2 Study setting 31

3.3 Study population 32

3.4 Sampling 32

3.4.1 Sample size 32

3.4.2 Sampling strategy 33

3.5 Measuring tools 34

3.6 Data collection 36

3.7 Data analysis 37

3.8 Pilot study 38

3.9 Study bias 38

3.9.1 Sampling and selection bias 38

3.9.2 Interview and measurement bias 39

3.9.3 Recall, reporting and information bias 40

3.10 Ethical considerations 41

CHAPTER 4: RESULTS 42

4.1 Introduction 42

4.2 Final sample size and missing data 42

4.3 Demographics 43

4.4 Clinical information 44

4.4.1 Duration of diabetes and presence of co-morbid conditions 44

4.4.2 Anthropomorphic profile 45

4.5 Processes of care 47

4.6 Receipt of lifestyle advice 47

4.7 Pharmacological management 48

4.8 Glycaemic control 49

4.9 Univariate associations of glycaemic control 51

4.9.1 The processes of care 51

4.9.2 Lifestyle advice on diet, exercise and weight control 52

4.9.3 Drug treatment 53

4.9.4 Demographics 54

4.9.5 Clinical parameters 55

4.9.6 Summary of variables associated with glycaemic control on univariate analysis 57

4.10 Logistic models of glycaemic control 57

4.10.1 The unadjusted model 57

4.10.2 Multivariate logistic models for glycaemic control 59

CHAPTER 5: DISCUSSION 61

5.1 Introduction 61

5.2 Demographics 61

5.2.1 Age and sex 61

5.2.2 Race and residence 62

5.2.3 Education and employment status 63

5.3 Glycaemic control 64

5.4 Processes of care 67

5.5 Lifestyle advice on diet, exercise and weight control 72

5.6 Diabetic medication 73

5.7 Associations of glycaemic control 75

5.7.1 Processes of care 75

5.7.2 Diet, exercise and weight control advice received 77

5.7.3 Diabetic medication 78

5.7.4 Co-morbid medical conditions 81

5.7.5 Race 83

5.8 Implications of key findings in this study 85

5.9 Limitations and strengths of this study 88

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS 91

6.1 Conclusions 91

6.2 Recommendations 92

REFERENCES 95

APPENDIX A: Interview questionnaire 110

APPENDIX B: Clinical record and process of care data extraction sheet 111

APPENDIX C: Ethics clearance certificate from WITS HREC 113

APPENDIX D: Permission from Sedibeng District Health 114

APPENDIX E: Patient information sheet 115

APPENDIX F: Informed consent form 117

APPENDIX G: Additional results 119

APPENDIX H: Change of title application 120

LIST OF TABLES

Table		Page
4.1	Demographic characteristics of the study sample	44
4.2	Profile of selected medical parameters	45
4.3	Anthropomorphic profile	46
4.4	Proportion of sample that met the standard for the selected processes of care	47
4.5	Reported receipt of lifestyle advice on diet, exercise and weight control	48
4.6	Prescribed diabetic medication by treatment type	48
4.7	Prescribed diabetic medication by medication class	49
4.8	Proportions of the study sample with controlled and uncontrolled glycaemia	49
4.9	Profile of glycaemic control delineated by the ACCORD criteria	50
4.10	Blood pressure monitoring and glycaemic control	51
4.11	HbA1c monitoring and glycaemic control	51
4.12	BMI monitoring and glycaemic control	51
4.13	Exercise advice and glycaemic control	52
4.14	Dietary advice and glycaemic control	52
4.15	Weight control advice and glycaemic control	52
4.16	Receipt of any advice and glycaemic control	53
4.17	Diabetic treatment type and glycaemic control	53
4.18	Diabetic medication class and glycaemic control	54

4.19 Glycaemic control amongst the 3 racial groups 55

4.20 Dichotomous association of race and glycaemic control 55

4.21 Glycaemic control according to residence in the catchment area 55

4.22 The presence of any co-morbid condition and glycaemic control 56

4.23 The presence of hypertension and glycaemic control 56

4.24 The presence CCF and glycaemic control 56

4.25 Univariate associations with glycaemic control 57

4.26 Unadjusted odds ratios for variables associated with glycaemic control 58

4.27 Multivariate logistic model for glycaemic control: Model 1 59

4.28 Multivariate logistic model for glycaemic control: Model 2 59

G.1 Duration of diabetes and insulin in individuals on oral and insulin therapy 118

G.2 Insulin duration by race 118

ABBREVIATIONS

ACCORD	Action to Control Cardiovascular Risk in Diabetes
ADA	American Diabetes Association
BG	blood glucose
BMI	body mass index
BP	blood pressure
CCF	congestive cardiac failure
CHC	community health centre
CI	confidence interval
DM	diabetes mellitus
FBG	fasting blood glucose
HbA1c	glycosylated haemoglobin
OR	odds ratio
P	P-value
PHC	primary health care
RBG	random blood glucose
SEMDSA	Society for Endocrinology, Metabolism and Diabetes of South Africa
UKPDS	United Kingdom Prospective Diabetes Study
WC	waist circumference

CHAPTER 1

INTRODUCTION

1.1 Background

Type 2 diabetes is a devastating condition responsible for high levels of morbidity and mortality. Four million diabetes related deaths occur each year worldwide and an estimated 5% of all deaths in Sub-Saharan Africa is attributed to the disease.[1] According to the International Diabetes Federation (IDF), deaths attributable to diabetes in South Africa in 2010 amounted to 45 957[2], a more than 2-fold increase on the figure estimated for 2000.[3]

The excess morbidity and mortality seen in individuals with Type 2 diabetes occur mainly as a result of macro-and micro-vascular pathology resulting in cardiovascular, neurological, ophthalmic and renal complications.[4,5]

An impressive body of evidence exists from studies such as the ground-breaking United Kingdom Prospective Diabetes Study (UKPDS)[6,7,8] demonstrating the link between glycaemic control and diabetic complications, especially those attributable to micro-vascular pathology. Even prior to the UKPDS, there existed strong evidence to suggest that improved glycaemic control decreased the risk of retinopathy, nephropathy and neuropathy in Type 2 diabetics.[9]

A cornerstone in the management of type 2 diabetes is the clinical management of glycaemia and protocols for doing this have been articulated in evidence-based guidelines both In South Africa and internationally.[10,11]

These protocols include both pharmacological and non-pharmacological modalities for glycaemic control together with a clearly defined set of processes of care; in addition, they emphasize the responsibility of health care professionals in the provision of advice on, inter-alia, lifestyle modification.

A number of South African studies demonstrate a pattern of inadequate compliance with these components of clinical management, as well as unsatisfactory levels of glycaemic control.[12-17] The majority of these studies describe the levels of glycaemic control and/or compliance with processes of care[12,13, 15-17]; one study documented receipt of lifestyle advice[14] while two other studies looked at the association of some processes of care and glycaemic control[13,15], one of which was at a tertiary level facility.[13] Of all the available studies reviewed at the time of the present study, none sought to comprehensively look at the influence of processes of care, lifestyle advice and drug treatment on glycaemic control.

1.2 Motivation and Rationale

In Sedibeng District, data on glycaemic control, drug treatment and process of care performance and dissemination of lifestyle advice by clinicians, are not integral components of the district health information system (DHIS). Consequently, this information is not captured and unknown. A previous audit focusing on processes of care amongst a sample of adult type 2 diabetics at the Johan Heyns Community Health Centre in Sedibeng District found that performance of some process of care elements varied between 0 and 49%, while controlled glycaemia was noted to be achieved in no more than 30%.[18]

While it has been documented that overall levels of glycaemic control in various primary care settings are inadequate, the influence of receipt of lifestyle advice by patients, clinicians' practice regarding processes of care, and drug treatment on such control, has not been adequately studied.

The current study therefore seeks to describe the provision process of care, drug treatment and lifestyle advice by health care workers to adults with Type 2 diabetes in a CHC in Sedibeng District. It furthermore assesses the influence of these factors on glycaemic control. It is envisaged that the identification of one or more of these, potentially modifiable components of clinical care, could inform interventions aimed at improving the quality of diabetic care and glycaemic control in primary care facilities within the district and in similar settings elsewhere.

1.3 Aim and Objectives

1.3.1 Aim

This study aims to describe the provision of lifestyle advice, selected processes of care and drug treatment to, and assess the influence of these factors on glycaemic control in, adults with type 2 diabetes mellitus attending the Johan Heyns Community Health Centre in Sedibeng District, Gauteng.

1.3.2 Objectives

- To estimate the current levels of glycaemic control in the study population.
- To estimate the proportion of patients that had each of the following processes of care performed with the indicated frequency in the preceding 12 months in accordance with Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) recommendations[10]:
    - BP measurement at every visit
    - BMI measured once in 12 months
    - Weight and waist circumference measured at every visit
    - HbA1c measured at least twice in 12 months
- To estimate the proportion of patients that reported receipt of information from a health worker at the facility in the last 12 months on the following lifestyle measures:
    - The importance of weight control
    - Exercise
    - Diet
- To describe the current diabetic drug regimens as prescribed in clinic records.
- To uncover possible associations between current glycaemic control and the following factors:
    - Reported receipt of advice on: weight control, exercise and diet
    - Processes of care indicators for HbA1c, blood pressure, weight, BMI and waist circumference monitoring
    - Current diabetic medication
    - Other demographic and clinical factors

CHAPTER 2

LITERATURE REVIEW

2.1 Literature search and structure of the chapter

Articles used for this literature review were identified primarily using PubMed and Medline, and were confined to studies on human subjects published in English. Initial searches were conducted on medical subject headings using the following terms either alone or in combination: “type 2 diabetes” , “glycaemic control” , “exercise”, “diet” , “weight control”, “lifestyle advice” , “processes of care” and “treatment”. Relevance of retrieved studies was assessed based both on study titles, as well as content and, cross referencing from these, identified further articles for consideration. References have been mainly limited to key articles published within the last 20 years; however, where deemed appropriate, older articles were also considered for inclusion.

This chapter on the literature review commences with a brief consideration of the patho-physiology and prevalence of type 2 diabetes and then proceeds to consider the key topics contained in the aim of the present research.

2.2 Pathophysiology of type 2 diabetes mellitus

Diabetes Mellitus is a group of metabolic diseases whose main characteristic is chronic hyperglycaemia arising from either defective insulin secretion from the pancreas, defective insulin action on target organs, or both.[19,20] The simplest way to classify diabetes is to look at whether the condition is primary or secondary.[5]

These 2 basic categories however, subsume a number of additional sub-categories that are accounted for in the following, much broader, clinical classification by the American Diabetic Association (ADA)[19,11] :

- Type 1 diabetes mellitus: results from β-cell destruction leading to an absolute insulin deficiency
- Type 2 diabetes mellitus: results from a variable combination of insulin secretion defects and insulin resistance ranging from a predominance of insulin resistance with relative insulin deficiency, to a predominantly insulin secretory defect with insulin resistance.
- Specific types of diabetes due to other causes:
    - Genetic defects in β-cell function
    - Genetic defects in insulin action
    - Diseases of the exocrine pancreas
    - Drug or chemically induced
- Gestational diabetes (GDM): diabetes diagnosed during pregnancy that is clearly not overt diabetes.

The patho-physiologic hallmark of Type 2 diabetes is insulin resistance with relative insulin insufficiency.[20] Initially, increase in pancreatic insulin secretion compensates for insulin resistance. When β-cell depletion occurs, the pancreas is no longer able to maintain compensatory hyperinsulinaemia and there is dysregulation of glucose homeostasis: peripheral uptake is compromised, counter-regulatory feedback on glucagon is diminished and glucose intolerance and hyperglycaemia supervene.[5,19,20]

Type 2 diabetes is a multi-factorial disease with both genetic and environmental risk factors. There is an increased risk associated with[5,20] :

- Inheritance
- Obesity
- Increasing age
- Lack of physical activity

Other determinants of the disease include[20,21] :

- Females with prior GDM
- Race/ethnicity

2.3 Epidemiology

Worldwide, this disease has reached epidemic proportions. Estimates from 2007 suggest that it had already affected 171 million people worldwide, with India, a hotbed of this disease, accounting for almost 32 million cases.[4] More recent estimates place worldwide prevalence even higher[22] : amongst adults in the 20-79 year age group, prevalence was estimated to be 6.4% or approximately 285 million people. This figure is expected to escalate to 7.7% or 439 million adults worldwide by 2030.[22] Between 2010 and 2030, developed countries are expected to experience a 20% increase in prevalence; the expected increase in the developing world is predicted to be over 3-fold higher at 69%.[22] In 3 of the 6 developing regions, namely the Middle East and North Africa, South Asia, and Sub-Saharan Africa, the prevalence is expected to double from 2000 to 2030. In Sub-Saharan Africa specifically, the prevalence increase is projected to be 97%.[23] In Africa as a whole, the prevalence of diabetes is expected to increase from just below 4% in 2010 to almost 5% in 2030.[1]

Prevalence figures for South Africa show a similar trend. Data published by the International Diabetes Federation (IDF) placed the prevalence of diabetes amongst adults aged 20-79 in 2003 at 3.4%. [24] This is expected to rise to 5.6% by 2030.[2]

There are very few recent province specific prevalence figures for South Africa but past studies from the period 1993-1999 reveal a varied picture: most studies were conducted in the Cape Town and Durban urban areas and most were race specific with only 2 of the 7 studies, conducted in Cape Town, looking at a mixed race study population.[25] In the latter, prevalence varied from 10.8% to 28.7%. A more recent study in rural southern Free State estimated the prevalence of the disease there to be 7.6%.[26]

2.4 The Importance of glycaemic control

Type 2 diabetes is not a benign disease; it is a devastating condition with high levels of morbidity and mortality. Globally, 4 million diabetes related deaths occur each year[4]; this translates to approximately 11 000 deaths each day. In Africa, diabetes related mortality as a proportion of all deaths was estimated to be 6% in 2010 with 1 in 20 of all such deaths occurring in Sub-Saharan Africa.[1] A study in 2007 by Bradshaw et al., to estimate the burden of diabetes related disease in South Africa in 2000, found that 14% of all ischaemic heart disease (IHD), 10% of all strokes and 12% of all renal disease amongst adults aged 30 years or older, could be attributable to the disease; in addition, 258 025 disability-adjusted life years (DALY's) and 22 415 deaths were attributed to the disease.[3] According to the IDF, deaths attributable to diabetes in South Africa in 2010 amounted to 45 957[2]; this represents a more than 2-fold increase on the figure estimated for 2000 by Bradshaw et al.[3]

The high levels of morbidity and mortality seen with the disease are largely due to micro- and macro-vascular complications.[4,17] A critical factor in the prevention of micro- and macrovascular complications is glycaemic control, a fact demonstrated by a number of extensive trials in the past decade and a half. [6-8,27,28]

The earliest convincing evidence for the link between glycaemic control and microvascular complications was provided by research which examined the effects of intensive glycaemic control in insulin dependent diabetics.[27,28] The first of these studies, the Stockholm Diabetes Intervention Study (SDIS), was a small randomized control trial that showed a significantly reduced occurrence of nephropathy, neuropathy and proliferative retinopathy requiring photocoagulation associated with better glycaemic control.[27] These results were observed despite the fact that the mean HbA1c achieved in the intervention arm was 7.2%, which is slightly higher than what is currently accepted as normal.

More evidence for the effect of intensive glycaemic control on long term microvascular complications in IDDM was demonstrated by The Diabetic Control and Complications Trial (DCCT).[28] In this large, multicentre, randomized clinical trial**,** a significant reduction in risk, for both the development and progression of retinopathy was demonstrated in the intervention arm: risk for development of retinopathy was reduced by 76% and progression of retinopathy was reduced by 54%. In addition, there were also significant reductions in the occurrence of microalbuminuria, albuminuria and clinical neuropathy.

While the DCCT provided the first clear evidence of an association between glycaemic control and complications, this association in Type 2 diabetics remained untested in any large scale trial. The landmark trial that firmly established the importance of glycaemic control in Type 2 diabetics was the United Kingdom Prospective Diabetes Study (UKPDS).[6-8] In this large, multicentre, prospective randomized trial conducted at 23 clinical centres, 5102 participants, aged between 25-65 years, with

newly diagnosed Type 2 diabetes were enrolled between 1977 and 1991.[8] The aim was to compare the effects of intensive blood glucose control with that of conventional treatment with diet alone, on the risk of developing microvascular and macrovascular complications in newly diagnosed Type 2 diabetics. Patients were randomized to receive either conventional therapy consisting of diet alone or intensive therapy consisting of diet and medication. The intervention cohort was further categorized into 2 groups:

- UKPDS 33:patients who received sulphonylureas or insulin or both[6]
- UKPDS 34: patients whose bodyweight was greater than 120% of ideal received metformin[7]

Median follow-up times were 10.0 and 10.7 years for the 2 groups respectively. The researchers used 3 aggregate endpoints to assess the difference in outcomes in the study arms[6,7] :

- Any diabetes related endpoint
- Diabetes related death
- All-cause mortality

A significant 12% lower risk (P=0.029) for any diabetes related endpoint, was achieved in the sulphonylurea/insulin arm compared to the conventional treatment arm.[6] While risk reductions of 10% and 6% were noted for any diabetes related death and all-cause mortality respectively, the associations were not statistically significant. The researchers also noted that the risk reduction for any diabetes related endpoint was achieved largely due to a 25% risk reduction in microvascular complications. An important negative finding was the absence of significant risk reduction for macrovascular complications. The metformin arm showed even more impressive risk reductions compared to the conventional treatment arm: 32% lower risk (P=0.002) for any diabetes related endpoint, 42% lower risk (P=0.017) for any diabetes related death and 36% lower risk (P=0.011) for all-cause mortality.[7] Furthermore, unlike the sulphonylurea/insulin arm, which failed to demonstrate any risk reduction for

myocardial infarction, a 39% risk reduction (P=0.01) for the same endpoint was observed in the metformin arm.[6-8] Prior to the UKPDS, results from a number of studies hinted at the beneficial effects of improved glycaemic control on complications in type 2 diabetes[9]; findings from the UKPDS provided the first clear evidence for this association.

