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MASTER'S THESIS

MEDICINE THERAPY MANAGEMENT FOR DIABETIC CLUB PATIENTS AT A PRIMARY HEALTH CARE CLINIC: EXPLORING A POTENTIAL ROLE FOR PHARMACISTS

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MEDICINE THERAPY MANAGEMENT FOR DIABETIC CLUB PATIENTS AT A PRIMARY HEALTH CARE CLINIC: EXPLORING A POTENTIAL ROLE FOR PHARMACISTS

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A thesis submitted in fulfilment of the requirements for the degree of Master of Pharmaceuticae in the School of Pharmacy, University of the Western Cape, South Africa.

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DECLARATION

I, Farhaana Sonday, hereby declare that the Medicine Therapy Management for diabetic club patients at a primary health care clinic: exploring a potential role for pharmacists is my original work, that it has not been previously submitted to any other university for the purpose of obtaining a degree, and that all sources I have used or quoted have been indicated and acknowledged as complete references.

Farhaana Sonday

Signed: ..... December 2019

University of the Western Cape

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To my mother and father for their spiritual support, sacrifices, love and strength.

DISSEMINATION OF FINDINGS

PARALLEL PRESENTATION
NATIONAL CONFERENCE

Results were disseminated at a national conference, Public Health Association of South Africa (PHASA) at the Indaba Hotel on the 6 September 2017.
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DEPARTMENT OF HEALTH

Findings of the study were presented at the sub-structure, Metro District Health Services, Cape Town, Pharmacy and Therapeutic Committee meeting held on the 08 March 2018. Research findings were also submitted to the Research Committee of the Department of Health, 20 October 2018. A summary of study findings was shared with facility staff participants at the facility after completion of the research study.

PUBLICATION

A manuscript will be submitted for publication.

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LIST OF ABBREVIATIONS

ADA:	American Diabetes Association
APA:	American Psychological Association
BMI:	Body Mass Index
CCMDD:	Central Chronic Medicine Dispensing and Distribution
CDC:	Community Day Centre
CDU:	Chronic Dispensing Unit
CHC:	Community Health Centre
CNP:	Clinical Nurse Practitioner
eGFR:	estimated Glomerular Filtration Rate
EML:	Essential Medicine List
FPG:	Fasting Plasma Glucose
HbA1c:	Glycosylated haemoglobin A1C
HDL:	High Density Lipoprotein
IDF:	International Diabetes Federation
LDL:	Low Density Lipoprotein
MTM:	Medicine Therapy Management
MTP:	Medicine Therapy Problem
NCD:	Non-Communicable Disease
NDoH:	National Department of Health
PHC:	Primary Health Care (PHC)
SEMDSA:	Society for Endocrinology, Metabolism and Diabetes of South Africa
STGs:	Standard Treatment Guidelines
UWC:	University of the Western Cape
WHO:	World Health Organization

ABSTRACT

Background

Diabetes mellitus is a complex chronic condition and has become a major public health concern worldwide. Many diabetic patients are accessing primary health care (PHC) clinics for diabetes care. Diabetic patients who are considered stable are referred to chronic diseases of lifestyle club at the PHC facility. Effective management of this chronic condition requires a multidisciplinary team approach to diabetes care. Pharmacists are not often included in a multidisciplinary team and would consist of doctors, nurses and dieticians. Teams may be expanded and require specialist healthcare members' expertise who can assist in the management of this disease, for example, ophthalmologists and podiatrists. Adherence to standard treatment guidelines (STGs) for the management of diabetes by healthcare professionals at a primary care level can improve glycemic control, decrease health costs and reduce the development of long-term diabetic complications.

The role of pharmacists is expanding into PHC and this is evident in diabetes care. Today, pharmacists are applying the process of medicine therapy management (MTM) to optimize and improve a patient's medicine therapy. Pharmacists are identifying and addressing medicine therapy problems through MTM and reducing health care costs at facilities. Trained in pharmacotherapeutics, pharmacists are in a position to encourage and promote adherence to standard treatment guidelines by prescribers. This further endorses rational prescribing practices at PHC level. Notably, pharmacist interventions serve as a valuable contribution to the multidisciplinary team for improved medication management and quality of care of diabetic patients.

The aim of this study was to assess the pharmacist's role in optimising MTM through pharmacist-led interventions for stable diabetic club patients attending a PHC clinic.

Methods

An evaluation study design was conducted over 8 months at a Community Day Centre (CDC) in Cape Town. Quantitative and qualitative research methods were used. The data was collected retrospectively and prospectively in the study phases. Quantitative methods was used to monitor and evaluate the stable diabetic patients using objective, clinical and physical parameters. Qualitative methods were used to explore the pharmacist's journey working in a multidisciplinary team on the management of stable diabetic patients. The study population included folder review of chronic stable diabetic club patients and prescribing staff at the CDC.

The researcher reviewed, monitored and evaluated stable diabetic club patient folders in accordance with STGs and the Essential medicines (EML) list.Data was extracted from the folders of stable diabetic patients who attended the diabetic clubband prescribers from the CDC who were involved with care of diabetic club patients were alerted to therapeutic discrepancies.

Quantitative methods included the pharmacist monitoring and evaluating baseline (pre-intervention) data of stable diabetic club patients. Pharmacist-led interventions assessed prescriber adherence to STGs and EML recommendations in the management of diabetic club patients. Medicine therapy problems (MTPs) types adapted from Cipolle and colleagues (2012) were used. Pharmacist recommendation(s) were noted on a label which was attached onto the folder to prompt prescriber (doctors and clinical nurse practitioners)action (intervention) upon patient follow-up. Prescriber uptake (post-intervention) towards the pharmacist's recommendation was recorded as either accepted, partially accepted or rejected. Estimated costs were calculated for rational and irrational prescribing during the MTM process. IMB SPSS Statistics computer program was used to analyse the quantitative data and included both descriptive and inferential statistics. Paired sample t-test was applied to compare the stable diabetic folder group at baseline (pre-intervention), post pharmacist-led intervention (post-intervention) and at 6-month club follow-up.

Qualitative methods included facility staff members attending workshops to discuss their role in diabetes management. Facility staff participants completed a semi-structured questionnaire to gauge their experiences and perceptions towards the role of a pharmacist in diabetes management. Transcriptions were analysed, interpreted and common themes were identified. Common findings from the qualitative and quantitative data obtained from the mixed method study endorsed the pharmacist's MTM role in diabetes management. The researcher's journal provided insight into MTM implementation at a CDC.

Results

Of the104 type 2 stable diabetic club patient folders reviewed, 70 (67.3%) were female and 34 (32.7%) male. Their mean age was 57.7 years (range: 26 to 80). The mean glycosylated haemoglobin A1c (HbA1c) for the diabetic group was 8.64% and fasting plasma glucose was 8.26mmol/L, indicating poor diabetes control, that is, above the recommended target range. Only 32 (20.2% at baseline, 5.7% at post-pharmacist intervention and 4.8% at 6-month follow-up, respectively) patients had an optimal HbA1c reading of less than 7%, while 71 (48.1% at baseline, 9.6% at post-pharmacist intervention and 10.6% at 6-month follow-up, respectively) patients who had total cholesterol performed, met the target range of less than 4.5mmol/L from baseline to 6-month follow-up visit. Despite patients categorised as 'stable' 14

(13.5%) patients encountered an emergency admission at the CDC. Obesity (BMI) was present in 41 (39.4%) of patients.