2.5 Prevalence of glycaemic control

Globally, glycaemic control amongst Type 2 diabetics is unsatisfactory. An analysis of National Health and Nutritional Examination Survey (NHANES) data by Saadine et al, showed that 47% of people with Type 2 diabetes had HbA1c < 7% and found a non significant improvement in the proportion of patients with poor (HbA1c > 9.0g/dl) glycaemic control between 1999 and 2002**.** More importantly, the same study noted that: "1 in 5 patients still had poor glycaemic control." [29] A more comprehensive picture of glycaemic control trends using NHANES data for the period 1999-2004 was provided by Hoerger et. al.[30] Their analysis showed that the proportion of individuals with HbA1c < 7% increased from 40% for the period 1999-2000, to 57% for the period 2003-2004. However, mean HbA1c, which was estimated to be 7.82% for the period 1999-2000, showed no statistically significant decrease.

As part of a diabetes quality improvement program in community health centres in the United States, the Community Health Centre Network measured the prevalence of diabetic control and found similar results: 27% had poor glycaemic control.[31] The Delhi Diabetes Community Survey, a cross-sectional study conducted by Nagpal and and Bhartia , which investigated the quality of diabetic care amongst a middle and high income population in Delhi, reported poor glycaemic control(HbA1c > 8) in 42% of diabetics surveyed.[32]

In South Africa, there is a dearth of data on glycaemic control amongst diabetics. Available information points to inadequate levels of control. In a survey of hypertensive and diabetic patients conducted at 18 community health centres in the Cape Peninsula, Steyn et.al., found that 76% had an HbA1c greater than or equal to 1% of the upper limit of normal (they used 5.9% as the upper limit of normal), while 57.9% had a random blood glucose greater than 11.1 mmol/l.[15] As part of a quality improvement project to address shortcomings in diabetic care at a rural hospital in KwaZulu-Natal, a post intervention audit showed that only 10% of patients with Type 2 diabetes had an HbA1c of less than 7; furthermore, in 57%, the HbA1c was greater than or equal to 10.[12] Another study also in rural KwaZulu-Natal amongst patients attending both primary and secondary care facilities, found a mean HbA1c of 11.2% in Type 2 diabetics.[16]

2.6 The processes of care in type 2 diabetes

A key responsibility of the physician entrusted with the care of diabetics is attention to processes of care issues. Processes of care refer to those activities that a physician undertakes such as regular HbA1c checks, urine checks, eye and feet examinations and others that define quality of care in diabetes.[33,34] As such, adherence to process of care measures is a necessary condition for the achievement of desired outcomes, which are: good glycaemic control, and, the detection and prevention of complications. A process of care has 2 components: the actual process or activity itself, and the frequency with which it should be carried out.[10] Recommendations for processes of care vary and are contained in various national and international guidelines based on current evidence.[10,11] They include a wide range of activities, from routine processes such as blood glucose, blood pressure and body weight checks, to more specialized activities such as retinopathy and nephropathy screening. Also included are adjunctive processes for the prevention of cardio- and renovascular complications using anti-platelet, lipid lowering

and ACE inhibitor medication. A useful categorization of the various processes is provided by Bailie et. al.[35] This distinguishes between ***basic*** and ***specialized*** processes, ***investigations*** and ***counseling/inquiry*** processes. Basic processes include monitoring the following:

- Weight
- Blood pressure
- Waist circumference
- Body Mass Index (BMI)
- Blood glucose
- Urine dipstix

Specialized processes include performing the following:

- Peripheral pulses check
- Visual acuity check
- Optic fundi examination
- Feet examination
- Opthalmologist referral
- Vaccinations

Investigations:

- Tests for renal function
- HbA1c
- Lipids

Counseling/inquiry processes:

- Diet
- Weight loss
- Exercise/Physical activity
- Substance use: alcohol and tobacco
- Vaccinations
- Diabetes control and medications

In accordance with the scope of the present study, this review will mainly focus on HbA1c and other selected basic processes of care measures.

The American Diabetes Association (ADA) guidelines for standards of care in diabetes[11] recommend biannual determinations of HbA1c in controlled patients; uncontrolled subjects should have this done quarterly. Blood pressure should be done at every visit. Apart from the initial assessment at diagnosis, this guideline is not clear on the routine performance of other basic processes such as weight, waist circumference and BMI measurements at follow up. The Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) recommends the following basic processes of care[10] :

- ***HbA1c*** : biannually if stable; quarterly if treatment changes of treatment goals not achieved.
- ***Weight:*** done at every visit
- ***Waist circumference***: done at very visit
- ***BMI***: done annually
- ***Microalbuminuria***: done annually if no persistent proteinuria.
- ***Blood pressure*** : done at every visit

Neither the ADA nor SEMDSA guidelines recommend routine office determinations of blood glucose levels.

2.6.1 Compliance with process of care standards

Despite the establishment of evidence based guidelines such as those by the ADA and SEMDSA, adherence to process of care issues show varying patterns. In the USA for example, some studies estimate the proportion of diabetics receiving care in accordance with ADA guidelines to be less than 5%.[36,37] These findings are borne out by larger scale studies examining trends of care over longer periods. The study by Saadine et al. assessed changes in diabetes care processes and intermediate outcomes for the period 1988-2002 in the United States and reported increases in compliance with process of care measures to range from 4% to 8%.[29]

Some studies in other contexts reveal a different picture. An audit conducted amongst a sample of general practices in Scotland by Guthrie and colleagues showed very high annual testing rates for HbA1c (88.1%) and cholesterol (77.8%).[38] An earlier study, which analyzed data from multiple practices in 3 health authorities in England, found similarly high proportions of patients who had annual checks for HbA1c (83%).[39] However, both studies reviewed diabetes care in general practice settings that served a largely insured population and as such, might not possibly be directly comparable to other contexts. Comparable studies in the public sector seem to confirm the trend of below par achievement in performance of process measures. One such study conducted in 19 health centres in the American Midwest catering for medically underserved population groups, demonstrated high performance of only 2 process of care indicators, yearly HbA1c and Lipid monitoring, at baseline, before implementation of a quality improvement program.[36] A survey conducted to evaluate diabetes care amongst First Nation populations living in reserves in Alberta, Canada demonstrated that only 46% of the study sample reported having met the required standard for frequency of HbA1c testing.[40]

Research in South Africa points to a similar pattern of unsatisfactory outcomes in basic process of care measures in primary and secondary level public health care facilities. A baseline audit of clinical records of 100 Type 2 diabetics attending the outpatients department of a small rural hospital in Kwazulu-Natal, revealed that blood pressure and random blood glucose were the only measures routinely recorded; no other diabetic process of care measure, including HbA1c, was documented.[12] Steyn et al., conducted a survey to identify provider-related factors in the provision of care to diabetic and hypertensive patients attending 18 community health centres in the Cape Peninsula.[15] Of the 455 diabetic patients' clinical files audited, only 2.6% had an HbA1c measurement recorded in the preceding 12 months. These results for HbA1c measurement contrast significantly with findings of at least one study at a tertiary care facility: Van Zyl and Rheeder conducted a quasi-experimental controlled before-and-after study to assess the impact of a physician education program on the quality of care in 2 diabetic clinics at a tertiary hospital in Gauteng.[13] At baseline, 65% of the intervention sample and 41.5% of the control sample had HbA1c measurements performed in accordance with SEMDSA recommendations; however, performance of the other process of care measures studied (foot exam, eye exam, test for micro-albuminuria and lipid profile) were all significantly below 50% in both groups.

2.6.2 Processes of care and glycaemic control

There is a substantial body of evidence to suggest that improved processes of care are not necessarily mirrored by concomitant improvements in glycaemic control. Results from a small cross-sectional study in 2002 which compared the quality of care received by uninsured diabetics attending private physicians to those attending community health centres in a rural area of the United States, found that while community health centres performed substantially better on process of care measures, glycaemic control did not differ between the two settings.[41]

Subsequent cross-sectional and large scale prospective observational studies that compared processes and outcomes have confirmed this finding.[42,43] Of particular note is the TRIAD study.[43] In this multi-centre prospective observational study, one of the questions researchers studied was whether the number of documented process of care indicators affected various metabolic outcomes. While the addition of one extra process of care measure improved mean LDL levels, no such association was demonstrated for effect on HbA1c levels. Intervention and quality improvement studies have similarly failed to demonstrate convincing evidence for concordance between process of care indicators and glycaemic outcomes[44-47]; in all cases, the interventions significantly improved the processes of care investigated without impacting glycaemic control. Likewise, as in the TRIAD study, Valk et al., compared quality improvement programs for Type 2 diabetics in 2 different countries and reported that the number of HbA1c measurements performed had no impact on long term HbA1c levels.[46]

Of the South African studies referenced, two attempted to assess the influence of selected processes of care on control.[13,15] In the study by Steyn et.al., the documentation of blood pressure and finger-prick glucose readings in patient files showed no association with glycaemic control; however, apart from the fact that finger-prick glucose monitoring is not a standard process of care measure, it is unclear if the levels of performance of either of these processes met any accepted standard.[15] Results of the quasi-intervention study by Van Zyl and Rheeder which reviewed a more comprehensive set of processes of care, including HbA1c monitoring, appear equivocal: while improvements in the performance of processes of care and mean HbA1c in the intervention arm were statistically significant, between-group difference in mean HbA1c was not; furthermore, both arms demonstrated non-statistically significant increments in the proportion of individuals with controlled glycaemia.[13]

Some researchers have tried to make the case for a possible link between processes of care and glycaemic outcomes. For example, in reporting their results of an intervention to improve processes and outcomes, Baillie et al., stated that an "increase in monitoring of HbA1c and the use of hypoglycaemic agents and insulin was associated with a greater proportion of individuals achieving HbA1c < 7%." [35] Whether these factors were individually or jointly responsible was not clear. Similarly, in a cross-sectional survey comparing changes in the quality of diabetic care in Norway between 1995 and 2005, Cooper et al., showed substantial improvement in the performance of a number of processes of care, as well as improvements in the proportion of people who achieved HbA1c $\leq$ 7%, but did not test the association in multivariate analyses.[48] However, the researchers noted that trends in HbA1c monitoring remained unchanged during the period which would suggest that this process of care was probably not responsible for the observed improvements in glycaemic control.

2.7 Weight, diet and exercise

While obesity has long been recognized as a risk factor for the development of type 2 diabetes[5,20,49], there is substantial evidence to show that visceral or intra-abdominal adiposity in particular, is the independent risk factor for insulin resistance which in turn leads to deranged glycaemic control and other associated metabolic abnormalities.[50,51] In light of these findings, it is reasonable to surmise on the converse question, i.e., does weight loss in overweight type 2 diabetics lead to improved metabolic outcomes? There is convincing evidence to suggest that this is indeed the case.

Weight reductions as moderate as 5-10% of baseline body weight can improve insulin sensitivity[49,52] and, consequently, enhance glycaemic control. In 2003, Anderson et al., as part of a larger review and meta analysis of trials looking at, inter-alia, the importance of weight management in type 2 diabetes, demonstrated a positive association between weight loss and improved glycaemic control in obese

individuals.[53] The researchers considered all trials over the preceding 30 years conducted on adults with a BMI > 30kg/m^2 or 120% of ideal body weight, who achieved at least a 5% reduction in baseline body weight at 12 weeks and concluded that: "Although study protocols and medication regimens differed across studies, there was a strong association between weight loss and improved glycemia irrespective of the study protocol."

Subsequent findings from the Look AHEAD (Action for Health in Diabetes) study, a multicentre, randomized controlled trial with the primary objective of measuring the impact of long term weight reduction on cardiovascular morbidity and mortality in overweight type 2 diabetics, confirmed the association between weight loss and glycaemic control.[54,55] Wing et al., reported results of additional analyses on the 1-year look AHEAD data.[56] Amongst others, they reviewed the association between HbA1c change and categories of weight loss. At a moderate weight loss of 5-10%, the odds ratio of achieving a 0.5% drop in HbA1c was 3.52. Equally important is the conclusion that: "The odds of clinically significant improvements in most risk factors were even greater in those who lost 10–15% of their body weight." In particular, the odds for achieving a 0.5% decrease in HbA1c in this case was 5.44.

The association between nutrition and glycaemic outcomes appears to be equivocal, a phenomenon possibly due to the dearth of research on the independent role of nutrition in the management of Type 2 diabetes.[57,58] This notwithstanding, in a 2002 review by Pastors et al[57], the authors concluded that, in respect of glycaemic control per se: "Randomized controlled nutrition therapy outcome studies have documented decreases in HbA1c of 2% in newly diagnosed type 2 diabetes, and 1% in type 2 diabetes with an average duration of 4 years."

A systematic review in 2007 by Moore et al[58], cast some doubt on the efficacy of nutrition as a sole intervention in glycaemic control, a finding which they attribute to the lack of high quality data; the

researchers were able to conclude that the addition of exercise to nutrition appeared to improve glycaemic control in the short term (6 to 12 months). Evidence from at least one, well designed albeit small scale randomized controlled trial, suggests that intensive dietary intervention alone in patients with type 2 diabetes who also have other CVD risk factors, can achieve HbA1c reductions of 0.4% at 6 months.[59]

Exercise, has been regarded as a key component of diabetes management and, since 1990, recommendations for the inclusion of physical exercise as a lifestyle management element have continued to evolve due to evidence that demonstrates beneficial effects on both primary prevention in individuals at risk for developing type 2 diabetes, as well as on secondary prevention in those with established disease.[60] Results from one of the first systematic reviews that established the beneficial effects of exercise on glycaemic control in type 2 diabetics were reported by Boule et al., in 2001.[61] The researchers selected 11 randomized and 3 non-randomized controlled trials where the duration of intervention was at least 8 weeks. Meta analysis showed a statistically significant 0.66% (P=0.001) decrease in HbA1c in the intervention arms, a result the researchers concluded, "is clinically significant and close to the difference between conventional and intensive glucose-lowering therapy in the UKPDS." More recent studies not only confirm the benefits of exercise on glycaemic control, but also demonstrate that these effects appear to be independent of exercise modality.[62,63]

2.7.1 Exercise, diet and weight loss advice by healthcare professionals

Based on mounting evidence for the role of lifestyle factors, not only in the primary prevention, but also in the management of type 2 diabetes, local and international guidelines recommend counseling on diet, exercise and weight control as integral components of initial and ongoing management in adults with the disease.[52, 64-66]

Data from a number of large population-based surveys reveal low levels of counseling regarding diet and exercise by health-care professionals. Overall rates for counseling on exercise range between 25% and 42%[67-69]; counseling rates for diet range between 21% and 37%.[68,69]

Studies aimed at obese subjects display a variable pattern of counseling. A 1999 survey by Galuska et al., based on data from the 1996 U.S. Behavioural Risk Factor Surveillance System (BRFSS), showed that 42% of obese adults were advised to lose weight.[70] Even lower rates of counseling were reported in a Lithuanian national cross-sectional study by Klumbiene et al., which reviewed receipt of counseling by overweight and obese adults from general practitioners.[71] Twenty three percent of males and 29% of females reported having received advice on changing diet; the corresponding rates for exercise advice were 16% and 19% for males and females respectively. However, other studies demonstrated an opposing trend. In a U.S. national survey conducted by Ko et al., 64 % of respondents were told to change diet, 86% were advised to increase levels of physical activity and 59% were advised to do both.[72] Counseling rates for diet and exercise of 55% and 52% respectively, were noted in a 2011 study amongst obese Mexican-Americans by Nguyen et al.[73]

Concomitant poor health status or chronic medical conditions appear to increase the rate for receipt of lifestyle counseling.[68, 69, 72, 74] More specifically, persons with diabetes have significantly increased odds of being counseled. In the Galuska study cited above, 64% of diabetics reported having been counseled on weight loss and the odds for receipt of such counseling was twice that of non-diabetics.[70]

A U.S. population-based survey conducted by Wee et al., showed that, in the overall sample, 34% received advice on exercise. Diabetics and patients with cardiac disease had almost twice the odds of being counseled as compared to individuals without these comorbidities.[67]

These findings amongst sub-samples of diabetics in general surveys are borne out by research on lifestyle advice in diabetics per se. In a study amongst a nationally representative sample of over 26 000 adults who, either had or were at risk of, type 2 diabetes, Morrato et al., assessed the prevalence of ever having received advice to exercise.[75] In this study, more than seventy percent of diabetics were told by a health professional to exercise more. Furthermore, this proportion increased to 76% in diabetics who also had heart disease. While this study provides reliable and convincing evidence, a key limitation is that it only assessed a single dimension of lifestyle modification. Earlier work by Jorgensen et al., researched the question more comprehensively, albeit on a smaller sample, by looking at the perceptions of adult diabetics regarding the receipt of counseling on weight, diet, exercise as well as diabetic self-management education (DSME).[76] Over ninety percent of the participants reported receipt of advice on weight reduction and diet, while only 38% reported having received advice on exercise.