The pharmacist identified a total of 453 MTPs, averaging 4 interventions per diabetic patient folder reviewed. The most common MTPs included the lack of physical measurements for BMI calculation (22.5%), no medical indication noted (19.2%) and laboratory tests not undertaken (18.3%). Overall, the prescribers' acceptance towards the pharmacist's recommendations was found to be low (27.2%). Doctors rejected almost 40% of the interventions whilst the clinical nurse practitioner's rejected 31.2%, suggestive of "clinical inertia". Aspirin was irrationally prescribed in diabetic patients (15.4%) and poor adherence to STGs and EML recommendations was found.

Researcher-led workshops revealed that facility staff participants seemed unaware of each member's role in diabetes management. Responses from facility staff suggest that such pharmacist-led interventions in MTM are possible at other PHC facilities. Pharmacists can provide training and education on the latest developments in diabetes management and rational medicine use.

Conclusion

This study identified that trained pharmacists could serve as a key team member in a multidisciplinary approach for the management of chronic stable patients with type 2diabetes. An operational framework was created for a trained pharmacist to identify medicine-related concerns by reviewing the club folders, and the pharmacist-led interventions alerted prescribers to STGs and EML recommendations. Findings from this study demonstrated that management of stable diabetic club patients at a PHC facility is sub-optimal as glycemic targets were not reached. Therefore, pharmacists trained in pharmacotherapeutics, could use their medicine-related expertise to optimize diabetes management at PHC facilities.

Key words

Pharmacist, diabetes, stable diabetic patients, primary health care, medicine therapy management, prescribers, standard treatment guidelines, multidisciplinary team

CHAPTER 1: INTRODUCTION

The introductory chapter provides background information on the research study problem, the problem statement, aims and objectives including operational terms used for the purpose of the study.

1.1 Background

Diabetes mellitus is a common non-communicable disease (NCD) worldwide and is identified as one of the most challenging health concerns of the 21st century. NCD is a disease that slowly progresses over a long period of time and is non-infectious and non-transmittable in nature (Puoane et al., 2012). Diabetes is a chronic disease characterised by glucose intolerance which is caused by an imbalance between insulin production and effective insulin usage in the body (International Diabetes Federation [IDF], 2015).

The World Health Organization (WHO) had estimated that in 1995, the prevalence of diabetes mellitus was 4.0% and had affected 135 million adults worldwide (King, Aubert & Herman, 1998). The International Diabetes Federation (IDF) report also considers diabetes mellitus a global burden, which affected 382 million (2013) people between the ages of 40 and 59 (IDF, 2015). Furthermore, the prevalence rate of all types of diabetes, particularly type 2 diabetes will increase by 55% by 2035 (IDF, 2015). The prevalence estimates of type 2 diabetes in South Africans have increased from 5.5% to 9.0% in adults aged 30 years and older since 2000 to 2009 (Bertram, Jaswal, Van Wyk, Levitt & Hofman , 2013). Diabetes accounted for approximately 5.1 million deaths in 2013 which was an 11% increase from 2011 (IDF, 2013). In 2014, WHO estimated that 422 million people, aged over 18 years, that is, a prevalence of 8.5% of adults globally had diabetes (World Health Organization [WHO], 2017). Consequently, diabetes is a costly disease to treat and manage, including diabetic complications, which have placed a financial burden on the total health expenditure within the health system, that being, 10.8% worldwide in 2013 (IDF, 2013).

Regarded as a metabolic disorder, diabetes can effectively be managed at primary health care (PHC) facilities through a multidisciplinary team approach (American Diabetes Association [ADA], 2013). A multidisciplinary team includes a group of professionals from two or more disciplines who work independently or in parallel on the same project who together make decisions and are working towards a common goal (Saint-Pierre, Herskovic & Sepúlveda, 2017). There is evidence that a multidisciplinary team in diabetes care can improve diabetes management, reduce

risk factors associated with type 2 diabetes, improve health care costs and reduce diabetes complications in patients (Willens, Cripps, Wilson, Wolff & Rothman, 2011; Sumpio, Armstrong, Lavery & Andros, 2010; Wolf et al., 2007). Management of diabetes requires healthcare professionals to offer regular and comprehensive therapeutic assessments of clinical, biochemical and physical parameters to reduce complications and minimise the risk of developing long-term diabetic complications (ADA, 2013). Inevitably, prescriber adherence to standard treatment guidelines (STGs) is crucial in optimizing medicine therapy and health outcomes among diabetic patients (ADA, 2013). The STGs for diabetes mellitus aid healthcare professionals such as doctors, nurses, pharmacists and other members in making appropriate and rational therapeutic decisions to improve the quality of care of patients (Ahmann, 2007). Pharmacists are therefore in an ideal position to provide medicine therapy management (MTM) services at public sector PHC facilities to optimize patient medicine therapy, deliver better quality of care and reduce health costs (Blouin & Adams, 2017; Pousinho, Morgado, Falcão & Alves, 2016). MTM is a patient care service, defined within the pharmacist's scope of practice, to assess the appropriateness, effectiveness, safety of each individual patient's medicine regimen and provide recommendations to optimize medication therapy (Cipolle, Strand & Morley, 2012).

1.2 Problem Statement

Diabetes is a major public health problem that is affecting populations worldwide (IDF, 2013). Despite evidence demonstrating the benefits of attaining glycemic control, management of this disease is still largely lacking as glycemic targets are not being met and can subsequently lead to diabetic complications (Klisiewicz & Raal, 2009). A report by Del Prato and colleagues (2005) showed that more than 60% of patients are not achieving the recommended glycemic targets. They proposed in this report the implementation of strict clinical practice guidelines to assist healthcare professionals in creating a higher proportion of patients to achieve their glycemic goal, minimise the risk of disease progression and improve the individual's quality of life (Del Prato et al., 2005). The Diabcare Africa study conducted across six sub-Saharan African countries evaluated diabetes control, management and late complications, found that less than half (47%) of type 2 diabetic patients had an HbA1c test performed and only 29% of these patients achieved the recommended glycemic target (Sobngwi et al., 2012). Furthermore, in the same study, neuropathy (48%), background retinopathy (18%) and cataract (14%) complications were found, indicating that diabetes care is inadequate in the African region (Sobngwi et al., 2012).

In South Africa, diabetes is managed at a PHC level and in the Western Cape, more especially so in the public sector, at community day centres (CDCs) and community health centres (CHCs). Approximately 25800 diabetic patients in the Cape Town metropole frequently access PHC services in the public sector (Mash, Levitt, Van Vuuren & Martell, 2008). Recognized as a main source of health care for South Africans, public health facilities are burdened and fragmented due to high patient loads (Mayosi et al, 2009). In addition, the deficiency of pharmacists, doctors and nurses impacts negatively on the quality of care at PHC clinics (Pillay & Aldous, 2016). Poor diabetes management in health care practice settings could be attributed to the lack of team collaboration amongst health care professionals (Borrill et al., 2000). This is exacerbated by lack of adherence to STGs, failure to draw patient bloods for biochemical evaluation (laboratory tests) and recording of body mass index are often overlooked by physicians (Igbojiaku, Harbor & Ross, 2013), leading to unfavourable patient health outcomes (Steyn et al., 2013; Igbojiaku et al., 2013).

Despite advances in pharmaceutical approaches, in South Africa, pharmacists traditionally operate as mechanical dispensers at PHC clinics (Bheekie & Bradley, 2016) and as a result, their active involvement in MTM is overlooked (Smith, 2009). MTM is therefore, a future cornerstone to diabetes management (Smith, 2009), and more especially in public sector primary care facilities, and a pharmacist who is trained in offering such a service would be a start.

1.3 Rationale for the study

Diabetes forms part of South Africa's quadruple burden of disease (Mayosi et al., 2009; Bradshaw, Steyn, Levitt & Nojilana, 2011) that requires comprehensive management. Pharmacists are in an ideal position to apply their clinical knowledge by monitoring and managing diabetes using their pharmacotherapy skills (Khunti et al., 2013). By working alongside health care practitioners in a multidisciplinary team approach they could collectively enable patients to achieve their glycemic goals Khunti, Willis, Davies & Khunti, 2013). Pharmacist interventions can further assist healthcare professionals to optimize medicine therapy to improve the quality of patient care (Shareef, Fernandes, & Samaga, 2016). Khunti and colleagues (2013) reviewed 18 studies on the role of pharmacists in the management of type 2 diabetes whereby pharmacist-led interventions had shown reductions in HbA1c levels in type 2 diabetic patients. Such interventions could potentially slow the progression of diabetic complications and reduce health costs (Khunti et al., 2013).

Pharmacists trained and skilled in pharmacotherapeutics can better achieve medicine therapy outcomes for patients by implementing MTM approaches in

practice setting (Bluml, 2005). By collaborating with other health care professionals, pharmacists could provide additional support to prescribing staff by alerting them to recommendations from diabetes STGs using specially designed intervention tools. By establishing such a communication link with prescribers, pharmacists would be in an ideal position to promote rational medicine use by recommending pharmacotherapeutic interventions to minimize polypharmacy, in the practice setting.

The overall purpose of this research study was to explore the potential role of a pharmacist working as part of a multidisciplinary team to optimize MTM of stable diabetic patients at a PHC clinic, in Cape Town.

1.4 Research Question

What could be the pharmacist's role in optimising MTM of stable diabetic patients attending a public sector PHC clinic?

1.5 Aim

The aim of the study was to determine the pharmacist's role in optimising MTM of stable diabetic patients attending a PHC clinic.

1.6 Objectives of the study

The main objectives of the study were to:

- Monitor and evaluate stable diabetic patient folders and prescribing patterns in accordance with STGs (baseline/pre-intervention).
- Create an operational framework to implement MTM pharmacist-led interventions in accordance with guideline recommendations (intervention).
- Determine prescriber uptake towards pharmacist recommendations and diabetes clinical and laboratory (patient health) outcomes (post-intervention).

1.7 Chapter description

Chapter 2 provides a background to the prevalence of diabetes and the pathophysiology of the disease. The clinical management of diabetes at PHC level with a multidisciplinary team approach to diabetes care is discussed. Furthermore, the pharmacist's role in optimising MTM is also discussed. A brief outline of South Africa's PHC health system, health policies and operational systems focusing on the management of NCD's at a PHC level is also provided.

Chapter 3 describes the quantitative and qualitative research methods and design used for the study. An outline describing the pharmacist MTM data collection process employed for this study is discussed.

Chapter 4 provides the results of the quantitative, qualitative and baseline data analyzed for the study. The quantitative results including the results from the pharmacist-led MTM process and irrational prescribing of medicines by prescribers were reported and discussed. The qualitative results were obtained from workshops facilitated by the researcher and staff feedback from a semi-structured questionnaire was analyzed for common themes. A description of the researcher's experience during the research study period was shared. In addition, limitations to this study are discussed.

Chapter 5 summarizes the overall findings of the study and provides an outline of best practices for conducting the study. Recommendations are provided for future studies embarking on investigations relating to aspects highlighted from the study.

Note: Each chapter provides a comprehensive account of the inquiry process. Therefore, it is inevitable that either definitions, concepts or principles may be repeated across the relevant chapters to further contextualise the topic under investigation.

1.8 Use of the words researcher and pharmacist

The words "researcher" and "pharmacist" are used interchangeably throughout this thesis.

1.9 Definition of a Community Day Centre

This research study was conducted at a community day centre (CDC) health facility. A CDC is a health facility that provides integrated PHC services and is open 8 hours a day or more reflecting the needs of the community to be served (Kwazulu-Natal Department of Health, 2001).

1.10 Referencing

The American Psychological Association (APA) style of referencing is employed in this study and appears in parenthesis in the text.

CHAPTER 2: LITERATURE REVIEW

This chapter discusses the literature pertinent to diabetes mellitus, the management of this disease at PHC facilities (Section A), including a multidisciplinary approach which elucidates the emerging role of the pharmacist in medicine therapy management (Section B). Background to South Africa's PHC system in the public sector, related health policies and organisational systems are discussed (Section C).

Section A: Diabetes Mellitus

In this section of the literature the following is discussed:

- The prevalence of diabetes in reference to the pathophysiolgy and classification of the disease;
- Management of diabetes mellitus at PHC level which includes clinical and laboratory tests performed;
- Antidiabetic pharmacotherapy recommended for the management of diabetic patients attending public sector facilities in South Africa are reviewed;
- Non-adherence to STGs by prescribers and;
- Lastly, development of diabetes complications following poor management of the disease.

2.1 Prevalence of diabetes mellitus

Diabetes mellitus is one of the most prevalent NCD's globally, and continues to grow in numbers with increased risk of developing serious complications (IDF, 2013). Diabetes is a condition characterised by elevated glucose levels in the blood which result from defects in insulin secretion, insulin action or both (ADA, 2010).

It was estimated that from the period 1980 to 2008 the number of people with diabetes increased from 153 million to 347 million and the age-standardised adult prevalence was slightly higher in men (9.8%) than women (9.2%) in 2008 (Danaei et al., 2011). The International Diabetes Federation (IDF) estimated that in 2013 there were 382 million people worldwide living with diabetes and that 80% of these individuals live in low-and-middle-income countries. It is projected that by 2035, if these trends continue, approximately 592 million adults will have diabetes.

Developing countries in South and Central America in 2013 had an estimated diabetic population of 24.1 million people, or 8.0% prevalence rate (IDF, 2013).

In sub-Saharan Africa, it was estimated that the prevalence of diabetes mellitus was 7.1 million in 2000 (Wild, Roglic, Green, Sicree & King, 2004). Moreover, the African region was estimated to have 19.8 million adults living with diabetes in 2013 (IDF, 2013). By 2040 this region is expected to have the largest proportional increase in adult diabetes numbers which will be more than double the number in 2015.This is due to economic development which has transformed lifestyles in both urban and rural areas (IDF, 2013). According to the IDF, the estimated prevalence of diabetes in South African adults between the ages of 20 to 79 years was 7.0% (2015), which represents 2.3 million people with diabetes (IDF, 2016). A Cape Town study (2009) estimated a high prevalence rate of 28% (Erasmus et al., 2012). Overall, the burden of NCD's is increasing rapidly and diabetes mellitus is one of the major NCD's contributing to South Africa's disease burden (Mayosi et al., 2009). An understanding of the pathophysiology provides insight into the complex nature of the disease which is discussed further in the next section.