There appears to be a paucity of published data in South Africa on the receipt of lifestyle advice by patients with type 2 diabetes. From available studies, the only one that considered the issue, albeit briefly and not really as a key objective of the study, was that by Moodly and Rambiritch which assessed diabetes knowledge amongst diabetics attending a primary care facility in KwaZulu-Natal.[14] Their findings appear to contradict the trend of generally high rates of lifestyle advice amongst diabetics elsewhere: less than 30% of the sample reported receipt counseling on diet and/or exercise; receipt of weight loss advice was not measured.

2.7.2 Lifestyle advice and glycaemic control

Despite its potential for influencing positive lifestyle changes and its recognition as a cornerstone of disease management, the impact of self-management education and, in particular, lifestyle counseling, on the key outcome of glycaemic control is unclear. In an extensive systematic review of randomized controlled trials that reviewed the effect of self-management education on various outcomes, Norris at al., reported that self-management training in general, failed to demonstrate any significant improvement in HbA1c.[77] Similarly, other studies in the same review that specifically focused on lifestyle change, also failed to show benefit on glycaemic control. A review of other randomized controlled trials that specifically studied the effect of self-management education on glycaemic control, reported beneficial effects on HbA1c, but only in the period immediately following the intervention.[78] In particular, the intervention decreased HbA1c by 0.76% more than the control; by 3 months, this difference had reduced to a non-statistically significant 0.26%. However, the more recent DESMOND study[79], reported in 2008, has cast some doubt on the latter finding. This multicentre randomized controlled trial, which evaluated the impact of a structured , group based education intervention on various metabolic and lifestyle outcomes amongst newly diagnosed type 2 diabetics in primary care in the UK , showed no benefit on HbA1c levels at 4, 8 and 12 months of follow-up.

There may be a place for individual counseling in particular contexts. For example, the LOADD study demonstrated that intensive, individual dietary counseling over an extended period, could realize beneficial drops in HbA1c compared to usual care in type 2 diabetic subjects who were uncontrolled despite optimal drug therapy.[59] Other evidence suggests that specific modes of counseling may be beneficial in a certain subset of patients: in one systematic review, face to face counseling, compared to usual care, showed beneficial effects on glycaemic control in individuals with baseline HbA1c > 8%.[80]

2.8 Diabetic medications

2.8.1 The need for pharmacological agents

A clear association between deteriorating glycaemic control and progressive loss of pancreatic β-cell function has been demonstrated.[81,82] A detailed analysis using homeostasis modeling (HOMA)[83] in the UKPDS found that, within 5 years, mean β-cell function deteriorated from 50% at diagnosis, to 25%. This was reflected in the progression of both FPG and HbA1c which rose at a rate of 2mmol/l and 0.2% per year respectively[81]. In the UKPDS 49[82] , a three yearly analysis of glycaemic control in the various treatment arms of the UKPDS, only 25% of the combined sample of normal and overweight subjects in the diet only cohort achieved an HbA1c < 7% in the first 3 years ; by 6 and 9 years, the proportions had dropped to 12% and 9% respectively. The corresponding proportions in the overweight only arm at 3, 6 and 9 years were similar. The obvious implication of this is that the initial step of lifestyle modification, as advocated by current guidelines[10,11], will inevitably prove inadequate and require pharmacological modalities for optimizing glycaemic control.[84]

The following three classes of anti-hyperglycaemic drugs are currently available for the management of type 2 diabetics in the South African public primary health care services[85]:

- Sulphonylureas (glibenclamide and gliclazide)
- Biguanides (metformin)
- Insulin (basal, biphasic and prandial)

In view of the above, the remainder of this review will mainly focus on these drug classes.

2.8.2 Diabetic medication and glycaemic control

2.8.2.1 The effectiveness of oral agents as mono-therapy

The UKPDS was the first large scale controlled trial that clearly demonstrated the effectiveness of oral monotherapy in lowering HbA1c.[6,7,82] All monotherapy arms achieved significant improvements in control: in the insulin and sulphonyluria arms of the overall sample, 47% and 50% of participants respectively achieved HbA1c < 7% at 3 years; in the overweight group, the corresponding proportions that achieved HbA1c < 7% in the insulin, sulphonyluria and metformin cohorts were 34%, 45% and 44% respectively.[82] Additionally, these figures were significantly better than that achieved with diet alone where, in the combined sample of normal and overweight individuals, 25% achieved HbA1c < 7%. As part of an in-depth systematic review of oral antihyperglycaemics, Inzucchi looked at a number of RCTs that investigated the efficacy of oral monotherapy, as compared to diet or placebo, in reducing HbA1c.[84]

In trials with sulphonylureas, the percentage drop in HbA1c ranged from 0.9 to 2.5%. The corresponding percentage drop in trials involving metformin ranged from 0.8 to 3.0%. Results from trials of head-to-head comparisons, showed overall equivalent efficacy of these drugs. Furthermore, the author noted that: "Only sulphonylureas and metformin have been shown to reduce microvascular complications with metformin exhibiting additional benefits on macrovascular risk."[84]

2.8.2.2 The need for additional drugs

After 9 years of follow-up, all treatment arms in the UKPDS showed significant decline in glycaemic control as evidenced by both, the mean FPG levels, as well as the proportion of patients with HbA1c < 7%.[81,82] The association of deteriorating β-cell function in this regard has been noted above. This phenomenon of secondary failure, defined as: "a switch or addition of antihyperglycaemics when the existing treatment fails to sustain adequate control"[86,87], has been demonstrated for oral anti-

hyperglycaemics in other studies.[88,89] Alvarsson et. al., conducted a 2-year prospective study in Sweden to compare insulin and sulphonylurea in their effects, inter alia, on metabolic control.[88] After one year, both treatment arms showed improvements in HbA1c but, by the end of the study period, the sulphonylurea arm experienced significant worsening of HbA1c levels. Results in this study were limited by the use of small sample sizes (n=21 and n=18 in the sulphonylurea and insulin groups respectively) and the short follow up period.

In the ADOPT study, which was a multicentre RCT comparing treatment efficacy of thiazolidinediones with that of metformin and glyburide (a sulphonylurea), proportion of patients that had controlled glycaemia (HbA1c < 7%) after 4 years in the latter two cohorts was 36% and 26% respectively. Incidence of secondary failure in the these two treatment cohorts was 21% and 34% respectively; yearly failure rates were estimated to be approximately 4% per year.[90]

Secondary failure of metformin was investigated in an observational cohort study by Brown, Connor and Nichols amongst 1 799 patients in a clinical setting who started metformin as their first line oral therapy.[89] Clinical data was analyzed for a follow up period of up to 5 years. Within a mean follow up period of under 28 months, secondary failure was demonstrated in 44% of subjects; the annual failure rate was estimated at 17% per year. In a large scale retrospective study of the effectiveness of oral treatment in Type 2 diabetics, Boccuzzi et al., demonstrated 12-month secondary failure rates of 22% and 19 % for metformin and sulphonylureas respectively.[86] A key strength of these two studies is that they investigated failure rates in real world clinical practice settings and the findings , specifically in the Brown et al., study, suggest that failure rates might be higher than those reported in clinical trials. [89,90]

Given the clear risk of treatment failures of both suphonylureas and metformin monotherapy, as well as the fact that these agents target different glycaemia lowering pathways, combination oral therapy is a plausible strategy in achieving glycaemic control. Convincing evidence for the efficacy of this approach

was provided by a supplementary trial of the UKPDS which reviewed the effect of adding metformin to sulphonylurea.[7] In reviewing the evidence for the efficacy of combination oral therapy, Inzucchi concluded that: "Each clinical trial that has examined the addition of an oral agent to that of another class has demonstrated additive HbA1c reduction. With few exceptions, the effect on HbA1c has been similar to the effect from using the added drug as monotherapy vs placebo." [84]

2.8.2.3 Adjunctive insulin therapy

Failure of oral monotherapy to achieve glycaemic control necessitates the addition of a second agent, and current guidelines commonly recommend the addition of a second oral agent.[10,11,66] However, β-cell function continues to decline in the face of dual therapy with sulphonylureas and metformin[91] since neither agent appears to preserve pancreatic secretory function and the former might even be detrimental to β-cells.[92]

The continued decline in glycaemic control after the addition of a second oral agent was demonstrated by Cook et al who conducted a retrospective analysis on medical records of patients in United Kingdom primary care practices.[93] Their sample comprised 2 200 individuals who commenced monotherapy with metformin before augmentation with sulphonylureas. Median HbA1c at baseline was 8.8% and, 76% of the sample had HbA1c > 8.0%. The lowest median HbA1c occurred at 6 months post-sulphonylurea augmentation, after which HbA1c started to deteriorate at a rate comparable to that prior to sulphonylurea augmentation. Given this deterioration, 85% of their sample was projected to reach HbA1c levels $\geq$ 8.0% within 4 years.

The efficacy of combined insulin and oral therapy in the improvement of glycaemic control compared with either insulin monotherapy or combination oral therapy has been studied. One of the early trials was conducted by Yki-Jarvinen et al., amongst Nordic diabetics attending out-patient department clinics [94]. A sample of 96 patients, poorly controlled on a sulphonylurea, were randomized into groups

on various combinations involving metformin, sulphonylurea and basal insulin, including one arm on insulin only. At the end of 1 year, the cohort on combined therapy with insulin and metformin displayed the greatest improvement in HbA1c: from 9.7% at baseline, to 7.2%.

Two systematic reviews, one by Yki-Jarvinen[95], and the other by Burke[96] reviewed the evidence for combination oral and insulin therapy. In the Yki-Jarvinen review, out of 15 studies, 10 demonstrated similar glycaemia lowering efficacy between the combination and insulin only cohorts; in 4 studies, the combination arm was superior.[95] According to the later Burke review, while there was evidence for the superiority of combined therapy with insulin and metformin over insulin alone, the potential of realizing a similar advantage by substituting metformin with other classes of oral agents was unclear.[96]

2.9 Conclusions

This review highlights a number of important findings relevant to the context of the present research. Key amongst these are:

- Prevalence of type 2 diabetes has reached epidemic proportions worldwide; recent estimates suggest that prevalence, both globally and in South Africa, will double by 2030.
- Pathologic effects seen in the disease are mainly due to micro- and macro-vascular complications. Research has clearly established the link between glycaemic control and micro-vascular pathology ; the association with macro-vascular pathology appears equivocal.
- Levels of glycaemic control are unsatisfactory with estimates of controlled glycaemia varying between 20% and 50%. Available data for SA suggest that levels of control might be as low as 10% and no better than 30% (inconsistent use of definitions of glycaemic control is a major drawback for comparison).
- Compliance with standards for processes of care, while displaying high levels of achievement in some settings, appear to be generally inadequate.
- Compliance with process of care standards, and particularly that for HbA1c monitoring, do not necessarily realize commensurate improvements in glycaemic control.
- There is convincing evidence to suggest that weight loss and exercise promote glycaemic control; nutritional interventions only appear to be effective in this regard when combined with exercise.
- While rates of counseling by health professionals on weight loss, exercise and diet are low in most contexts, the presence of co-morbidities in general, and diabetes in particular, appear to increase the odds of receipt of such counseling.

- With the possible exception of particular modes of counseling in specialized groups of patients, the effect of lifestyle advice on glycaemic control is uncertain.
- There is a substantial body of compelling evidence demonstrating both the efficacy of, as well as the necessity for, anti-hyperglycaemic drugs in achieving glycaemic control. In particular, both classes of oral medications available in the South African public primary health care sector are effective as mono- and dual therapy. However, the progressive failure of pancreatic secretory function requires augmentation with insulin. Except possibly for the combination of insulin and metformin, evidence for the superiority of combined insulin and oral therapy over insulin mono-therapy is unequivocal. In addition to its synergism with insulin in glycaemic control, metformin has the added benefit of improving other metabolic parameters.

Processes of care, delivery of lifestyle advice and pharmacological treatment represent a cluster of factors that describe what clinicians do as part of an overall management plan to achieve specific quality and metabolic outcomes in individuals with type 2 diabetes mellitus. While there exists a plethora of research that studied either of these factors, there appeared to be none at the time of the current study that comprehensively investigated all three. This lack of a comprehensive consideration of these factors is likewise reflected in studies that assessed their impact on glycaemic control. The latter shortcoming is particularly notable in South African research. At the time of the present study, the influence of key process of care parameters such as HbA1c monitoring, the provision of lifestyle advice by healthcare professionals, and pharmacological treatment, either individually or in combination, on glycaemic control amongst individuals with type 2 diabetes attending a public primary health care facility is largely unknown. A key objective of the present study was to address this important gap in the corpus of current research.

CHAPTER 3

METHODOLOGY

3.1 Study design

A cross-sectional design was used in this study. This particular design is subsumed under the general class of observational studies that have a descriptive component which facilitates calculations of prevalence figures for exposures and outcomes, as well as an analytical component which allows cross-classifications between exposures and outcomes for the purpose of statistical investigation of possible relationships between these.[97]

3.2 Study setting

The study was conducted at the Johan Heyns Community Health Centre (CHC), one of two large primary health care (PHC) facilities in the Emfuleni sub-district of the Sedibeng District, Gauteng Province. Located approximately 75 km south of Johannesburg, this health centre has an estimated catchment population of 70 000, mainly black and white uninsured patients both from the town itself, as well as from surrounding areas. In addition to offering a full range of PHC services, the facility also serves as the referral centre for five smaller PHC clinics in the area.

3.3 Study population

All adults 18 years and older, with type 2 diabetes attending the Johan Heyns CHC for treatment at the time of the research formed the study population.

3.4 Sampling

3.4.1 Sample size

Since a key objective of this study was to estimate the prevalence of glycaemic control, this parameter was used to determine an appropriate sample size. Studies elsewhere suggest that glycaemic control appears to be no better than 47% [29,31,32] , while the local study by Steyn et al., found 24% of their sample to have controlled glycaemia.[15] Results from a previous audit at the site of the present study suggested that glycaemic control was approximately 30%.[18]

Given these observations, a hypothesized value for glycaemic control in the present study was set at 30%. Furthermore, the power of detecting a prevalence of glycaemic control within $\pm$ 10% of the hypothesized value, with a significance level of 0.05, was set at 80%. The relevant formulae for determining the minimal sample size under these assumptions is discussed in Kirkwood and Sterne (2005).[98] Calculations, conducted with the aid of Stata release 12 (StataCorp LP, College Station, Texas, USA) statistical software, yielded a sample size of 153. In addition, the calculated sample size was adjusted to mitigate for possible effects of loss to follow-up or non-response. If a potential loss to follow-up of 20% is assumed, then the appropriate adjustment factor that the calculated sample must be multiplied by is 1.25.[98] This resulted in the adjusted sample size of 153x1.25 = 191.25 participants. Based on this, and for ease of data analysis, a final sample size of 200 was chosen.

3.4.2 Sampling strategy

An appropriate sample was drawn from a sampling frame consisting of all adults with diabetes who are patients at the facility. The inclusion and exclusion criteria were as follows:

- **Inclusion criteria**:
    - Adults 18 years or older presenting at the facility for routine diabetic care .
    - A diagnosis of type 2 diabetes for at least 12 months as indicated in clinic records.
    - Must have had at least 2 clinic encounters for diabetes management in the last 12 months
    - Participant ability to understand and respond to interview questions in any of the 4 major languages spoken in the area: Sotho, Zulu, Afrikaans and English
    - Ability to voluntarily give written, informed consent
- **Exclusion criteria**:
    - Failure to meet any inclusion criterion
    - Any patient managed at another facility and attends the study clinic to collect medications only.
    - Any medical emergency, mental incapacity or pregnancy

Participants were recruited through the following consecutive sampling strategy:

Chronic visits at the study facility are booked daily from Mondays to Thursdays, excluding public holidays. Daily, clinic records of all chronic patients with appointments for the next day are arranged in the admissions area by admissions personnel. Records of adult patients with diabetes, whose numbers range between 5 and 15 per day, were inspected by the researcher for compliance with all inclusion criteria except those pertaining to voluntary consent and language requirements. All eligible records

were then set aside and each of these patients was consecutively approached for participation in the study on the morning of their appointment. At this time, the remaining selection criteria were applied to determine final eligibility and, whenever an individual was excluded on this basis, the next person in the sequence was considered.

Participant recruitment was conducted by two PHC nurses, who were appropriately trained to do this. Sampling occurred daily from Monday to Thursday and was continued until attainment of the desired sample size.