2.2 Pathophysiology of diabetes mellitus

Diabetes mellitus develops when the body cannot produce enough insulin or is unable to use the insulin effectively in the body. Insulin is a hormone produced inside the pancreas. One of the functions of insulin is to transport glucose from the bloodstream into the body's cells, where it is converted into energy. A person is diagnosed with diabetes when glucose persistently circulates in the blood stream and not absorbed by cells in the body. Over time, high levels of blood glucose may lead to long term damage and failure to various organs, especially the eyes, kidneys, nerves, heart and blood vessels (IDF, 2013).

Diabetes mellitus is referred to as a complex metabolic disorder which is characterized by the accompanying presence of hyperglycemia and abnormalities in biochemical markers such as carbohydrates, lipids and proteins (Baynes, 2015). A metabolic disorder is a group of risk factors associated with the development of NCD's such as diabetes which include high blood pressure, high glucose levels, non-optimal cholesterol levels, overweight and obesity (Bradshaw et al., 2011). Therefore, for a multidisciplinary team to work collaboratively, regular monitoring of blood glucose levels, blood pressure, cholesterol levels, weight and body mass index are necessary to prevent the onset of complications.

2.3 Classification of diabetes mellitus

There are a number of different types of diabetes but the two main categories are type 1 and type 2 diabetes. These are discussed below:

Type 1 diabetes formerly called juvenile diabetes or insulin-dependent diabetes, accounts for 5-10% of people who have diabetes. This type of diabetes is usually diagnosed in children, teenagers and young adults. In type 1 diabetes, the body's immune system attacks and destroys the beta cells of the pancreas that release insulin, eventually eliminating insulin production from the body (ADA, 2010).

Type 2 diabetes formerly called adult-onset diabetes or non-insulin dependent diabetes is the more prevalent category and accounts for 90-95% of people who have diabetes. It can develop at any age but is most often associated with older age. In type 2 diabetes, insulin resistance occurs which is the body's inability to use insulin correctly in the body. In the beginning, the pancreas produces extra insulin to keep up with the demand. Eventually, the pancreas loses its ability to produce sufficient insulin to maintain normal blood glucose levels (ADA, 2010).

2.4Diabetes management at a Primary Health Care level

Appropriate management for diabetes can prevent or delay complications as health care professionals interpret clinical data, adhere to guideline-based treatment approaches and work collaboratively within a team (Pinchevsky, Butkow, Raal & Chirwa, 2013). The management of type 2 diabetes mellitus at the primary level of care therefore requires stringent monitoring of clinical parameters to optimise therapy (Berg, Dodd & Dodd, 2009). Prescribing staff and pharmacists would therefore be expected to work collaboratively to interpret laboratory and clinical data to optimise medicine therapy in accordance with STGs (Berg et al., 2009).

STGs and recommendations for the management of diabetes mellitus serve to assist healthcare professionals in the control of parameters such as glycemia, blood pressure and lipid levels. They are based on findings from evidence-based studies and are subject to periodic review (Ahmann, 2007). In various countries, many professional healthcare organizations have developed diabetes guidelines to improve quality of care for patients (Ahmann, 2007), for example, the American Diabetes Association (ADA) and the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) (ADA, 2010; Society for Endocrinology, Metabolism and Diabetes of South Africa [SEMDSA], 2012).

Guidelines used in practice generally consist of the SEMDSA guidelines in South Africa (SEMDSA, 2012). The STGs for the management of diabetes mellitus are synthesized from the SEMDSA guidelines in the public health sector. Primary care practitioners use the STGs as their primary reference source. Therefore, in this study, STGs served as a key reference to monitor and evaluate prescriptions for the chronic diabetes mellitus patients (National Department of Health [NDoH], 2014).

In South Africa, health care professionals at PHC level are required to adhere to the PHC STGs and EML (NDoH, 2014). The STGs and EML recommend that patients with diabetes and who are considered "stable", (defined in Section 2.12) be reviewed at 6-monthly clinical visits in which clinical measurements and laboratory tests are performed. The STGs and EML (NDoH, 2014) provide a benchmark for diabetic treatment targets. Health care professionals in practice follow the antidiabetic medicine therapy stepwise approach in diabetes treatment to manage unstable diabetic patients.

2.4.1 Clinical measurement and laboratory testing for the management of type 2 diabetes mellitus

Diabetes mellitus is a serious and complex metabolic disorder that requires management from a multidisciplinary team of health care professionals. The PHC STGs recommend that clinical measurements and laboratory testing be performed at each patient's clinic visit by a health care professional (NDoH, 2014; Sacks et al., 2002). Health care professionals can thus interpret results of biochemical markers and measurements which are used to engage patients in glycemic control and prevention management strategies of diabetes and its complications.

Some of the key recommendations amongst healthcare organizations for diabetes management are summarized in Table 2.1.

Performing the tests and recording the clinical measurements, requires health care professionals to work collaboratively in the management and control of diabetes (see table 2.1).Treatment target values beyond the specified or acceptable range require additional management approaches (ADA, 2010; SEMDSA, 2012).

Despite the recommended guidelines and target values for clinical and laboratory parameters being published in the management of diabetes, globally, these targets are not being met in practice. A United States study which demonstrated a decline in glycemic control rates in type 2 diabetes adults, that is, an HbA1c level of less than 7% was noted to be 44.5% (1988 to 1994) and 35.8% (1999 to 2000) respectively (Koro, Bowlin, Bourgeois & Fedder, 2004). In a South African study an intervention using the national guidelines for diabetes management was introduced at 18 public sector CHCs (1999 and 2000), and the results showed no improvement in diabetic

care and at follow-up 64.1% of the patients having an HbA1c value of more than 7% (Steyn et al., 2013).

Table 2.1 Treatment target recommendations from healthcare organizations required for the management of type 2 diabetic patients

Test and Organization	Frequency of assessment	Treatment goal or recommendation
HbA1c		
American Diabetes Association (ADA)	Twice yearly if controlled. Quarterly if therapy has changed or not controlled.	<7% <6.5%: more stringent goals for individual patients without hypoglycemia <8%: Less stringent goals for patients with a history of severe hypoglycaemia
Society of Endocrinology Metabolism and Diabetes of South Africa (SEMDSA)	Every 6 months if therapy has not changed and controlled. Every 3 months if therapy has changed and not controlled.	<7% <7.5%: for frail older adults, limited life expectancy or with hypoglycemic unawareness
Primary Health Care Standard Treatment Guidelines and Essential Medicine List (PHC STGs and EML)	Annually if controlled. Every 3 to 6 months if therapy has changed and until goal is reached.	<7%: optimal goal 7-8%: Less stringent goals for patients considered acceptable
Lipids		
ADA	Annually. Every 2 years if low risk.	Total cholesterol: <5.1 mmol/l LDL: <2.6 mmol/l HDL: >1.0mmol/l in men and >1.3 mmol/l in women Triglycerides: <1.7mmol/l
SEMDSA	Annually if results are satisfactory. Repeat in 3 months if results are unsatisfactory.	Total cholesterol: <4.5 mmol/l LDL: <1.8 mmol/l HDL: >1.0mmol/l in men and >1.2 mmol/l in women Triglycerides: <1.7mmol/l
PHC STGs and EML	At diagnosis.	Total cholesterol: <4.5 mmol/l LDL: <3 mmol/l HDL: >1.0mmol/l in men and >1.3 mmol/l in women Triglycerides: <1.7mmol/l

Serum Creatinine and eGFR		
ADA, SEMDSA and PHC STGs and EML	At diagnosis and annually.	Measure serum creatinine and use to calculate eGFR and stage the level of chronic kidney disease, if present.
Blood Pressure		
ADA	Every visit	<140/80 mmHg
SEMDSA	Every visit	≤140/80 mmHg
PHC STGs and EML	Every visit	<140/90 mmHg
HbA1c indicates glycosylated haemoglobin *LDL indicates Low-density lipoprotein* *HDL indicates High-density lipoprotein* *eGFR indicates estimated Glomerular Filtration Rate* *Source: ADA, 2013; SEMDSA, 2012 and NDoH , 2014*		

2.4.1.1 Glycosylated Haemoglobin A1c testing at a primary care level

The term “stable patient” refers to a patient’s health condition. Stability requires a patient to adhere to their medicine regimen and when there is minimal change in the current disease status (Meintjies & Maartens, 2012).

Glycosylated haemoglobin also referred to as haemoglobinA1c (HbA1c), is used as a prime determinant for the evaluation of glycemic control (ADA, 2001). It enables healthcare professionals to make timeous adjustments to diabetic medicine therapy where deemed necessary. In South Africa, the HbA1c test is conducted annually for “stable” diabetic patients. However, the test is repeated every 3 to 6 months if the patient’s medication has been altered and until stable (NDoH, 2014). Oral diabetic agents in combination with dietary modification and physical exercise are recommended to achieve treatment targets (ADA, 2013).

Haemoglobin is a protein in red blood cells, which has a survival rate of three months. The HbA1c test measures the amount of glucose attached to haemoglobin. Therefore, HbA1c reflects the mean blood glucose concentration during the preceding 2 to 3 months, incorporating both pre-and postprandial glucose measurements (ADA, 2001). The PHC STGsand EML (NDoH, 2014) recommends a treatment target for HbA1c of less than 7% in diabetic patients. Epidemiological evidence based studies indicate to use HbA1C of less than 7% as the target and type 2 diabetic patients with an HbA1c level of more than 7.5% have a 2.5 to 5-fold greater relative risk of developing microvascular complications (SEMDSA, 2012).Therefore, if HbA1c values are within the recommended target range,

clinicians have a reliable indication that the medicine therapy is appropriate, which in turn has potential benefit of reducing microvascular complications (ADA, 2010).

Despite the advancement made in diabetes care since the 1960's, the issue of monitoring glycemic control remains a problem. A Western Cape audit (De Vries, 2011) across health facilities revealed that only 48% of diabetic patients had an HbA1c test done in the preceding year and only 35% were controlled (HbA1c less than 7%). Reasons for limited HbA1c testing being conducted is due to the high costs of HbA1c test and budget constraints which negatively impacted on such laboratory investigations being performed (Steyn et al., 2013).

2.4.1.2 Fasting plasma glucose test and postprandial glucose test

Fasting Plasma Glucose (FPG) test is a measure of blood glucose levels in a person who has fasted for at least 8 hours before the test. Fasting is defined as no caloric intake for at least 8 hours (ADA, 2010). This test is most reliable when done in the morning before a meal. The PHC STGs and EML (NDoH, 2014) blood glucose target for FPG is optimal between 4 to 7mmol/L and acceptable at less than 8mmol/L. This is the most common test used in government facilities and it is less expensive (SEMDSA, 2012; NDoH, 2014).

Postprandial glucose test is a measure of blood glucose in a person that has had a meal. Postprandial is defined as after a meal (ADA, 2001). The PHC STGs and EML (NDoH, 2014) guidelines blood glucose target for postprandial glucose is optimal between 5 to 7mmol/L and acceptable between 8 to 10 mmol/L.

The HbA1c measurement is an acceptable indicator for long term glycemic monitoring. However, for short-term observations of glucose control, FPG and postprandial glucose are suitable measurements for glucose measurements throughout the day. These blood tests are done through a simple method of finger-prick point-of-care test (SEMDSA, 2012).

2.4.1.3 Urine test for blood glucose

In primary care clinics, dipstick tests are done as part of routine examination, which is a quick and easy method to test urine for metabolic products. A doctor or nurse dips the chemical strip into the urine sample and the results appear after a few seconds. Colour changes on the strip indicate normal and abnormal values. In diabetic patients glucose, proteins and ketones are detected using the dipstick test andif any one of the metabolic products are present, health care staff will request further testing (Informed Health, 2006).

2.4.1.4 Fasting lipoprotein profile test

One of the main characteristics of a metabolic disorder is “dyslidpidemia’, which is the term used to describe abnormal changes in lipid profile. Dyslipidemia is a common co-morbidity in diabetes and is a major contributor to microvascular disease and atherosclerosis (Dixit et al., 2014), thereby increasing cardiovascular risk among diabetic patients.

Diabetic dyslipidemia encompasses elevated triglycerides and decreased high-density lipoprotein (HDL) cholesterol (Peters, 2008). An increased presence of low-density lipoprotein (LDL) cholesterol leads to conversion ofsmaller particles, which makes the LDL cholesterol atherogenic. These lipoproteins are called small dense LDL (Peters, 2008). The fasting lipoprotein profile is a collective measurement of total cholesterol, triglycerides, LDL cholesterol, and HDL cholesterol (SEMDSA, 2012).

Patients are advised to fast 10 hours before the blood sample is taken as food and beverage consumption may cause a brief increase in triglyceride levels. These tests are conducted in diabetic patients to evaluate and identify any abnormalities. Further tests are performed for patients that have high lipid levels in their blood and also for those patients with more complex abnormalities (SEMDSA, 2012).In diabetic patients the fasting lipoprotein profile is recommended to be repeated annually only if their results are found to be satisfactory. However, the test is repeated three monthly if lipid levels are unsatisfactory (SEMDSA, 2012).

Routine blood tests for glucose and lipid profile are an essential part of diabetes management (Dixit et al., 2014) which health care professionals are required to monitor regularly in practice.

2.4.1.5 Albumin and Serum Creatinine concentrations

Diabetes is the most common cause of diabetic nephropathy. Diabetic nephropathy also known as diabetic kidney disease is the chronic loss of kidney function. It is the leading cause of end-stage kidney disease which is associated with increased rates of mortality particularly from cardiovascular disease (Pálsson & Patel, 2014).

Kidney damage especially in diabetic nephropathy (causing the kidney’s filtering function to drop) is related to an increased amount of albumin in the urine (Narva & Bilous, 2015). Albumin excretion rate and creatinine based glomerular filtration rate (estimated) are two biochemical markers (Narva & Bilous, 2015) which are used to identify and monitor diabetic nephropathy.