3.5 Measuring tools

Two measurement tools were used to collect the required information. The first was a close-ended questionnaire used to interview study participants for socio-demographic information, lifestyle and information relating to other patient factors (Appendix A). Variables measured were:

- Socio-demographic data: date of birth, gender, residence, employment, educational level.
- Diabetes duration.
- Diabetic self management information: receipt of advice from a health worker on one or more of the following:
    - weight control
    - exercise
    - diet

In addition, anthropomorphic measurements comprising waist circumference (WC) and, for the purpose of calculating BMI, height and weight, were done at the time of the interview and recorded on this document. Information regarding performance of process of care elements and diabetic treatment was extracted from patient records using a separate data collection sheet (Appendix B).

For processes of care elements in this study, variables measured reflected the performance frequency in the preceding 12 months of the following:

- BP montoring
- HbA1c monitoring
- BMI measurement
- Weight and WC measurement

In addition to the above, BG monitoring, although not a recognized core process of care element in local guidelines[10], was also recorded.

For information on diabetic treatment, the current pharmacological treatment, as recorded in the prescription charts, was used. Also extracted from clinical records was information on co-existing medical conditions.

The main outcome, current glycaemic control, was assessed as follows:

- If available, the latest HbA1c value not older than 1 month was used.
- Where this was not available, participants were requested to have blood drawn for an HbA1c test after the interview.

3.6 Data collection

Data collection was accomplished in 2 stages. The first stage occurred during the recruitment process and was carried out voluntarily by 2 trained PHC nurse clinicians. During this phase, all eligible individuals who initially agreed to participate, were taken to a separate clinical area where each was briefed on the purpose and contents of the study, ethical issues were explained and voluntary consent sought. The interview questionnaire was then administered to each participant after signed consent was obtained. Following this, all participants, even those that declined consent after being briefed, were attended to by the researcher for their usual medical care and thereafter had blood drawn for HbA1c according to the criteria stated in 3.5 above. Also measured here were parameters for the anthropomorphic profile which was done in accordance with current guidelines from the National Department of Health.[99]

The second stage of data collection consisted of a record review of all consenting participants' clinical files for the purpose of extracting information in respect of process of care elements, treatment details and other clinical data described in 3.5 above . Since this also required the recording of the latest HbA1c results in cases where blood was drawn during the first stage, all information for the second stage was collected by the researcher at a convenient time after the first stage.

For the purpose of later access to clinical records, which are stored at the facility, each participant's clinic reference number was recorded on the interview sheet; this reference was later expunged once the required information from the relevant clinical record had been abstracted.

3.7 Data analysis

All analyses were conducted by the researcher using Stata release 12 (StataCorp LP, College Station, Texas, USA) statistical software. Descriptive statistics were used to summarize all measured variables. Means and medians were the descriptive measures for continuous variables while proportions and frequencies were the summery measures for categorical data. Comparison of means was carried out using analysis of variance (ANOVA) and, where this was precluded due to non-homogeneity of variances, a non-parametric test, the Kruskal-Wallis rank test, was applied. Where deemed appropriate, continuous data was re-coded as categorical data and analyzed accordingly. Associations of glycaemic control were initially explored through univariate analysis, using χ^2 (chi-squared) methods to identify possible outcome predictors from amongst the explanatory variables measured; subsequently, all significant covariates were subjected to univariate logistic regression analysis to derive crude odds ratios for strengths of association. Finally, composite parsimonious explanatory models with adjusted odds ratios for glycaemic control in this study were constructed through multivariate stepwise logistic regression.

A 2-tailed $P < 0.05$ was considered to be statistically significant for measures of association and the probability level for statistical significance of confidence intervals was set at 95%.

3.8 Pilot study

After the required approvals for conducting the research were secured, a pilot study was undertaken at the research site prior to actual data collection to:

- Refine the quality and structure of the questionnaire as well as uncover potential problems regarding sensitivity of questions.
- Ensure uniformity in the administration of questionnaires by the fieldworkers
- Assess the feasibility of the sampling procedure
- Address other logistical issues such the average time taken for each interview and other potential inconveniences to participants

A small sample of 10 participants who satisfied the required criteria were chosen for the pilot study. These individuals were excluded from the final study sample.

3.9 Study bias

In general terms, bias is the "deviation of results or inferences from the truth" [100,101]. Specifically, in the research process, bias refers to any "trends in the collection, analysis and interpretation" of information that can lead to such deviation.[100]

A number of potential biases were identified in the present study.

3.9.1 Sampling and selection bias

Selection bias results when there are systematically differing characteristics in those that agree to participate in the study compared to those that decline. Sampling bias results from systematic errors induced by non-random sampling methods. [100]

The sampling strategy adopted in this study took account of all potential candidates on each data collection day to minimize any bias due to adoption of a specific sampling procedure. However, since participation in the study was entirely voluntary, selection bias on account of non-participation was unavoidable. In particular, some of those who refused to participate might have done so for reasons of employment, and non-participation of such individuals would entail the obvious effect of underestimating the proportion of employed individuals in the final study sample. Finally, there is the question of individuals who presented at the facility on Fridays. Since no patients are routinely booked for Friday chronic care visits, it is reasonable to surmise that these individuals presented at this time for extraordinary reasons such as an emergency, and if so, would necessarily be excluded on account of the preset exclusion criteria. Alternatively, if these patients presented on Fridays for reasons other than those precluding them from inclusion based on the set exclusion criteria, bias in certain outcome measures is unavoidable.

3.9.2 Interview and measurement bias

Systematic errors induced by conscious or subconscious selectivity in information gathered by interviewers is termed interview bias , while measurement bias is said to occur when such errors result from inaccurate measurements of study variables.[100]

To minimize interview bias, both fieldworkers, PHC trained nurse clinicians of similar standing and experience, were trained in the administration of the interview questionnaire. Also during this stage, anthropomorphic measurements were performed and, to facilitate uniformity in this process, the field workers were trained to conduct these in a standardized manner according to accepted guidelines[99] using the same tape measure and the same, combined height and weight, measuring scale for all participants. Problems arising from both these data gathering procedures were identified and addressed in the pilot study. Nonetheless, the possibility of operator induced interview or

measurement bias cannot be entirely excluded; however, there was no a priori reason to suppose that any such error was dependent on the main outcome of this study and, consequently, any misclassification here is likely to be non-differential.

3.9.3 Recall, reporting and information biases

Any inaccuracies or incompleteness in memory recollection that result in systematic errors is referred to as recall bias[100]; reporting bias, on the other hand, occurs when respondents either suppress, or selectively volunteer information.[100]

During the interview stage, participants were expected to recall any lifestyle advice they might have received in the preceding twelve months and each one was also asked when they were first diagnosed with diabetes. In both these instances, differential misclassification based on information recall cannot be excluded. Furthermore, in the former instance, there is the added possibility of reporting bias: participants could have volunteered information that they believed the interviewers wanted to hear.

Since record reviews are limited by the quality of information recorded therein, any data abstracted here is also subject to measurement bias. Where it was not possible to reliably ascertain details of treatment and co-morbidities due to either incomplete or missing records, such records were excluded during analyses involving these variables and any bias in this regard cannot be avoided. These records were, however, small in number compared to the overall sample size and as such were not expected to exert a significant influence on the outcomes studied.

3.10 Ethical considerations

Prior to the commencement of this study, ethical approval was sought and obtained, clearance number: **M 080635** (Appendix C), from The University of the Witwatersrand Human Research Ethics Committee (Medical). Permission to conduct the research at the study site was obtained from the Sedibeng district health management (Appendix D).

Participation in the study was completely voluntary, subject to prior informed consent and, the right of any participant to withdraw at any point , was respected at all times. To this end, an information sheet detailing the nature of the study, the data sought both, during the interview, as well as the record review stages, and the rights of participants during the data collection process (Appendix E), was attached to each interview questionnaire and explained to all participants prior to obtaining written consent; the latter was captured on a separate form (Appendix F) also attached to each questionnaire.

Participant identification details were recorded during each initial interview to facilitate subsequent linkage to the relevant patient clinic file for the purposes of the record review; following the latter, all data was entered anonymously into a computer database for subsequent storage and analysis.

CHAPTER 4

RESULTS

4.1 Introduction

The structure of this chapter comprises three broad sections. First, a description of the various parameters investigated in this study is given using the appropriate descriptive statistical measures. Following this, results of univariate analyses of associations with glycaemic control are presented. Here, results pertaining to the core parameters of this study viz., processes of care, lifestyle advice and drug treatment will be presented in detail. Finally, logistic models for glycaemic control in this study are constructed using, as explanatory variables, all parameters found to be statistically significant on univariate analysis. All results are depicted by means of tables, with additional statistical and other relevant information appended as appropriate.

4.2 Final sample size and missing data

Recruitment occurred over a period of approximately 6 weeks and a total of 200 individuals who met the inclusion criteria and consented to interview, constituted the final study sample. No record was kept of people who declined to participate.

Missing data was encountered during the various stages of the data collection process so that the totals for some parameters will not always equal 200. During the interview phase, all patients in the sample had blood drawn for HbA1c. However, results were unavailable for 8 patients and this was due to the laboratory not processing these samples on account of missing information on the blood test forms (missing clinician MP numbers). Consequently, HbA1c data was available for 192 patients in the sample.

Also, during this phase, education level was not recorded in 1 questionnaire, 7 patients couldn't remember when they were diagnosed with diabetes and, information on patient's sex was either missing, or not clearly recorded, in 6 interview questionnaires. In the record review phase, 7 patient files could not be located which resulted in process of care information being available for 193 patients. A further 2 files had either missing, or incomplete information on drug treatment and co-morbid conditions.

4.3 Demographics

Demographic characteristics measured in this study are shown in table 4.1 below.

Participants' ages ranged from 20 years to 84 years with a mean of 57.76 years (SD= 9.960); (95%CI: 56.37; 59.14). Blacks, females and people in the 50-64 year age group made up the majority of the sample. Mean ages of females and males were 56.67 and 59.79 respectively and the difference between these means was statistically significant ($p = 0.034$).

Vanderbijlpark, which is the catchment area of the facility, had just over a quarter of the patients. With the exception of Evaton and Residensia, patients from outside the catchment population lived in townships surrounding Vanderbijlpark, mainly Bophelong, Sebokeng, Boipatong and Sharpeville. Most individuals (87.4%), had some form of education, mainly at the secondary level while a small minority reported having completed either matric or tertiary education.

Just under 60% derived income from either from some form of employment, or a state pension. Four individuals did not specify their source of income. Almost 41% reported being unemployed and having no other source of income.

Table 4.1 Demographic characteristics of the study sample

Demographic Parameters	Categories	Frequency	%
Age Group (n = 200)	Under 35	3	1.5
	35-49	31	15.5
	50-64	115	57.5
	65-79	49	24.5
	80+	2	1
	Total	***200***	***100***
Sex (n = 194)	Female	122	62.89
	Male	72	37.11
	Total	194	100
Race (n = 200)	Black	175	87.5
	Indian	1	0.5
	White	24	12.0
	Total	***200***	***100***
Residence (n = 200)	Catchment Area	53	26.5
	Outside Catchment	147	74.5
	Total	***200***	***100***
Education (n = 199)	Primary	68	34.2
	Secondary	95	47.7
	Matric	8	4
	Tertiary	3	1.5
	None	25	12.6
	Total	***199***	***100***
Employment Status (n = 200)	Unemployed	81	40.5
	Pensioner	59	29.5
	Employed	56	28
	Unspecified	4	2
	Total	***200***	***100***

4.4 Clinical information

4.4.1 Duration of diabetes and presence of co-morbid conditions

Time since diagnosis of diabetes ranged from 1 to 34 years, with a mean (SD) and median of 7.97 (5.56) and 7 years respectively. Almost 95% reported having diabetes for less than 20 years and the majority of these had the condition for less than 10 years. The vast majority of patients had at least one co-

morbid condition with hypertension by far the commonest, followed by CCF. Apart from these, 8 other co-morbidities were identified and combined into a single category. These observations are depicted in table 4.2 below

Table 4.2 Duration of diabetes and presence of co-morbidity

Clinical parameter	Categories	Frequency	%
Duration of Diabetes (years) (n= 193)	Less than 10	131	67.88
	10 – 19	54	27.98
	20 – 29	7	3.63
	More than 30	1	0.51
	Total	***193***	***100***
Presence of Co-Morbid Condition (n = 191)	Present	177	97.7
	Absent	14	2.3
	Total	***191***	***100***
Co-Morbid Condition by Disease Type (n = 191)*	Hypertension	176	92.15
	CCF	19	9.95
	Other	16	8.32

**** Totals here don't up to 191 and 100% since some patients had > 1 condition***

4.4.2 Anthropomorphic profile

Anthropomorphic measurements of the sample are shown in table 4.3 below. BMI values ranged between 20.2 and 64.21kg/m^2 with a mean of 33.51kg/m^2 (95% CI: 32.51; 34.51); median BMI was 31.88kg/m^2. By BMI category, the majority were either overweight or moderately obese.

Waist circumference ranged from 72-144cm; the mean and median values of this parameter were 106.69cm (95% CI: 104.88; 108.52) and 107cm respectively. Amongst either sex, the overwhelming majority had a WC that placed them at substantial cardio-metabolic risk.

Table 4.3 Anthropomorphic profile

Anthropomorphic Parameters	Categories	Frequency	%
BMI (kg/m^2) (n =200)	< 18 (Underweight)	0	0
	18.5-24.9 (Healthy)	11	5.5
	25-29.9 (Overweight)	59	29.5
	30-34.9 (Moderately Obese)	62	31
	35-39.9 (Severely Obese)	36	18
	>40 (Morbidly Obese)	32	16
	Total	***200***	***100***
Waist Circumference (cm): Females (n = 122)	≤ 80 (Normal Risk)	1	0.82
	> 80 (Increased Risk)	5	4.10
	> 88 (Substantial Risk)	116	95.08
	Total	***122***	***100***
Waist Circumference (cm): Males (n = 72)	≤ 94 (Normal Risk)	17	9.28
	> 94 (Increased Risk)	10	7.73
	> 102 (Substantial Risk)	45	82.99
	Total	***72***	***100***

4.5 Processes of care

The vast majority of patients' blood pressure measurements were done in accordance with the required standard. Although 4 patients had their height recorded at least once during the preceding 12 months, only 3 patients had their BMI measured. None of the sample had their weights recorded monthly; this did not however prevent BMI determinations since, according to the standards used, the BMI need only be done once in 12 months. Apart from that for blood pressure measurements, less than 2% of the patient records fulfilled the required standards for the remaining process of care measures. The following table depicts these findings.

Table 4.4 Proportion of sample whose medical record met the standard for the selected processes of care

Processes of care	Frequency (n=193)	%
Blood Pressure measurement	180	93.26
Weight	0	0
HbA1c	3	1.55
BMI	3	1.55
WC	0	0

In addition, 76.7% of the clinical records had a finger-prick blood glucose recorded at every routine diabetic visit

4.6 Receipt of lifestyle advice

The proportions of individuals who received advice on exercise, diet and weight control from a health worker are shown in table 4.5

Most patients reported having received advice on at least one of these self-care parameters. For those who reported advice on at least one of the topics (n=158), responses were further categorized to

determine what combinations of topics advice was received on. As shown in table 4.5, only a minority reported advice receipt on just one or two topics; the majority reported advice on all three. No participant reported receiving advice on exercise alone or weight control alone.

Table 4.5 Reported receipt of lifestyle advice on diet, exercise and weight control

Advice Combinations	Frequency (n=158)	%
Diet, exercise and weight	127	67
Diet alone	14	7
Diet and weight	8	4
Exercise and diet	8	4
Exercise and weight	1	0.5
No advice	42	21
Total	***200***	***100***

4.7 Pharmacological management

An overwhelming majority, 95.29%, were prescribed oral drugs either alone or in combination with insulin. The various combinations by treatment type are shown in table 4.6.

Table 4.6 Prescribed diabetic medications by treatment type

Treatment type combinations	Frequency (n = 191)	%
oral only	120	62.83
oral and insulin	62	32.46
insulin only	9	4.71
Totals	***191***	***100***

The breakdown of treatment combinations by medication class is shown in table 4.7. Metformin was the most commonly prescribed drug class with the majority on a combination of metformin and sulphonylurea. Slightly less than 20% of the sample was on a single medication class. Insulin was most commonly combined with metformin.

Table 4.7 Prescribed diabetic medications by medication class

Medication class combinations	Frequency (n = 191)	%
metformin + sulphonylurea	93	48.69
insulin + metformin	30	15.71
insulin + metformin + sulphonylurea	27	14.14
metformin only	21	10.99
insulin only	9	4.71
sulphonylurea only	6	3.14
insulin + sulphonylurea	5	2.62
Totals	***191***	***100***

4.8 Glycaemic control

For the available data (n=192), HbA1c values ranged from 4.8% to 14.6% with a mean and median of 8.55% (95% CI: 8.25; 8.86) and 8.4% respectively. The proportions of patients with controlled and uncontrolled glycaemia are shown in the table 4.8. Only a quarter of the sample had controlled glycaemia

Table 4.8 Proportions of the study sample with controlled and uncontrolled glycaemia

HbA1c	Frequency (n = 192)	% (95% CI)	Mean HbA1c	Median HbA1c
< 7% (Controlled)	47	24.48 (18.6 ; 31.2)	6.11	6.1
≥ 7% (Uncontrolled)	145	75.52 (68.8 ; 81.4)	9.3	9.0
Totals	***192***	***100***		

As demonstrated by their respective 95% CI's, the difference in the proportions between those with and without controlled glycaemia was statistically significant. The difference in mean and median HbA1c between the 2 groups was also statistically significant (*ANOVA and Kruskal-Wallis: P = 0.00*)

Glycaemic control was further classified using the definitions of control in the ACCORD trial[102], as shown in the following table:

Table 4.9 Profile of glycaemic control delineated by the ACCORD criteria

Classification	Frequency (n = 192)	% (95% CI)	mean HbA1c	median HbA1c
Optimal target (HbA1c <7)	47	24.5 (18.6 ; 31.2)	6.11	6.1
Standard target (HbA1c : 7- 7.9)	39	20.3 (14.9 ; 26.7)	7.37	7.7
Poor control (HbA1c $\geq$ 8)	106	55.2 (47.9 ; 62.4)	10.06	10.9
Totals	***192***	***100***		

A statistically significantly higher proportion of the sample was classified as poorly controlled as compared with those who had optimal or standard control while the differences in proportions in the latter 2 categories were not. All differences in mean and median HbA1c between the 3 categories were statistically significant (*ANOVA and Kruskal-Wallis: P = 0.00*).

4.9 Univariate associations of glycaemic control

In this and all subsequent analyses of glycaemic control, controlled glycaemia is defined as HbA1c < 7%; this corresponds to the "optimal target" definition in ACCORD.[102]

4.9.1 The processes of care

Since none of the patient records met the process of care standard for weight and WC measurement, these parameters could not be tested for association. Of the remaining processes of care parameters, none attained statistical significance for glycemic control. However, a pattern of lower proportion of control is present amongst those in whom the standard for HbA1c and blood pressure monitoring was attained. These findings are depicted in the tables below:

Table 4.10 Blood pressure monitoring and glycaemic control

Monthly Blood Pressure monitoring	% controlled	% uncontrolled
standard attained	23.70	76.30
standard not attained	30.77	69.23

Pearson $\chi^2 = 0.3295$, $p = 0.566$

Table 4.11 HbA1c monitoring and glycaemic control

HbA1c monitoring	% controlled	% uncontrolled
standard attained	0	100
standard not attained	24.49	75.41

Pearson $\chi^2 = 0.9731$, $p = 0.324$

Table 4.12 BMI monitoring and glycaemic control

BMI monitoring	% controlled	% uncontrolled
standard attained	33.33	66.67
standard not attained	24.04	75.96

Pearson $\chi^2 = 0.1389$, $p = 0.709$

4.9.2 Lifestyle advice on diet, exercise and weight control

None of the topics of lifestyle advice showed a statistically significant association with control. As the tables below demonstrate, there was a trend toward lower proportion of control amongst participants who reported receiving advice.

Table 4.13 Exercise advice and glycaemic control

Exercise Advice Received	% controlled	% uncontrolled
yes	22.14	77.86
no	29.51	70.49

Pearson $\chi^2 = 1.2231$, $p = 0.269$

Table 4.14 Dietary advice and glycaemic control

Diet Advice Received	% controlled	% uncontrolled
yes	22.37	77.63
no	32.50	67.50

Pearson $\chi^2 = 1.7583$, $p = 0.185$

Table 4.15 Weight control advice and glycaemic control

Weight Control Advice Received	% controlled	% uncontrolled
yes	22.90	77.10
no	27.87	72.13

Pearson $\chi^2 = 0.5557$, $p = 0.456$

To assess the joint effect of advice received , a binary categorical variable was defined containing the following categories: “no” if no advice was reported on any of the topics, and “yes” if any advice was reported on one or more topics. Again, as depicted in table 4.16 below, the association with control was not statistically significant but the trend of higher proportion of control amongst those reporting no advice was preserved: 50% more individuals were controlled amongst those that received no advice compared with those that received any advice.

Table 4.16 Receipt of any advice and glycaemic control

Any Advice Received	% controlled	% uncontrolled
yes	22.22	77.78
no	33.33	66.67

Pearson $\chi^2 = 2.0754$, $p = 0.150$

4.9.3 Drug treatment

Associations of drug treatment with glycaemic control were tested, first using treatment types, and thereafter, using medication classes as explanatory variables. Outcomes of these analyses are displayed in tables 4.17 and 4.18 below.

Table 4.17 Diabetic treatment type and glycaemic control

Treatment Type Combination	% controlled	% uncontrolled
oral only	30.70	69.30
insulin only	44.44	55.56
oral and insulin	14.9	46.1

Pearson $\chi^2 = 11.4105$, $p = 0.003$

Table 4.18 Diabetic medication class and glycaemic control

Medication Class Combination	% controlled	% uncontrolled
metformin only	38.89	61.11
sulphonylurea only	50.00	50.00
metformin and sulphonylurea	27.78	72.22
insulin only	44.44	55.56
insulin and metformin	10.34	89.66
insulin and sulphonylurea	20.00	80.00
all three	7.41	92.59

Pearson $\chi^2 = 14.0593$, $p = 0.029$

Both analyses showed a statistically significant association with glycaemic control. However, the association with medication class is not valid since a number of cells in the χ^2 cross-tabulation had an expected value < 5.

4.9.4 Demographics

Race and Residence were the only demographic variables that showed association with glycaemic control. The proportion of control amongst Whites was more than double that amongst Blacks. There was only one Indian in the sample which precludes any conclusion about control in this group. Also, the association with race, although statistically significant, was not valid. This was probably due to there being only one individual of a racial group other than Black or White. After race was re-coded as a binary variable with 2 categories, "Black" and "Other", the association was both valid and significant Participants living in the catchment area had a higher proportion of control than those living outside. These findings are depicted in tables 4.19, 4.20 and 4.21 below.

Table 4.19 Glycaemic control amongst the 3 racial groups

Race	% controlled	% uncontrolled
Black	21.3	78.70
White	45.45	54.55
Indian	100	0

Pearson $\chi^2 = 9.2438$, $p = 0.01$

Table 4.20 Dichotomous association of race and glycaemic control

Race	% controlled	% uncontrolled
Black	21.3	78.7
Other	47.83	52.17

Pearson $\chi^2 = 7.5986$, $p = 0.006$

Table 4.21 Glycaemic control according to residence in the catchment area

Residence	% controlled	% uncontrolled
catchment	37.25	62.75
outside catchment	19.86	80.14

Pearson $\chi^2 = 6.1314$, $p = 0.013$

4.9.5 Clinical parameters

Amongst the clinical parameters, only co-morbidity was associated with glycaemic control. Specifically, the presence of CCF, irrespective of the presence of any other co-morbidity, conferred a higher proportion of control. The presence of any co-morbidity in general and, hypertension in particular, did not influence control.

Table 4.22 The presence of any co-morbid condition and glycaemic control

Any Co-Morbid Condition	% controlled	% uncontrolled
present	25.29	74.71
absent	14.29	85.71

Pearson $\chi^2 = 0.8484$, $p = 0.523$ (Fisher's exact)

Table 4.23 The presence of hypertension and glycaemic control

Hypertension	% controlled	% uncontrolled
present	24.85	75.15
absent	20.00	80.00

Pearson $\chi^2 = 0.1756$, $p = 1.00$ (Fisher's exact)

Table 4.24 The presence of CCF and glycaemic control

CCF	% controlled	% uncontrolled
present	44.44	55.56
absent	22.29	77.71

Pearson $\chi^2 = 4.3145$, $p = 0.047$ (Fisher's exact)

4.9.6 Summary of variables associated with glycaemic control on univariate analysis

Variables that showed a statistically significant association with glycaemic control are summarized in table 4.25 below. Also included were variables whose associations were statistically significant but not valid.

Table 4.25 Univariate associations with glycaemic control

Variable	p-value
Race*	0.006
Residence	0.013
Combinations of Treatment Type	0.003
Combinations of Medication Class	0.029**
Presence of CCF	0.047

**Dichotomous classification*

***statistically significant but not valid*

In summary, on univariate analyses, race, residence in the catchment area, the presence of CCF and, drug class, types and combinations thereof, all appear to influence glycaemic control in this study. Processes of care and the reported receipt of lifestyle advice demonstrate no such association.

4.10 Logistic models of glycaemic control

4.10.1 The unadjusted model

As an initial step to developing a multivariate logistic model , each variable found to have a statistically significant association with glycaemic control on prior univariate analysis was tested individually to determine ***unadjusted odds ratios*** (OR's). These are depicted in table 4.26. Statistically significant OR's and their associated p-values are shown in bold.

Table 4.26 Unadjusted odds ratios for variables associated with glycaemic control

Variable	Categories	Unadjusted OR's	p-value
race	Black	1	
	Other	***3.387***	***0.008***
residence	Outside catchment	1	
	Catchment	***2.396206***	***0.015***
treatment type combinations	Insulin only	1	
	Oral and insulin	***0.1363636***	***0.012***
	Oral only	0.5537975	0.399
medication class combinations	Insulin only	1	
	Insulin and metformin	***0.1442308***	***0.033***
	All three	***0.1***	***0.021***
	Metformin only	0.7954545	0.782
	Sulphonylurea only	1.25	0.833
	Metformin and sulphonylurea	0.4807692	0.303
	Insulin and sulphonylurea	0.3125	0.372
CCF	CCF absent	1	
	CCF present	***2.789189***	***0.044***

For treatment type, compared to insulin only, lower odds of control was associated with being on a combination of oral and insulin medication. A similar pattern was noted for medication class: compared to insulin monotherapy, lower odds of control was associated with being on a combination of insulin and metformin, or being on a combination of all 3 medication classes. The odds of control associated with the other medication combinations were not statistically different from that associated with insulin monotherapy.

4.10.2 Multivariate logistic models for glycaemic control

To develop a parsimonious multivariate logistic model for glycaemic control, all the variables in the previous section were simultaneously tested for association using logistic regression. Due to the collinearity between the treatment type and medication class variables, 2 logistic models were derived: one with treatment type and the other with medication class. These models are detailed in the following tables:

Table 4.27 Multivariate logistic model for glycaemic control: Model 1

Variable	Categories	Adjusted OR's	p-value
treatment type	Insulin only	1	reference
	Insulin and oral	0.2154445	0.001
CCF	Absent	1	
	Present	3.374822	0.026

Table 4.28 Multivariate logistic model for glycaemic control: Model 2

Variable	Categories	Adjusted OR	p-value
medication class	Insulin only	1	reference
	Insulin and metformin	0.2161132	0.020
	All three	0.1858542	0.027
CCF	Absent	1	
	Present	3.172564	0.035

Collinearity was also evident between race and residence but this was of no consequence since both were eliminated from either model. The association patterns for the remaining variables reflect those found on univariate analyses: pharmacological treatment and the presence of a co-morbidity, CCF, were the only factors demonstrated to be independently associated with glycaemic control in this study.

Compared to insulin only, combined treatment with insulin and an oral medication was associated with an almost four-fold lower odds for control. Combination treatment with insulin and metformin, as well as treatment with the combination of all three classes of medications, were associated with similarly low odds for control compared to treatment with insulin monotherapy. Individuals with CCF were three times more likely to have better control than those without CCF.

CHAPTER 5

DISCUSSION

5.1 Introduction

This chapter is presented in two parts. The first part deals with the descriptive aspects of this study and comprises sections 5.1 to 5.5, while in the second part, section 5.6, analytic aspects are considered. In either case, discussion is primarily focused on the components relating the aim of this study viz., processes of care, lifestyle advice, treatment and glycaemic control. Additionally, in the analytic section, other variables found to have statistically significant associations with glycaemic control in both the un-adjusted, as well as adjusted models, are also discussed. Comparisons are made with results in other research and, where possible, explanations for findings in the present study are advanced.

5.2 Demographics

5.2.1 Age and sex

Mean age of subjects in this study was 58 years and the majority were aged 50 years or more. These figures are consistent with those in most other studies.[3,15,29,103,104] According to IDF estimates for South Africa in 2010, individuals in the 40-79 age group accounted for 82.2% of adult diabetics in the country.[2] This finding is reflected in the present study where the age group 50-79 years comprised 82% of the sample.

Females constituted the majority, 63%, of the sample in the present study. This differs from some local studies in primary care settings. In the Moodly and Rambiritch study, almost 70% of the sample were

female[14]; a similar proportion of females occurred in the study by Steyn et al., which looked at both diabetics and hypertensives.[15]

In contrast, the sex distribution in the present study is consistent with country-wide epidemiological estimates and, moreover, while actual estimates differ, echo the overall trend of female preponderance.[2,3] According to Bradshaw et al., prevalence of the disease amongst females over 30 years in 2000 was 6.2% as compared to 4.7% in males.[3] More recent estimates by the IDF show a preservation of this trend: for 2010, the IDF estimated females to constitute almost 61% of all adult diabetics in South Africa[2]; furthermore, the IDF predicts that this proportion will remain unchanged for 2030.

Elsewhere sex distribution in studies on adult diabetics display varying trends. According to Saadine et al[29], in their analysis of data from the Behavioural Risk Factor Surveillance System (BRFSS) for 2002, females made up 51% of the sample. Data from the National Health and Nutritional Examination Survey (NHANES) for 1999-2002 in the same study showed the opposite: 47% were females. In the UKPDS (UKPDS 35)[105], females only made up 30% of the sample. Other studies however show a clear pattern of females outnumbering males.[103,104]

5.2.2 Race and residence

By racial groups in South Africa, prevalence appears to be highest amongst the Indian population with estimates varying from 10 to 17%.[3,25] Estimates in the Black population vary from 4.8% to 8%[25,3], while that for the Whites is 6.2%.[3]

In the present study, Blacks constituted 87.5% of the sample and this figure does not appear to conform with accepted estimates for race specific prevalence of the disease in this country.

However, since this study did not measure actual prevalence, any number of other factors could have influenced this finding.

A likely explanation is the observed association between race and residence: surrounding Vanderbijlpark, the catchment area of the study facility, are a number of townships whose populations are overwhelmingly Black and, individuals from these areas constituted three-quarters of the present study sample.

5.2.3 Education and employment status

Most individuals in this study, 87%, had some form of education while only 5.5% had achieved either matriculation or some form of tertiary education. In most of the local studies that were consulted, education levels of their samples were not explicitly described. One local study found that almost half of their sample had either primary school or no education at all.[15] This is comparable to that in the present study where 46.8% were noted to have either primary school or no education

Comparison with international studies is problematic on account of differing standards and classifications of educational achievement. However, some differences are possible to glean. For example, in the NHANES and BRFSS analyses by Saddine et al., at least 66% had at least a high school education.[29] On the other hand, in a study by Rothman et al., whose sample had a wide socio-economic spectrum, almost 57% had less than a high school education.[106]

Almost 41% of participants reported being unemployed and this reflects the overall unemployment rate in Sedibeng district which, at the time of this study, was estimated to be between 35 and 40%.[107] Of those that receive some form of income either through formal employment or a state pension, the latter accounted for 30% of the total sample. What this implies is that, given the fact that a state

pension cannot adequately meet all of the needs of the beneficiary, more than 70% of individuals in this study have either an inadequate, or no income. These patterns are reflected in other South African studies in similar settings.[15,16]

Not only is lower socio-economic status associated with a higher prevalence of type 2 diabetes[108], low income earners and individuals with low literacy levels suffer greater morbidity as a result of the disease.[109] In particular, low socio-economic status amongst type 2 diabetics is associated with greater levels of obesity, LDL cholesterol levels and poor glycaemic control.[108] This observation has obvious relevance in the present study where the majority of participants were found to have an inadequate income.

Health literacy, which is influenced by education status[110], has been shown to impact diabetes knowledge and self-care practices.[111] However, the presence of education , while necessary, might not in itself be sufficient-the level of education is also important: Schiller et al., demonstrated that individuals with either some or less than, high school education had inadequate levels of health literacy.[110] In the present study, while nearly 90% had some form of education, less than 6% were noted to posses either matric or some form of tertiary education. What this demonstrates is that the vast majority of the study sample possibly lacks a sufficient level of literacy required to positively influence vital diabetic self-care practices.

5.3 Glycaemic control

Local and international guidelines for glycaemic control in type 2 diabetes recommend an HbA1c level of less than 7% as ideal.[10,11] There is however no clear consensus on classification of control for HbA1c

above this target value. Nagpal and Bhartia define "poor control" as an HbA1c greater than 8% [32], while Maizlish et al[31] and Saaddine et al[29] use an HbA1c > 9% as their definition of poor control.

Oster et al., on the other hand, define as "inadequate", HbA1c levels above 8.4%. [40] Still other researchers use the term "controlled glycaemia" for HbA1c below 8%.[35]

In the present study, the mean HbA1c was 8.55%. The lower limit of the 95% CI for the mean HbA1c demonstrates clear statistical evidence for overall poor control which is confirmed by the finding that less than a quarter of the sample had controlled glycaemia. Using the ACCORD criteria [102], 20% percent were classified as having achieved the standard glycaemic target while the majority, 55%, were classified as poorly controlled.