Albumin excretion is a well-known marker of kidney damage in patients with type 2 diabetes. Albumin levels are ideally measured in an early morning urine sample (first pass). A diagnosis for diabetic nephropathy can be made if the urine dipstick is positive 1+ or if the dipstick is negative the urine sample is sent for further laboratory testing to determine the albumin-to-creatinine-ratio. If the ratio is more than 3mg/mol a diagnosis for kidney disease can be made (NDoH, 2014). The PHC STGs and EML (NDoH, 2014) recommends that serum creatinine be measured annually through laboratory blood tests and estimated Glomerular Filtration Rate (eGFR)calculated based on serum creatinine in adult diabetic patients. In adults, the Cockcroft-Gault equation and Modification of Diet in Renal Disease equation (Rossiter, Blockman & Barnes, 2016) have been developed to calculate the eGFR in diabetics. The Cockcroft-Gault equation is as follows:

The equation is provided below:

$$\textit{estimated}\ \text{GFR (mL/min)} = \frac{(140\text{-age}) \times \text{weight (kg)} \times \text{constant*}}{\text{serum creatinine (umol/L)}}$$

where the *constant is 0.85 for females. The Modification of Diet in Renal Disease equation is as follows:

$$\textit{estimated}\ \text{GFR (mL/min)} = 186 \times (\text{SrCreatinine (umol/L)} \times 0.011)^{-1.154} \times (\text{age})^{-0.203} \times (1.212 \text{ if black}) \times (0.742 \text{ if female})$$

Table 2.2 provides a description of the degree of kidney damage and staging of kidney disease, based on the estimated GFR.

Table 2.2: Staging of kidney disease

Chronic Kidney Disease Stage	Glomerular Filtration Rate (GFR) mL/min/1.73m^2	Description
1	>90	Slight kidney damage with normal or increased filtration
2	60 - 89	Mild decrease in kidney function
3	30 - 59	Moderate decrease in kidney function
4	15 - 29	Severe decrease in kidney function
5	<15	Kidney failure- end stage (dialysis or kidney transplant needed)

Source: National Department of Health, 2014

It is crucial that health care professionals engage timeously with the albumin and serum creatinine biochemical markers by making appropriate therapeutic adjustments to avoid the onset of diabetic complications such as diabetic nephropathy.

2.4.1.6 Blood pressure measurements in diabetes mellitus

Patients with diabetes often develop high blood pressure (hypertension) and are at greater risk of developing microvascular and macrovascular diseases (Arauz-Pacheco, Parrott & Raskin, 2002).

Blood pressure is a measurement of the force applied against the walls of the arteries as blood flows through them. Blood pressure readings are given as two figures, that is, systolic and diastolic. The systolic pressure (top figure) equals the pressure as blood is pushed into the arteries as the heart contracts. The diastolic pressure (bottom figure) is the pressure in the arteries as the heart relaxes and refills with blood. Therefore, hypertension is defined as a systolic pressure of ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg (Arauz-Pacheco et al., 2002).

With each clinic club visit, a blood pressure measurement is taken and recorded (SEMDSA, 2012). The PHC STGs and EML (NDoH, 2014) has recommended that the blood pressure target goal for patients with diabetes be less than 140/90 mmHg.

In a South African study, the presence of co-morbidities especially hypertension (84%) amongst diabetic patients underpinned the need for improved disease management, particularly diabetes within PHC clinics in South Africa (Folb et al., 2015). Therefore, pharmacists included in a multidisciplinary team approach could contribute significantly to the pharmacological management of diabetes.

2.4.2 Pharmacological treatment of diabetes mellitus

When lifestyle changes, diet modification and exercise fail to adequately control glucose levels, pharmacological treatment is initiated (NDoH, 2014). The oral and subcutaneous antidiabetic treatment for type 2 diabetic patients recommended for PHC level is outlined below.

2.4.2.1 Oral antidiabetic therapy

Oral antidiabetic class agents used in the management of type 2 diabetes mellitus is biguanides and sulphonylureas. The effectiveness of oral pharmacotherapy is determined by postprandial finger prick or FPG finger-prick and HbA1c target levels. The PHC STG sand EML recommends an HbA1c target of 7 to 8% (NDoH, 2014).

Biguanide

Metformin belongs to the biguanide class and is the initial medicine therapy of choice in the management of type 2 diabetics (NDoH, 2014). When patients do not reach glycemic targets, metformin is then used in combination with other oral antidiabetic medicines and/or insulin therapy. It acts by reducing hepatic glucose production, increases the uptake of glucose into the peripheral cells and reduces glucose absorption (Rossiter et al., 2016).

Sulphonylureas

Sulphonylureas commonly used in PHC are glimepiride or glibenclamide (NDoH, 2014). They are used as second-line treatment in combination with metformin in type 2 diabetic patients when glycemic control is not adequately achieved. Sulphonylureas act by binding to specific receptor on pancreatic beta cells resulting in increased endogenous insulin release (Rossiter et al., 2016).

2.4.2.2 Insulin therapy

Insulin therapy is initiated in type 2 diabetics when glycemic targets are not obtained with oral antidiabetics. Insulin lowers blood glucose levels by stimulating peripheral glucose uptake, especially in skeletal muscle and fat, and by inhibiting hepatic glucose output (SEMDSA, 2012).

Intermediate to long-acting insulins

Insulin is formulated as a suspension to promote slower absorption and a longer duration of action, which is due to the addition of protamine. The intermediate to long-acting insulin dose is administered subcutaneously, daily in the evening before bedtime to control blood glucose overnight (Rossiter et al., 2016; NDoH, 2014).

Biphasic insulins

This pre-mixed preparation contains short-acting and intermediate-acting insulin. It is administered subcutaneously, twice daily. The total daily dose is divided as follows, that is, $^{2}/_{3}$ of the total dose is administered 30 minutes before breakfast and ⅓ of the total daily dose is administered 30 minutes before supper (Rossiter et al., 2016; NDoH, 2014).

2.4.2.3 Aspirin therapy

The STGs and EML (NDoH, 2014) recommend aspirin for the following indications:

- Atherosclerotic peripheral arterial disease
- Ischemic heart disease (angina)
- Myocardial infarction (heart attack)
- Pre-eclampsia
- Systemic Lupus Erythematosus
- Cerebrovascular accident (stroke)

The circular, "*H141/2017: Aspirin Medicine Use Evaluation Feedback*" (Appendix 1), was released in 2017 to re-enforce the appropriate use of aspirin as indicated in the EML (NDoH, 2014).

Due to the cardiovascular risk factor in diabetes, The STGs and EML (NDoH, 2014) advises prescribers to initiate aspirin therapy, 150mg orally daily (NDoH, 2014), in diabetic patients with a history of cardiovascular disease.

2.4.2.4 Lipid lowering therapy

The PHC STGs and EML recommends patients with type 2 diabetes mellitus be initiated on lipid lowering agent regardless if their lipid levels are normal. The criteria for these patients are:

- Older than 40 years of age or has been diagnosed with diabetes for more than 10 years, or
- Has one or more cardiovascular disease, or
- Chronic kidney disease (eGFR less than 60ml/min)

The first line treatment used in PHC level is statins, for example, simvastatin. Statins act by inhibiting the synthesis of cholesterol in the liver. The PHC STGs and EML recommend simvastatin 10mg be given orally to patients at night to improve efficiency (Wallace, Chinn & Rubin, 2003) because most cholesterol is synthesised at night. Simvastatin is a short-acting statin with a short half life ($T_{½}$=1.9 hours).

2.4.2.5 Primary Health Care standard treatment guidelines for the management of type 2 diabetes in South Africa

The PHC STGs and EML provide a stepwise approach to guide healthcare providers on the pharmacological management of type 2 diabetes mellitus (NDoH, 2014). The purpose of medicine therapy is to achieve and maintain postprandial blood glucose, or fasting plasma finger-prick blood glucose, and or HbA1c levels below or within the target range for an individual patient. Parameters above the target range calls for action by the prescriber; apart from lifestyle, medication must be adjusted as shown in Table 2.3.

At step 1, metformin, oral, is added to lifestyle measures which include dietary modification and weight loss. As indicated in step 2, failure of the individualised patient to not achieve the HbA1c target results in combination of oral therapy of metformin plus a suphonylurea together with lifestyle modification. Shifting to step 3 is recommended when oral combination medicine therapy fails, the patient is initiated on one insulin type and the sulphonylurea is withdrawn from regimen but continues on metformin (NDoH, 2014).

Pharmacological treatment listed in the South African PHC STGs, is evidence based and a review of medicine safety, effectiveness and costs are considered (NDoH, 2014).

Pharmacists can improve patient regimens to minimize side-effects, avoid drug-interactions, make recommendations and adjust medicine doses. The stepwise approach to diabetes medicine treatment further endorses the pharmacist's vital role at the primary care level.

Table 2.3 Stepwise approach of treatment adjustment when glucose levels are not controlled

Step 1: Lifestyle modification plus metformin		
Entry to Step 1	**Treatment and duration**	**Target**
» Typical symptoms- thirst,	» Lifestyle modification for	» 2-hour post-prandial

tiredness, polyuria. **AND** » Random plasma glucose>11.1 mmol/L. **OR** » Fasting plasma glucose ≥7 mmol/L	life. » Appropriate diet. » Weight loss until at ideal weight. Initiate therapy with: • Metformin. » Assess monthly.	finger-prick blood glucose: 8-10 mmol/L. **OR** » Fasting finger-prick blood glucose: 6-8 mmol/L. **AND/OR** » HbA1c:7-8%
Step 2: Add sulponylureas		
Entry to Step 2	**Treatment and duration**	**Target**
» Failed step 1: HbA1c> 8% or fasting finger-prick blood glucose >8 mmol/L despite adherence to treatment plan in step 1 and maximal dose of metformin for 2-3 months **OR** » 2-hour postprandial finger-prick blood	» Lifestyle modification for life. **AND** » Combination oral hypoglycemic agents, i.e.: • Metformin. **AND** • Sulphonylurea.	» 2-hour post-prandial finger-prick blood glucose: 8-10 mmol/L. **OR** » Fasting finger-prick blood glucose: 6-8 mmol/L. **AND/OR** » HbA1c:7-8%
Step 3: Insulin therapy		
Insulin type	**Starting dose**	**Increment**
Add on therapy: • Intermediate	10 units in the evening before bedtime, but not after 22h00.	If 10 units not effective: increase gradually to 20 units (2-4 units increase each week).
Substitution therapy: • Biphasic	Twice daily. Total daily dose: 15 units divided as follows: ⅔ of total daily dose, i.e. 10 units, 30 minutes before breakfast. ⅓ of total daily dose, i.e. 5 units, 30 minutes before	4 units weekly. First increment is added to dose before breakfast. Second increment is added to dose before supper.

	supper.	

Source: National Department of Health, 2014

2.4.3 Prescriber non-adherence to treatment guidelines

Non-adherence to guidelines may lead to uncontrolled biochemical markers and unsatisfactory patient health outcomes (Igbojiaku et al., 2013). Literature from South African studies, highlight the need to improve prescribing practices and compliance to recommended guidelines amongst prescribers in the public sector across provinces (Cassimjee, & Suleman, 2009; Igbojiaku et al., 2013; Sooruth, Sibiya & Sokhela, 2015;Siko & van Deventer,2017). A Kwazulu-Natal study revealed that doctors at a tertiary hospital did not adhere to guidelines resulting in poorly controlled blood pressure, elevated HbA1c levels and abnormal lipid results (Igbojiaku et al., 2013).

Prescribing practices seem to vary among physicians and nurses. Physicians were found to be inconsistent in prescribing first-line hypertension therapy (Nelson & Knapp, 2000) while nurses were more consistent in prescribing medicines regimes in accordance with the STGs and EML (Siko & van Deventer, 2017). Furthermore, practice of polypharmacy at PHC facilities (Awad & Al-Saffer, 2010) could be attributed to lack of availability (or access) to STGs by health workers. Thus, appropriate pharmacotherapeuticinterventions are needed to improve prescribing practices at PHC level.

In PHC facilities prescriber adherence to the STGs and EML endorses rational prescribing practice, which is aligned with South Africa's National Drug Policy (1996). One approach to achieve rational prescribing is to promote health information exchange on updated pharmacotherapeutic approaches among health care professionals (Kapadia-Kundu, Sullivan, Safi, Trivedi & Velu, 2012; Igbojiaku et al., 2013). In addition, pharmacotherapy training programs which orientate newly appointed and current health care professionals on the correct use of the STGs and EMLat PHC facilities (Sooruth et al., 2015; Igbojiaku et al., 2013) also facilitate rational prescribing practices. Such interventions could capacitate prescribers to monitor and evaluate therapeutic outcomes (Cassimjee, & Suleman, 2009).Therefore, a pharmacist trained in pharmacotherapy and skilled in interpreting the patient's laboratory and clinical data would be ideally suited to offer medicine therapy recommendations to prescribing staff.

2.4.4 Pharmacist-led interventions in the management of diabetes mellitus

Pharmacist's medicine therapy interventions for the management of diabetes is well documented (Hughes, Wibowo, Sunderland & Hoti, 2017). Among others pharmacist-led interventions in patient educational interventions, pharmacotherapy review, medication adherence, and review of clinical measurements have resulted in positive health outcomes for patients (Wubben & Vivian, 2008).

A systemic review and meta-analysis conducted by Machado and colleagues (2007) of pharmacist-led interventions demonstrated that HbA1c values decreased significantly in diabetic patients. However, a limitation of this study was that the monitoring and recording of diabetic patient's body mass index (BMI) were lacking (Machado, Bajcar, Guzzo & Einarson, 2007). The body weight of patients with type 2 diabetes mellitus is needed to calculate BMI. If a patient is overweight or obese an intervention from a health care professional (Rose, Turchin, Grant & Meigs, 2009), such as a pharmacist, could be initiated. Therefore, pharmacists can contribute to recording of physical and basic clinical measurements on standardised diabetes management templates.