The trend of low proportions of individuals with type 2 diabetes mellitus achieving optimal target HbA1c levels is reflected in local and international studies. Moreover, this trend appears to be preserved across differing socio-economic strata.[32,25,40] In a survey of glyceamic control trends in the USA using NHANES data, Koro et al., demonstrated that the proportion of adults with type 2 diabetes achieving optimal control declined from 44.5% to 35,8% between the years 1988 to 2000.[112] In the study by Bhartia and Nagpal which looked at diabetes care amongst a sample of middle and high income group individuals in Delhi, 37.8% of the sample had optimal glycated haemoglobin levels.[32] A diabetes care survey amongst First Nation communities in Alberta showed that only 30% achieved optimal HbA1c levels.[40] In a baseline survey, carried out as part of an intervention study to improve diabetes processes of care and outcomes amongst two Aboriginal communities in Australia by Baillie et al., 19 % of the study sample had optimal HbA1c levels.[35]

In South Africa, the paucity of large scale studies obviate the availability of reliable figures on glycaemic control but existing data from primary care as well as hospital settings point to a pattern of low proportion of glycaemic control.

While some studies demonstrate levels of control comparable to the present study, others display a more pessimistic picture. Govender and Klop, in their post-intervention study at a rural hospital in KZN, achieved optimal HbA1c levels in 10% of their sample.[12]

A survey carried out a an OPD of a large Tshwane hospital by Westaway et al., showed optimal HbA1c in just one-third of the study sample.[113] In a study of diabetes care amongst a population in a rural KwaZulu-Natal district served by primary care facilities, Rotchford and Rotchford found that just under 16% of their sample had an HbA1c of less than 7.7%.[16] While the sample in this study consisted of both type 1 and type 2 diabetic patients, the former comprised only 7.1% of the total sample. The proportion of optimal glycaemic control in the present study reflects similar results from the larger survey carried out by Steyn et al., in a number of primary care facilities in the Cape Peninsula; there, 24% had optimal glycaemic control.[15]

Quite independently of other risk factors, the presence of diabetes has been demonstrated to confer twice the excess risk for a wide range of cardiovascular diseases (CVD) as compared to individuals without diabetes.[114] Seminal studies such as the DCCT[28] and the UKPDS[7,8], have clearly demonstrated the benefits of proper glycaemic control. In the latter study, these benefits were shown to accrue largely due to reductions in microvascular complications.[7] Moreover, not only do these benefits persist, long term treatment has subsequently been shown to also reduce macrovsacular risk[8], a finding not demonstrated in the original UKPDS.[7]

While these landmark studies clearly established the benefits of glycaemic control, the question of a possible relation between the degree of glycaemia and risk of complications over time in Type 2 diabetics had not been adequately addressed. The risk of micro- and macrovascular complications at different levels of glycaemia was investigated in a sub-study of the original UKPDS.[105]

Based on the participants of UKPDS 33, this study, UKPDS 35, revealed a clear correlation between levels of glycaemia and the incidence of complications.

Specifically, for every 1% drop in mean HbA1c, the following risk reductions were demonstrated:

- 21% in any endpoint related to diabetes
- 37% for microvascular endpoints
- 43% for amputation or death from peripheral vascular disease
- 14% for myocardial infarction
- 16% for heart failure
- 12% for stroke

This finding is of particular relevance to the target population of the present study: while the latter clearly highlights the huge strides that are still required to achieve adequate glycaemic control, the above results point to the potential benefit of reducing mean HbA1c by one percentage point. One implication of this is that a shift from looking only at the proportion of individuals with optimal control, to focusing on incremental reductions in HbA1c levels without necessarily achieving optimal glycaemia, is a plausible first step in reducing morbidity and mortality especially in resource constrained settings such as the one in which the present study was conducted.

5.4 Processes of care

The majority of patients, 93%, had their blood pressure recorded at every visit. Proportions for frequency of performance in the remaining processes of care ranged from 0 to 2%. Only 1.6% of the sample met the criteria for frequency of HbA1c and BMI determinations while none of the sample met the criteria for frequency for weight or WC monitoring.

Selection of process of care indicators for management of type 2 diabetes vary between local and international guidelines[10,11,33], a phenomenon reflected in studies looking at processes of care in various settings. However, amongst the large variety indicators, HbA1c determination is ubiquitously recommended as a core process of care measure[10,11,33] and there are 2 reasons for this:

- HbA1c reflects the average blood glucose over at least the preceding 6 weeks[5]
- HbA1c levels are correlated with micro- and macro-vascular complications[105]

Findings for frequency of HbA1c determinations in most international studies vary according to country and setting. Results from a diabetes care survey in 5 OECD countries (Australia, New Zealand, UK, Canada and USA) by Damin et al., revealed high rates of annual HbA1c determinations.[115] The lowest countrywide overall rate of testing (65%) was found in Australia. There was however considerable sub-group variation: in New Zealand for instance, testing rates amongst Maoris was noted to be 39% whilst that amongst individuals of Pacific Island origin was 99%. In the study of diabetes care amongst First Nation individuals in Alberta, Canada with type 2 DM by Oster et al., 46% had an HbA1c done within the preceding 6 months while a further 20% had one within the preceding 6-12 months.[40] Similarly, in an intervention study to improve trends in processes of care amongst an Aboriginal population in Australia, Bailie et al., found that, at baseline, 53% of their sample met the criteria for frequency of HbA1c testing.[35] In the USA, findings of a study amongst Latinos with diabetes in managed care revealed over 80% of subjects had an HbA1c level done in the preceding 12 months.[116] A similar high proportion was noted in the Maizlish study.[31]

Alberti et al, who conducted a large study looking at quality of care issues amongst mainly Type 2 diabetics from low to mid-income groups at 48 primary care facilities in Tunisia, found that only 5% of patients in their sample had at least one HbA1c determination in the previous year.[104]

What this clearly demonstrates, is that the proportion of patients meeting the accepted criteria for frequency of HbA1c assessment in the present study falls markedly below levels achieved in similar settings in other, mainly western, countries and reflects a slightly better proportion of monitoring than that shown in one other local study in a primary care setting: Steyn et al., found that only 2.6% of subjects had an HbA1c recorded in the last 12 months.[15] It is well established that diabetic complications are related to glycaemic levels as measured by HbA1 and, more importantly, that reductions in HbA1c of 1% can achieve significant risk reductions for any diabetes related endpoint.[105] Consequently, in the effort to realize such benefits, proper monitoring assumes a critical role in alerting clinicians to the need for reducing HbA1c. In this regard, the low level of HbA1c monitoring demonstrated in the present study represents a significant shortcoming in the overall management of diabetes and, in particular, the prevention of diabetes related complications.

Over three-quarters of the available patient records for the sample in the present study was noted to have a routine finger-prick blood glucose determination recorded at every diabetic visit and , while this high proportion seems encouraging, its merits are questionable given that neither the ADA nor the SEMDSA guidelines appear to recommend routine office determinations of blood glucose levels. [10,11] A partial explanation for its exclusion as a core process of care measure is provided by van Zyl who argues that, while both fasting and random blood glucose levels can give an indication of glycaemic control, patients sometimes change their behavior prior to follow up visits: “They tend to skip meals or inject more insulin a few days before they visit..” [117] This notwithstanding, the use of finger-prick glucose determinations cannot be entirely discounted. Of particular importance is its obvious utility in the detection of individuals presenting with asymptomatic hypo- or hyperglycaemia during routine diabetic visits. Additionally, there is evidence to suggest the existence of a moderate association between FPG and CHD.[114] The routine use of FPG is however limited by the inconvenience of having to fast prior to measurement.

Comparisons for attainment of process of care measures for BP monitoring with other studies are hampered by the application of differing standards. In some studies, authors required that BP be measured at least once a year[45,118], while in others, no specific standard was made explicit.[15,16] Nevertheless, in studies that applied the accepted standard of requiring BP measurements at every follow-up visit , levels of attainment approached 80% [119,120] ; in the Alberti study, 92% of the sample met the standard for BP monitoring.[104]

The finding in the present study that levels of BP monitoring are not only comparable to, but exceeded that found in other studies referenced, is important. Not only is hypertension one of the two commonest co-morbidities found in type 2 DM[11,121] , it is also an important risk factor for CVD and micro-vascular complications.[11] For these reasons, the detection and control of this condition forms a cornerstone in prevention of mortality and morbidity in patients with type 2 DM.[10,11]

Weight control is a key component in the overall management of type 2 diabetes and clear recommendations exist for BMI and WC targets.[10,11] Necessarily then, screening and monitoring of these parameters becomes an important process of care activity. Current South African guidelines suggest that weight and WC be measured at each visit, while BMI only be determined yearly.[10] Studies where either weight or BMI monitoring was assessed, revealed achievement of recommended standards to exceed 50%.[45,104] In the study by Bailie et al., attainment of monitoring at baseline for BMI approached 30% despite the requirement that this parameter be measured twice a year.[35]

It had been previously supposed that within a given BMI category, risk for obesity-related co-morbidity was related to WC[122] ; this possibly explains why, both in the present study as well as in the majority of studies referenced, with the exception of that by Bailie et al[35], WC monitoring does not appear to be a routine process of care measure. Subsequent research by Janssen and co-workers has, however, called into question this previously held relationship between BMI and WC.[123]

According to the researchers, “the primary finding of this study, that BMI coupled with WC did not predict obesity-related health risk better than did WC alone when these 2 anthropometric measures were examined on a continuous scale, indicates that WC, and not BMI, explains obesity-related health risk” and add that “when WC is dichotomized as a normal or high-risk value according to the NIH obesity guidelines, BMI remains a significant predictor of metabolic health risk.”

These findings suggest that WC, instead of BMI, should be the primary parameter for assessing obesity related risk; moreover WC measurement is easy to perform, is not time-consuming and requires no specialized equipment

Whether considered in isolation or in comparison with other studies, the significantly low rates of achievement of accepted standards for processes of care measured in this study, highlights a serious problem in the monitoring of quality and the identification of gaps in the delivery of diabetic care. While the exact reasons for this are not immediately clear, a number of explanations might be postulated. One possibility is the lack of clinician awareness or understanding of the importance of routinely assessing these parameters in accordance with accepted guidelines.[124] Other, often cited, barriers are lack of resources and consultation time pressure in busy primary care settings.[125,126] Barnes et al., conducted a study documenting consultation times amongst patients attended to by general internal medicine residents at a busy general medical clinic and found that clinicians spent an average of 5 minutes on diabetic patient consultations.[127] This latter finding is particularly relevant in the present study where, at the time of data collection, the study facility served a catchment population of over 70 000 people with 2 full-time and 2 part-time medical officers .

5.5 Lifestyle advice on diet, exercise and weight control

Twenty-two percent of participants reported not receiving any information on the 3 lifestyle management components of weight loss, diet and exercise. Advice on exercise and weight control was reported by 68% of the sample while nearly 79% reported receipt of advice on diet. Very few individuals received advice on only one or two of the components; the vast majority (80%) reported receipt of information on all 3 components. These findings differ markedly with those in the South African study by Moodley and Rambiritch.[14] One component of their investigation looked at, inter alia, receipt of counseling on diet and exercise. Their results showed that 32% were counseled on diet and exercise, and 29% received counseling on exercise only; no figure was reported on diet counseling alone.

The relatively high rates of reported advice in the present study are similar to those found in large surveys elsewhere: In the Galuska study[70], nearly two-thirds of obese diabetics were advised to lose weight while 73% of diabetics in the Morrato study[75] were told by a health professional to exercise more. One shortcoming in these comparisons is that both studies considered only a single component of the lifestyle parameters investigated in the present study. A more direct comparison can be made with the Jorgensen study[76], which looked at all 3 parameters. Here, frequency of advice on weight reduction and diet management both exceeded that found in the present study while the reverse was true for receipt of exercise advice.

Overweight and obesity in diabetes significantly increase the risk of CVD and other co-morbidities [128] due to worsening insulin resistance, dyslipidaemia, blood pressure and vascular endothelial dysfunction.[129] For this reason, weight control is a key therapeutic objective.[53,130] Exercise and diet are the main ways of achieving and maintaining weight control[130], and, the provision of advice in this regard is recognized as an important component of lifestyle management.[10,11,130] In light of this, and the fact that the majority of the sample were obese, the high level of reported receipt of weight loss,

exercise and diet advice in the present study is noteworthy. Caution should, however, be exercised in regarding this as a genuinely positive finding since information for this was self-reported and prone to both recall as well as reporting bias.

5.6 Diabetic medication

It was noted in Section 4.0 that complete information on medicines prescribed was only available for 191 individuals and all of these were on some form of drug treatment. Even considering a worst-case scenario where it is assumed that the other 9 patients were on no diabetic medication, we can still conclude that at least 95% of the original sample of 200 were on drug treatment.

Oral medications alone were prescribed in 63%, insulin was prescribed alone in 5%, and 32% were on a combination of both. Comparison with other local studies reveal higher insulin use but comparable or lower oral medication use. In the Steyn study[15], nearly 10% of the sample was on insulin while 68% were on oral medications; 18% of the cohort in the hospital based study by Van Zyl and Rheeder was on insulin, 53% on oral drugs and 28% on a combination of both.[13]

Data from elsewhere reveals similar[35] or lower[131] proportions of insulin use compared to the present study. The reverse trend was noted for oral medication use with generally higher use of oral agents elsewhere.[35, 104]

Ninety-five percent of the patient sample in the present study who were on oral treatment only (n= 120), either as mono- or combination therapy, had been prescribed metformin, while nearly 80% were on two drugs; only 5% were on sulphonylurea monotherapy. While these findings appear to contradict trends elsewhere[131,132], they are consistent with that found in at least one local study[133] and

possibly reflect suggestions in current South African guidelines that recommend metformin, in the absence of contra-indications, as first line oral treatment.[10]

Insulin therapy, either alone or in combination with oral agents, was prescribed in 71 (37%) individuals in the present study. Of these, the majority were on combined insulin and metformin (42%) or on triple therapy (38%). A minority were either on insulin only (13%) or on a combination of insulin and a suphonylurea (7%). Comparison with other data was hampered by the fact that most of the studies referenced did not describe a breakdown of specific oral drug classes but mainly described prescription patterns in terms of oral or insulin use.

The second most frequent drug combination in the present study was that of insulin and metformin. This combination holds a number of advantages. One is the potential of metformin to counteract the weight gain due to insulin; another is the lower incidence of hypoglycaemic episodes. [95] Additionally, meformin can improve lipid profiles and improve macrovascular risk.[84,96]

It is noteworthy in the present study that 17% of patients were on a combination of insulin and a suphonylurea, with or without metformin. Current opinion on the combination of insulin and sulphonylureas appear equivocal: SEMDSA recommends that sulphonylureas be continued if basal insulin is initiated but should be stopped in the case of biphasic insulin[10] ; other experts appear to advocate continuation of sulphonylureas irrespective of insulin regime.[20,117] The combination of sulphnylureas with insulin is controversial for two main reasons: first, both sulphonylureas and insulin promote weight gain[20,117] and second, sulphonylureas may adversely affect β-cell function with progressive use.[88,92] As noted elsewhere in this report, both of these have negative repercussions on metabolic control in type 2 DM and the relatively high proportion of individuals on this combination, with or without metformin, is of concern. However, there may be some benefit in combining all three drug classes: the insulin sparing effect appears to be highest with the triple combination.[95,96]

A small proportion of the sample, 8%, in the present study was on insulin monotherapy. While this at first might seem counter to current recommendations that advise retaining oral treatment, especially metformin, after augmentation with insulin, there is evidence in the literature suggesting the viability of using insulin as monotherapy in Type 2 diabetes.[92] Some caution should be exercised in the interpretation of such evidence : while suphonylureas appear to compromise β-cell function, metformin has a number of beneficial metabolic effects**,** not least of which is the added potential of counter-balancing insulin induced weight gain[7,95,96] and its continued use with insulin is recommended in local and international guidelines.[10,11,134] However, insulin mono-therapy has the practical advantage of reducing poly-pharmacy and could be considered in individualized cases.

5.7 Associations of glycaemic control

5.7.1 Processes of care

With the exception of monthly BP monitoring, which was demonstrated to have no influence on glycaemic control, the proportions for the other processes of care that met the standard for performance were too small to test for association with glycaemic control in the present study.

Since the influence of process of care in respect of HbA1c, BMI and WC monitoring on glycaemic control could not be determined in this study, direct comparisons with other studies becomes difficult. Comparisons with other South African research are further hampered by the fact that, with the exception of the study by Van Zyl and Rheeder[13], none of the South African studies explicitly stated the applicable standard for process of care assessments.

Research elsewhere however, reflects a pattern of non-concordance of processes of care indicators with glycaemic control. Pederson conducted a cross-sectional study to assess the management of type 2 diabetics in Greenland attending primary health clinics and found no association between processes of care and HbA1c levels.[118] In a comparison of diabetes management in 5 countries, Damin et al., demonstrated better glycaemic control in countries that measured worse for levels of processes of care.[115]

While these findings suggest that generally, there is no association between process of care measures and glycaemic control, it might be reasonable to speculate as to whether there might exist specific conditions in the present study that could possibly have influenced the null association. Two such factors bear further scrutiny. First is the limited number of processes investigated. Second is the fact that diabetic care is rendered by non-specialist clinicians. Evidence suggests that both these might play no role. In the TRIAD study, researchers sought to determine whether variations in the number of process of care was associated with, inter alia, HbA1c and found that the addition of one more documented process of care had no influence on glycaemic control.[43] De Bererdis et al., compared quality and outcomes of care amongst type 2 diabetic patients attending either diabetic outpatient clinics or general practitioners and found that while attainment for process of care measures was better in the former, metabolic control showed no statistical difference.[42]

5.7.2 Diet, exercise and weight control advice received

No statistically significant association between self-reported receipt of counseling on any one of diet, exercise or weight loss and glycaemic control was demonstrated in this study although there appeared to be a trend of greater proportion of controlled glycaemia amongst those reporting no advice.

Similarly, receipt of any advice compared with no advice showed no association with glycaemic control but again the trend of higher proportion of control amongst those reporting no advice received was preserved.

These results confirm some findings some studies while differing from others. In a similar cross-sectional sectional study by Blaum et al., absence of dietary advice was independently associated with poor glycaemic control.[135] It should be noted that the authors characterized HbA1c $\geq$ 11% as poorly controlled glycaemia. Two follow-up studies, one of which included a nutritional education component in its self-management education intervention[136] while in the other diet, exercise and weight management advice were all given[137], showed no post-intervention impact on glycaemic control. A recent systematic review found that while exercise advice alone had no impact on glycaemic control, improvements in HbA1c were realized when exercise advice was combined with nutritional advice.[138]

Although no association between receipt of lifestyle advice and glycaemic control could be demonstrated in the present study, it should be noted that the nature, content and frequency of such advice was not ascertained and neither was the category of HCW delivering this advice identified. This is important since other studies have shown that specialized forms of lifestyle counseling in certain contexts do in fact yield beneficial effects on glycaemic control.[59,80] Also, as pointed out elsewhere in this chapter, since information for this aspect of the present study was self-reported, the role of bias cannot be excluded.

In the final analysis, the potential of any beneficial effect of lifestyle advice upon glycaemic control can only be realized upon translation into practice, an effect not investigated in the present study. However, some idea of the degree of this translation might be gleaned from the observation that the majority of participants in this study had an unsatisfactory anthropomorphic profile.

5.7.3 Diabetic medication

Types of treatment and combinations thereof had a significant influence on glycaemic control. In particular, patients on a combination of oral and insulin treatment had the lowest proportion of control. This finding was further elaborated after sub-division into actual medication classes and combinations thereof. Here, the lowest proportion of control occurred in patients on a combination of all 3 treatment classes as well as in those on a combination of insulin and metformin. Statistical confirmation of this was demonstrated on univariate and multivariate logistic regression where odds of lower proportions of controlled glycaemia were significantly associated with both these combinations.

The highest proportions of control occurred in patients on mono-therapy: 50%, 44% and 39% in the suphonylurea, insulin and metformin groups respectively. These findings appear similar to results in the sulphonylurea, insulin and metformin treatment arms of the UKPDS 49 study where 50%, 47% and 44% of subjects respectively, achieved control after 3 years of treatment initiation.[82]

With the exception of the insulin and sulphonylyurea combination, the finding in the present study of lower odds of glycaemic control for all other combinations involving insulin as compared to insulin alone is not supported by literature. There is clear evidence, for example, that the insulin plus metformin combination achieves glycaemic control comparable to, or better than, insulin alone. [94,96,139]

Similarly, compelling evidence from at least one controlled trial suggests that the addition of any insulin regime to a baseline combination therapy of metformin and sulphonylurea results in significantly better glycaemic control.[140]

A number of factors might be postulated to explain these discordant findings . Clinical inertia and the delayed recognition of secondary failure are possibilities. Clinical inertia may be described as the failure to intensify treatment in the face of inadequate control.[141] Shah et al., who studied this phenomenon amongst specialist and generalist physicians attending to a large cohort of elderly diabetics on oral drugs in Ontario noted that treatment intensification in response to inadequate glycaemic control occurred in 45% of patients attending specialists ; the corresponding figure for generalists was 37.4%.[142] In the primary care context, Calvert et al., looking at the management of diabetics on oral therapy attending general practitioners found that "oral treatment was not started until glycaemic control is poor" and patients remained on monotherapy for a median of almost 4 years before addition of a second oral agent.[132] In the present study, the cohort on combination insulin and oral therapy had a median disease duration of 7 years and were on insulin for a median of 16 months (Appendix G, table G.1) which suggests that this group had insulin added nearly six years after initial diagnosis. These figures point to a possible delay in the recognition of the secondary failure phenomenon of oral drugs and the consequential failure in the timeous initiation of insulin. One factor contributing to this delay is the significantly inadequate level of HbA1c monitoring noted in this study. Additionally, clinicians might delay initiation and/or intensification of insulin to avoid weight gain, risks of hypoglycaemia or polypharmacy.[83] The influence of polypharmacy and weight gain is particularly relevant in the present study where obesity and the presence of at least one documented co-morbidity was noted in the vast majority of the cohort. Finally, the possible role of patient-provider interaction might also be mentioned: on the one hand, patients and providers often differ in treatment priorities[143] while on the

other, patients and clinicians often "collude in implicit and unspoken contracts to continue oral agents for as long as possible." [83]

A small proportion of the sample, 8%, in the present study was on insulin monotherapy , and both this as well as the suphonylurea only group, had highest proportions of glycaemic control. While this at first might seem counter-intuitive, there is evidence in the literature regarding the viability of using insulin as monotherapy in Type 2 diabetes.

In a comprehensive review on the question, Massi-Benedetti and Orsini-Federici make a compelling case for the use of insulin monotherapy after failure of oral treatment.[92] They cite the following well founded evidence to support their case:

- Insulin preserves β-cell function whereas sulphonylureas have been shown to be detrimental
- Insulin provides better glycaemic control
- Monotherapy reduces poly-pharmacy

Some caution should be exercised in the interpretation of these findings. It does not necessarily follow that insulin monotherapy is better than any combination of insulin and an oral agent: while suphonylureas appear to compromise β-cell function, metformin , despite the possibility of secondary failure, has other beneficial metabolic effects[7,96] and its continued use with insulin is recommended in local and international guidelines.[10,11,134] These guidelines, however, also recommend the continued use of sulphonylureas with insulin.

While patterns of glycaemic control associated with drug classes and combinations thereof in the present study appear to differ from results elsewhere, the overall finding that treatment, after controlling for other factors , emerged as an independent co-variate of control is borne out by at least one systematic review that investigated the relation between quality of care indicators and diabetic outcomes.[144]

Reporting on their findings, the authors of this study concluded that: "Process indicators focusing on intensification of drug treatment were significantly associated with better surrogate outcomes…" [144]

5.7.4 Co-morbid medical conditions

Figures reported in the literature demonstrate that most diabetics have at least one co-morbid condition[143,145] and that 40% of diabetics have three or more.[145] The former observation is borne out by the present study where over 90% of the sample were found to have at least one such condition; however only 18% had more than one documented co-morbidity and none of the patient records reflected more than two.

One useful categorization of co-morbidities has been suggested by Piette and Kerr who distinguish between "concordant" and "discordant" co-morbidities: concordant conditions are those that "represent parts of the same overall pathophysiological risk profile." [145] According to this typology, in respect of diabetes, conditions such as CVD, dyslipidaemia and hypertension would represent concordant co-morbidities.

Of the co-morbidities noted in the present study, the overwhelming majority were concordant conditions: 92% were hypertensive while 10% had been diagnosed with CVD (19 had CCF and 1 had IHD) and 1 person had documented dyslipidaemia; less than 9% had discordant disease. The high prevalence of hypertension reflects the observation that not only is this condition one of the two commonest co-morbidities in diabetes[11], but is also thought to occur in more than two-thirds of diabetic patients.[121]

Other South African studies that looked at co-morbidity mainly focused on hypertension[15,16,17] and , compared to findings in these, the proportion of hypertension is significantly higher in the present study: Rotchford and Rotchford, noted hypertension in 65.4% of the subjects studied[16]; in the Motala study[17], 68% of type 2 diabetics in their sample were hypertensive.

While the overall prevalence of hypertension is consistent across both these studies, the results must be interpreted with some caution: one difficulty in the Rotchford study[16] is that the sample comprised a mixture of both Type 1 and Type 2 diabetics, although the former made up only 7.% of the sample; in the Motala study[17], borderline hypertension was defined as a blood pressure of greater than 140/90 which seems to imply that patients with blood pressure equal to 140/90 were not classified as hypertensive.

In the present study, a greater proportion of glycaemic control is apparent in individuals with co-morbid conditions than in those without. However, although glycaemic control appeared to be better amongst the former, the actual proportion of glycaemic control in this group was 25% which is significantly lower than that reported in other studies.[146,147] Also, in the present study, the association between any co-morbidity and glycaemic control did not reach statistical significance. The only exception was CCF: the presence of this concordant condition tripled the odds for controlled glycaemia.

Other studies that looked at co-morbidities in terms of the Piette and Kerr typology demonstrate differing influence on gylcaemic control. Alshamsan et al., found that mean HbA1c was lower in a cohort with concordant co-morbid conditions than in those with discordant or no co-morbid conditions[148], while LeChauncy et al., showed that the presence of any co-morbidity, concordant or discordant, had twice the odds for better control than the absence co-morbidity.[149] A more recent study by Pentakota et al., showed a still different pattern: after controlling for a number of co-variates, those with either a discordant or a combination of a discordant and concordant condition, had lower odds for glycaemic control compared with those without any co-morbidity; the presence of a concordant condition did not confer better odds of control compared to not having any co-morbidity.[150] What these results suggest is that analyses of glycaemic control using broad categorizations of co-morbidity appear to be less informative than focusing on specific conditions, an observation

demonstrated in the present study and at least one other study elsewhere.[151] Despite the lack of a clear pattern, the overall impression is that concordant co-morbidities appear to improve glycaemic control or, at worst, not degrade it.

One likely explanation for this is the relationship between the primary condition and concordant co-morbidities: since these share similar pathophysiological characteristics and treatment goals, the implication is that treating one leads to commensurate benefits on the other which in turn might lead clinicians to more easily prioritize the management of this category of co-mobidity.[143] On the other hand, discordant conditions represent diagnoses not related to the primary condition, often require more medications, and increase management demands on the clinician[145]; additionally, conditions such as depression have adverse effects on self-care behaviours such as medication adherence.[151] The role of patient perceptions regarding the presence of co-morbid conditions as a motivating factor in better self-management is less clear. A survey by Laiteerapong et al., suggests that the influence of such perceptions is a complex one since patients not only vary in their health priorities, but often disagree with health care providers on issues such as the importance of various co-morbidities and treatment preferences.[143]

5.7.5 Race

In the present study, the unadjusted odds for controlled glycaemia in individuals who were not Black was over three-fold of that for Black subjects. Sub-optimal control amongst Black individuals has been demonstrated in various studies elsewhere. Egede et al., who analysed variations in glycaemic control in a national sample of veterens in the U.S.A., found that odds for poor glycaemic control (which they defined as HbA1c $\geq$ 8%), was 1.33 for Blacks as compared to that for Whites.[152]

In a study that assessed trends of HbA1c levels amongst diabetics in the USA between 1999 and 2004, data for the period 2003-2004 showed that 44% of African Americans had an HbA1c < 7% compared to 64% of Whites.[153]

Similarly, in the small South African study by Westaway et al., that looked at, inter alia, racial distinctions in glycaemic control, 12% of Blacks and 21% of Whites respectively, were noted to have good glycaemic control.[113]

In the present study, whether this racial association with glycaemic control reflects a relative disparity in socio-economic status, access to care or some other factor or factors, is not immediately evident since only a limited number of co-variates were tested. The only other demographic factor that was significant in the unadjusted model was residence, but this was on account of collinearity with race. A number of explanations have been advanced by other researchers, and while there appears to be no clear consensus at this time, race specific HbA1c disparities appear not to be influenced by processes[154] or quality of care.[155] Other clinical factors such as medication adherence and co-morbidity also seem to play no role.[152] The influence of medication is unclear: a 1994 study by Eberhardt showed that insulin use, while not eliminating, did diminish the association between race and HbA1c[156]; the more recent study by Egede et.al., demonstrated persistence of Black- White HbA1c disparity even after controlling for treatment type.[152] Clinical inertia has been implicated in a 2011 study by Traylor et al., who demonstrated that African-Americans were less likely to receive treatment intensification compared to Whites.[157] This might be relevant in the present study where the mean duration of insulin therapy in other race groups was double that in Blacks.(Appendix G, table G.2).

Another idea, postulated by Adams et al in 2008, suggests that Blacks might have more severe disease at diagnosis.[155] This hypothesis has gained merit following subsequent work by Ziemer et al. in 2010.[158]

In this large cross sectional study, based on data from 2 other surveys in the USA, the investigators demonstrated that mean HbA1c levels were higher in Blacks as compared to that in Whites in non-diabetic, pre-diabetic and diabetic subjects ; also, the differences were independent of glycaemic levels and were more pronounced in pre-diabetics and most pronounced amongst diabetics.

An additional, important finding was that, since the diabetic cohort in their study was newly diagnosed and not on any treatment at the time of the study, treatment modality was excluded as a possible factor.

5.8 Implications of key findings in this study

Key findings pertaining to the aim and objectives of this study are the low level of glycaemic control and the almost non-existent attention to some important processes of care. These findings have significant and far reaching implications, on various levels, for the study population.

Individuals with type 2 diabetes mellitus are at increased risk of neurological, cardiovascular and renal complications and these in turn have devastating effects on individual morbidity. According to recent data released by the ADA, diabetes in adults confers a greater than 2-fold increased risk of cardiovascular disease, is the leading cause of blindness and kidney failure, and accounts for more than 60% of non-traumatic lower limb amputations.[159] Since, as demonstrated in the literature review , complications in type 2 DM are strongly correlated with poor glycaemic control, the clinical implications for the target population of the present study are serious: more than three-quarters are at significant risk of developing one or more of the potentially life-threatening complications noted above. This in turn translates to added socio-economic burden by way of increased health care costs, loss of income, productivity and stunted economic development through premature morbidity and mortality in the

economically active population.[1] Increase in health care costs for diabetes is a particularly important challenge. Estimates in the USA by the ADA, suggest that the cost of health care is more than 2-fold higher in patients with diabetes than in those without.[159] According to projections by the IDF[160], the prevalence of diabetes in Africa is expected to double by 2030, while expenditure on diabetes related health care is only expected to increase by 61%, a significant shortfall that is further likely to erode efforts aimed at controlling the disease.

In view of this, the WHO, in concert with the World Bank, has proposed 3 interventions that are cost-effective, life saving and feasible in resource constrained settings[161]:

- Moderate blood glucose control with oral medication and, where needed, insulin.
- Blood pressure control
- Foot care

The first of these has particular relevance to the present study where pharmacological treatment emerged as the only modifiable co-variate of glycaemic control. While clear guidelines exist for the initiation and intensification of glucose lowering agents, the extent of clinician adherence to these is unclear and requires elucidation through further research. In this regard, the question of possible delay in augmentation of oral medications with insulin is important. One South African study, conducted in primary care clinics in Cape Town, demonstrated a number of patient, service and clinician related barriers to insulin initiation.[162] Similar research aimed at identifying and addressing barriers in the context of the present study has the potential for significantly improving glycaemic control.

Processes of care, while not shown to influence glycaemic control, both in the present study as well as in other literature, is nevertheless an important component of diabetes care. Process parameters measured in this study, as well as others such as regular, cholesterol measurements, urine screening for albuminuria, foot examinations and fundoscopy are vital in the monitoring of control and the

identification of complications. Inadequate adherence to process of care issues pose a number of challenges to the patient, the clinician and the health care system. First, there is failure to identify and prevent the onset of the many life threatening complications of diabetes. Second, improvements in adherence to guidelines by clinicians will require a multi-faceted program comprising a baseline audit, training in, and implementation of, current guidelines for processes of care and, regular post-implementation audits and feedback to clinicians for monitoring performance. That such an approach is effective in realizing the desired outcome of improved adherence to process of care standards, has been demonstrated in studies both locally and elsewhere.[13,120] What is not clear, is whether this approach is feasible in the current context and this requires further study. Finally, the implementation of adequate process of care practice has an attendant implication on health system resources by way of added costs of laboratory investigations and referrals. However, simple processes such as BMI and WC monitoring, while realizing potentially enormous benefits accruing from monitoring overweight related cardio-metabolic risk, require no special skills or equipment. Furthermore, not all process need to be implemented at once: in addition to the processes of care measured in the present study, a reasonable point of departure would be the implementation of the following cost-saving WHO recommendations[161]
:

- Screening and treatment of retinopathy to prevent blindness
- Screening for early signs of diabetic-related kidney disease.

Given the limited access to specialist ophthalmic services, the first of these is probably not immediately feasible in the context of the present study. However, recruitment of optometrists into the district health services could be a reasonable alternative for the establishment of an adequate retinopathy screening program. The second, while both feasible and easily implemented is often precluded on account of the lack of bed-side tests for albuminuria.

According to data released recently by Statistics South Africa on causes of death in this country for 2010, not only was diabetes responsible for more deaths than HIV, but, compared to 2009, there was a 3.8% increase in deaths due to diabetes; the corresponding increase for HIV-related deaths was 3%.[163] Of particular note are the figures for Sedibeng District, where the present study was conducted: here, compared to the national figure of 3.9% of deaths attributable to diabetes, the disease accounted for 4.1% of all identified causes of mortality.[163] These facts have two vital implications. First, a significant proportion of morbidity and mortality can be reduced by improving diabetic care and second, given the successes of the national HIV program, that a national, comprehensive plan, akin to that for HIV, is required to address the burgeoning diabetic epidemic and its attendant consequences. In this regard, IDF recommends an integrated approach involving three levels[160]:

- Macro-level: development of policy and financing frameworks
- Meso-level: communities and health institutions where diabetic care is delivered
- Micro-level: the individuals with diabetes, their families and immediate care-givers

5.9 Limitations and strengths of this study

Processes of care, delivery of lifestyle advice and pharmacological treatment represent a cluster of factors that describe what clinicians do as part of an overall management plan to achieve specific quality and metabolic outcomes individuals with type 2 diabetes mellitus. While there exists a plethora of research elsewhere that studied either of these factors, there appeared to be none locally, at the time of the current study, that comprehensively investigated all three. This shortcoming is likewise reflected in studies that assessed the impact of these factors on glycaemic control. Such studies were further compromised by a lack of consistent definitions of important parameters such as glycaemic and blood pressure control.

One strength of the present study is the attempt to address these critical gaps in the corpus of local research. In addition, this study looked at actual clinical practice and outcomes and thereby sought to provide insights into the management of type 2 diabetic patients within the constraints and challenges of a real world primary health care setting. Additionally, analyses in this study were not limited to descriptive statistics; inferential and regression techniques were employed to uncover associations and control for potential confounders.

This study has a number of limitations. Potential sources of bias have been previously noted and some of these need to be emphasized in so far as they potentially skew the outcomes reported in this study: first, since participation was entirely voluntary, selection bias is unavoidable and characteristics of non-participants could not be checked for similarity to the final sample; second, absence of documentation of any process of care in patient charts was deemed to indicate non-performance and this might have under-estimated the proportions of achievement in this regard, and, finally recall bias as well as the Hawthorne phenomenon limits the validity of information on reported receipt of lifestyle advice by study participants . While every reasonable effort was made to locate research of relevance to the present study, the dearth of published South African studies in this regard restricted meaningful comparisons; logistic constraints precluded the possibility of accessing un-published work.

The observational design of this study is an important limitation. Results of cross-sectional analyses, while revealing of associations between exposure and outcome variables, cannot be used to infer causality. Furthermore, limitations on the number of explanatory factors that can be tested within a given sample size leave open the possibility of unmeasured confounding variables in the absence of a control sample.

Finally, findings in this study have limited potential for extrapolation to other facilities within the district. While catchment populations served by the various facilities might be similar, inter-facility variations with respect to clinical staff complements, protocols, practice and other factors such as access to laboratory tests, cannot be excluded.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The typical individual in this study was between 55 and 60 years of age, had some form of secondary education and was either employed or in receipt of a state pension. The majority of the sample was diagnosed less than 20 years ago and had anthropometric profiles that conferred high cardio-metabolic risk. More than 90% of the sample had at least one co-morbid medical condition and of these, hypertension was the commonest.

High proportions of reported receipt of lifestyle advice in the past 12 months from a health care worker on weight control, diet or exercise were noted, with the majority reporting advice on all three topics. With the exception of blood pressure monitoring, significant shortcomings in clinicians' adherence to SEMDSA guidelines for process of care measures in respect of HbA1c, weight, BMI and waist circumference monitoring in the preceding 12 months were demonstrated. Oral hypoglycaemic drugs, either alone or in combination, were the most commonly prescribed drug type. Insulin was most often combined with metformin, a prescription pattern in keeping with local guidelines for treatment intensification with adjunctive insulin therapy. Only a minority of individuals was on insulin mono-therapy.

The majority of the sample were found to have sub-optimal glycaemic control and, in the final adjusted logistic model, hypoglycaemic drug class emerged as the only modifiable parameter associated glycaemic control among the preset explanatory variables.

The presence of CCF as a co-morbidity was associated with a higher proportion of glycaemic control compared to those without the condition and there was an inverse association demonstrated between glycaemic control and therapeutic combinations involving insulin. In particular, combination therapy comprising either insulin and metformin or insulin, metformin and a sulphonyluria, conferred significantly worse levels of glycaemic control compared to that achieved using insulin alone.

A critical gap in the management of adult diabetics identified in this study is the sub-optimal adherence to accepted standards for key process of care measures. While improvements in process of care measures do not necessarily lead to commensurate improvements in glycaemic control, the importance of such measures inheres in their ability to detect and improve quality of care and cardio-metabolic risk.

6.2 Recommendations

A number of gaps in the quality of care provided to adult diabetics were identified in this study. Critical amongst these, and one requiring immediate attention, is the low level of adherence by clinicians to accepted standards for key processes of care. The following are some recommendations to address this challenge:

- Implementation of a continuous education program aimed at familiarizing clinicians with the contents and importance of process of care measures in the holistic management of adult diabetics. It is vital that such a program be continuous since initial gains eventually fade as enthusiasm wanes.
- Adoption of a standard set of guidelines, such as those recommended by SEMDSA, and the provision of practice aids in the form of charts and protocols.

- Provision of a reminder system, either paper- or computer-based, for anthropometric monitoring, laboratory investigations and referrals.
- Regular practice audits to monitor and improve these strategies for enhancing process of care measures

The District Family Medicine Unit is responsible for the implementation and monitoring of clinical quality in primary care facilities within Sedibeng District and, as such, responsibility for the implementation of these recommendations falls within its ambit. As an initial step, the development and dissemination of process of care guidelines can be accomplished through the existing program of continuous medical education for district medical officers. Subsequent implementation and monitoring should be conducted by sub-district family physicians through a combination of record reviews, audits and observed consultations.

While a computer based reminder system might not be possible in the short term, the provision of a paper based system using pro-forma sheets in patient records detailing the various process of care schedules and reminders for clinicians, is both feasible and practical for immediate implementation

In addition, further research is required to elucidate two other issues arising from this study:

- Despite high levels of reported receipt of lifestyle advice, the anthropomorphic profiles of patients in this study was unsatisfactory. Since not all forms of lifestyle advice are efficacious, information regarding the type, quality and content of such advice currently being received is required to identify and address possible shortcomings in this regard.
- A number of hypotheses have been postulated to explain the inverse association between glycaemic control and drug combinations comprising insulin and oral hypoglycaemics found in this study. Additional investigations are required to test these and other possible explanations for this anomalous finding. The identification and management of barriers in this regard has the

potential benefit of significantly improving overall rates of glycaemic control in the study population given that one-third of the sample is on combined insulin and oral treatment.

In addition to a general program of continuing medical education, the District Family Medicine Unit maintains an academic program for family medicine registrars. As part of their academic training , registrars are required to conduct clinical audits , quality improvement projects as well as research projects in district facilities. In this regard, the unit is ideally placed to address these research questions within its existing academic program without the necessary deployment of additional resources. This is both practical as well as cost-effective, particularly in resource-constrained settings such as that where the current study was conducted. Research recommendations will be communicated to the HOD of the Family Medicine Department at WITS Medical School for consideration as topics of research for future family medicine registrars.

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APPENDIX A

INTERVIEW QUESTIONNAIRE

SOCIO-DEMOGRAPHIC DATA AND DIABETIC SELF-CARE INFORMATION

Section A. Socio-demographics

Reference: _____ Date:_____

Date of birth:_____ Sex: M / F

Place of residence: _____

Highest level of schooling: primary/secondary/other_____

Employment status: Employed/unemployed/self-employed

Section B. Self-care information

1. When were you diagnosed with diabetes?
2. Over the last 12 months, has any health worker at the clinic advised you about the following issues regarding diabetes:
    - Exercising regularly Y/N
    - Following a healthy diet Y/N
    - Controlling your weight Y/N

4. Anthropomorphic measurements

Height_____ Weight_____ Waist Circumference_____

APPENDIX B

CLINICAL RECORD AND PROCESS OF CARE DATA EXTRACTION SHEET

1. Co-morbid conditions: 1)_____2)_____3)_____4)_____

2. Medications and doses:

    a. Glibenclamide
    b. Glicazide
    c. Metformin

3. Insulin (Y/N) Duration (Months)_____ Type (Basal/Biphasic/ Basal-Bolus)

4. Process of care performance over the preceding 12 months

Month	1	2	3	4	5	6	7	8	9	10	11	12
Visit Y/N												
Blood glucose												
HbA1c												
WC												
Body weight kg												
BMI												
BP												

5. HbA1c requested Y/N Result_____%

APPENDIX C

WITS HREC CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Kalain

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M080635**
PROJECT	The role of patient factors and the processes of care in glycaemic control amongst Type II diabetic patients attending the Johan Heyns Com Health Centre -Sedibeng
INVESTIGATORS	Dr A Kalain
DEPARTMENT	Family Medicine
DATE CONSIDERED	08.06.27
DECISION OF THE COMMITTEE*	Approved unconditionally

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

DATE 08.07.15 **CHAIRPERSON** .....
(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr OB Omole

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 D

SEDIBENG DISTRICT HEALTH SERVICES PERMISSION TO CONDUCT RESEARCH

Department of Health
Lefapha la Maphelo
Departement van Gesondheid
Umnyango wezeMpilo

SEDIBENG DISTRICT HEALTH SERVICES

Private Bag X 023
VANDERBIJLPARK
1900

Enquiries: MRS M DICHABA
Tel: (016) 950-6267
Fax: (016) 950-6016

TO: : Dr A Kalain, CMO: Sedibeng DHS
cc : Dr OB Omole, District Family Physician and Principal Specialist: Sedibeng DHS Family Medicine Unit.

FROM: MRS M Dichaba , Acting Director, Sedibeng DHS

PURPOSE: Permission for conducting a study on diabetes at the Johan Heyns CHC

Permission is hereby granted by Sedibeng District for you to undertake the proposed research entitled: " The role of patient factors and processes of care in glycaemic control amongst patients with type 2 diabetes attending the Johan Heyns Community Health Centre"

This permission is granted with the proviso that the research will only commence pending academic and ethical approval from Wits as well as ethical approval from research committee of the Gauteng Dept. of health. It is furthermore understood that the district reserves the right to withdraw any permission to conduct or continue the study should there occur infringement of any prior agreement/s.

Regards

Mrs M Dichaba, Acting Director: Sedibeng DHS

Date: 08. 04. 29

Cnr. Frikkie Meyer Blvd/Pasteur Blvd. Vanderbijlpark 1911

APPENDIX E

PATIENT INFORMATION SHEET

THE ROLE OF PATIENT FACTORS AND PROCESSES OF CARE IN THE GLYCAEMIC CONTROL OF TYPE II DIABETES AMONGST ADULTS ATTENDING THE JOHAN HEYNS COMMUNITY HEALTH CENTRE.

Dear Sir/Madam,

My name is Dr Kalain and I am a post-graduate student in Family Medicine at WITS University. As part of my studies, I am doing a research project on diabetes at Johan Heyns Clinic. I want to find out how well diabetes is controlled in patients attending this clinic and also to understand some of the reasons for satisfactory or unsatisfactory control.

To obtain the necessary information to answer these questions, I request your voluntary participation to do the following:

- Conduct a short interview where I will ask questions about diet, weight and exercise.
- Look at your clinic file to see whether things like blood sugar, weight ,height and waist are checked and also to find out what medications are being taken for diabetes and other problems
- If necessary, I will have your height ,weight and waist measured and also request a blood test for sugar to be done.

The **interview should take no longer than 10 minutes** and your usual consultation for which you are attending will not be affected. There are no risks or benefits to you from participating in the study.

I want to re-assure you that:

- Participation is completely voluntary and that it is your right to withdraw at any point during the process without giving a reason. Non-participation or withdrawal carries no penalty whatsoever and will in now way adversely affect your medical care at the clinic
- No sensitive information will be required and any information obtained will be treated with the strictest confidentiality. Your name will not be recorded during the process.
- The information required for this study is no different from that required by your doctor or nurse during your usual consultations at the clinic for diabetes. This is also true for the height, weight and waist measurement as well as the blood sugar test.

Should you volunteer to participate in the study, you will be requested to give written consent after reading and signing the attached consent form.

Should you have any queries or concerns, please feel free to contact me, Dr A Kalain, at the following telephone numbers:

- 016 950 6000 – Johan Heyns Community Health Centre.
- 016 950 6267- Sedibeng District Health Office.
- 083 468 6922 – 24 Hours

Thank you

Dr A Kalain.

APPENDIX F

INFORMED CONSENT FORM

INFORMED CONSENT:

- I hereby confirm that I have been informed by the study doctor, Dr A Kalain, about the nature, conduct, benefits and risks of clinical study : " **The role of Patient Factors and Processes of Care in Glycaemic control amongst patients with Type 2 Diabetes attending the Johan Heyns community health centre in Sedibeng District."**
- I have also received, read and understood the above written information (Participant Information Leaflet and Informed Consent) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the study doctor.

- I may, at any stage, without prejudice, withdraw my consent and participation in the study.

- **I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.**

PARTICIPANT:

Printed Name	Signature / Mark or Thumbprint	Date and Time

I, Dr A Kalain herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

STUDY DOCTOR:

Printed Name	**Signature**	**Date and Time**

TRANSLATOR / OTHER PERSON EXPLAINING INFORMED CONSENT……**(DESIGNATION):**

Printed Name	**Signature**	**Date and Time**

WITNESS (If applicable)**:**

Printed Name	**Signature**	**Date and Time**

APPENDIX G

ADDITIONAL RESULTS NOT SHOWN IN CHAPTER 4

Table G.1 Duration of diabetes and insulin in individuals on oral and insulin therapy *(n=62)*

	Minimum	Maximum	Median
Diabetes duration (years)	1	21	7
Insulin duration (months)	1	104	16

Table G.2 Insulin duration by race

	Blacks	Other races	p-value for difference in means
Mean insulin duration (months): insulin and oral therapy or insulin only *(n=70)*	26.2	51.33	0.0165
Mean insulin duration (months): insulin and oral therapy *(n=62)*	23.6	40.8	0.0864*

**not statistically significant*

APPENDIX H

APPLICATION FOR CHANGE OF TITLE

Postgraduate Office, Faculty of Health Sciences
Wits Medical School, 7 York Road, PARKTOWN, 2193, Johannesburg • Tel: (011) 717 2000 • Fax: (011) 717 2119

APPLICATION FOR CHANGE OF TITLE OF APPROVED RESEARCH REPORT, DISSERTATION OR THESIS

Motivation / Reason for title change: **The primary thrust of this research is to look at the effect of primary health care services on diabetic outcomes, i.e., factors that are within the ambit of the health care system to modify. In particular, this study seeks to investigate the relationship between various dimensions of care provided by clinicians and glycaemic control amongst Type 2 diabetics attending a public primary health care service. Originally, these dimensions of clinical care, which also include non-medical activities such as lifestyle advice, were thought to be adequately subsumed by the rubric " Processes of Care". However, as some of the literature suggests, the term usually applies to a defined set of activities that exclude things like lifestyle advice and pharmacological treatment. Consequently, the words "Selected patient factors" were deemed superfluous, and the words " Lifestyle advice" and "Treatment" become necessary to clarify the afore-mentioned distinction implied by the words "Processes of care".**

Recommendation of Department / School:

_____

_____

_____

Student Surname and Initials: **KALAIN A** Student Number: **8159869**

Degree: **MFAMMED**

Department: **FAMILY MEDICINE** Telephone: **083 468 6922** E-mail: **aswink@gpg.gov.za**

Previous Title: **The Role of Patient Factors and Processes of Care in Glycaemic Control amongst Adults with Type II Diabetes attending the Johan Heyns Commmunity Health Centre in Sedibeng District.**

New Title: **PROCESSES OF CARE, LIFESTYLE ADVICE, TREATMENT AND GLYCAEMIC CONTROL AMONGST PATIENTS WITH TYPE 2 DIABETES MELLITUS ATTENDING THE JOHAN HEYNS COMMUNITY HEALTH CENTRE IN SEDIBENG DISTRICT.**

Supervisor/s: **DR O B OMOLE**

Departments: **FAMILY MEDICINE**

Supervisor'/s Telephone: **0764721289**

Supervisor'/s E-mail: **alagbaomole@gmail.com**

Signatures of Student: _____ Supervisor 1: _____

*HEAD OF DEPARTMENT / HEAD OF SCHOOL: *(Where the HOD is Supervisor, the HOS must sign)*

_____ _____ _____
(Surname and Initials) (Signature) (Date)

DECISION OF CHAIR OF THE PG COMMITTEE: _____ **Signature:** _____

Date: _____