A Canadian study revealed that pharmacist prescribing intervention in type 2 diabetic patients improved the patients' glycemic control. Change in HbA1c was used as a primary outcome measurement from baseline to week 26. The study found that HbA1C was reduced from 9.1% at baseline to 7.3% at week 26. At the end of the study, an HbA1c value of less than 7% (target range) was achieved in 51% of patients. Pharmacist interventions led to 48% of the patients' oral antidiabetic medicine regimen being altered by week 26, the most frequent change was stopping the sulphonyurea in 46% of patients (Al Hamarneh, Charrois, Lewanczuk & Tsuyuki, 2013). This underpins the pivotal role of pharmacists in diabetes care who can identify patients with poor glycemic control.

A systematic review undertaken by Wubben & Vivian (2008) assessed the effectiveness of pharmacists' interventions in primary care in diabetes patients. They reviewed 21 articles and more than half of the articles noted an improvement in the primary marker of interest, HbA1c. Most of the studies reviewed also found a decrease in blood pressure and cholesterol levels in patients (Wubben & Vivian, 2008).

At a PHC level, pharmacist's management in diabetes is especially significant (Wubben & Vivian, 2008), since the majority of the diabetic population access the public health sector PHC facilities in South Africa (Steyn et al., 2008). MTM services should therefore not exist in isolation from other health care services, but provided in partnership with other health care services at the facility (Dupotey Varela et al., 2011).Managing diabetes effectively requires collaboration between the patient and

health care professionals to help reduce the risk of complications by improving medicine therapy (IDF, 2015; Powell, Corathers, Raymond,& Streisand, 2015).

2.5 Complications of diabetes mellitus

The IDF (2015) reports that people with diabetes are at risk of developing a number of life-threatening problems. In addition, if poorly managed can lead to serious complications and death (IDF, 2015). Diabetes is characterized by hyperglycemia which can impair the structure and function of many organ systems in the body including the vascular system (Lotfy, Adeghate, Kalasz, Singh & Adeghate, 2017). This metabolic disorder is also linked to co-morbidities which include hypertension, obesity and cholesterol (Lofty et al., 2017).

Diabetes complications are divided into vascular complications categories, namely, microvascular and macrovascular. Microvascular complications is damage to smaller blood vessels which include the eyes (retinopathy), kidneys (nephropathy) and nerves (neuropathy). Macrovascular complications is damage to larger blood vessels which include the heart and blood vessels (coronary artery disease, peripheral arterial disease, and stroke) (Fowler, 2008). Non-classical complications of diabetes which may impair the oral cavity, bones and skin include diabetic conditions such as periodontal disease, diabetic bone disease, bacterial and fungal skin disorders. Furthermore, development of other chronic conditions that may be associated with diabetes is hypertension and obesity (Lofty et al., 2017).

Table 2.4 contrasts the different types of complications of diabetes mellitus.

South African studies reveal that diabetes complications place a significant burden on the health care system. The national burden of disease study (2000) conducted by Bradshaw and colleagues, reported that diabetes attributed to14% of ischaemic heart disease, 10% of stroke, 12% of hypertensive disease and 12% of renal disease and that 4.3% of all deaths in South Africa were also due to diabetes (Bradshaw, Norman, Pieterse & Levitt, 2007). A systematic review of literature (2009), reported estimates of 8000 new cases of blindness and 2000 new amputations annually, were caused by diabetes (Bertram et al., 2013).

Table 2.4: Complications of Diabetes Mellitus

Macrovascular complications	Microvascular complications	Non-classical complications	Others
Angina	Diabetic nephropathy - micro-/macro-albuminuria	Periodontal disease	Hypertension
Myocardial infarction (heart attack)	Diabetic retinopathy	Diabetic bone disease	Obesity
Stroke	Diabetic Neuropathy • Peripheral neuropathy • Autonomic Neuropathy - gastrointestinal dysfunction - erectile dysfunction	Diabetes and skin diseases - bacterial and fungal infections, leading to pruritus	
Peripheral arterial disease	Diabetic retinopathy		
Congestive heart failure	Diabetic foot - loss of sensation - unhealed wound infections - ulceration - foot amputation		
Atherosclerosis			

Source: International Diabetes Federation, 2015 and Lofty et al., 2017

Section B: Multidisciplinary teams and the pharmacist role in Medicine Therapy management at Primary Care

This section of the literature discusses the MTM role of pharmacist's in a multidisciplinary team in the management of diabetes.

2.6 Multidisciplinary team approach in Primary Health Care

Successful management of chronic disease depends on a multidisciplinary team approach where individuals from multiple disciplines work collaboratively to deliver patient-centred care (Saint-Pierre et al., 2017; Harris et al., 2011; Wagner, 2000). The term 'multidisciplinary team' refers to a group of professionals from two or more disciplines who work independently or in parallel on the same project, through a process of problem-solving, shared responsibility for decision-making and the ability to carry out a health care plan while working towards a common goal (Saint –Pierre et al., 2017). Among others the multidisciplinary team consists of pharmacists, nurses, doctors, physiotherapists, occupational therapists, dieticians, and administrative service staff (Saint –Pierre et al., 2017).

When conducting reviews, author search terms generally include 'multidisciplinary', 'interdisciplinary' and 'interprofessional' as part of their search strategy (Mulvale, Embrett & Razavi, 2016). A Cochrane systematic review attested that collaborative planning or reflection activities may slightly improve health professional's adherence to recommended practices and use of healthcare resources (Reeves et al., 2017). Another systematic review identified the importance of formal and social processes that are essential in setting a common vision, whereby health professionals are part of a team and are led by a team facilitator or champion to improve collaboration (Mulvale et al., 2016).However, at the primary care level collaboration between the team members may be hampered by hierarchical relationships among professional and support staff. Findings from a systematic review revealed that nurses tend to collaborate more closely with team members, whereas medical practitioners tend to work in a more isolated way and collaborate indirectly (Saint-Pierre et al., 2018). Therefore defining the roles of team members is essential when fostering a multidisciplinary approach at the primary care level.

The pharmacist's role in a multidisciplinary team yielded positive results in the management of chronic diseases. In an Australian general practice pilot study, pharmacists offered pharmacotherapeutic services, recommending medicine therapy adjustments during consultations, that resulted in step down (15%; n=25 consultations) and step up (22.3%; n= 37 consultations) of their asthma therapy; and over a third (42%; 8/19) of the asthma patients had improved from poor to well-

controlled asthma status (Deeks et al., 2018).The findings from a systematic review of a few (n=5) studies which had met the inclusion criteria, found thatpharmacists who contributed to medication review and pharmacotherapeutic follow-up for patients with epilepsy in nursing homes, primary care clinics and hospitals,had resolved potential prescribing errors, and offeredtherapeutic recommendations to physicians in a multidisciplinary team (Reis, Campos, Nagai & Pereira, 2016).

A meta-analysis which compared usual care to multidisciplinary team-based approach included pharmacists in cardiovascular disease management, had noted reductions in:*heart failure* hospital admissions [odds ratio 0.69 (95% CI 0.51-0.94)]; *hyperlipidaemia*: LDL weighted mean difference [-13.4mg/dl (95% CI -23.0—3.8)]; *hypertension*: systolic blood pressure weighted mean difference [-8.1mmHg (95%CI=10.2 to -5.9)] and *diabetes*: HbA1c weighted mean difference [-0.76% (95% CI -1.06 to -0.47)]; fasting blood glucose weighted mean difference [- 29.32mg/dl (95% CI -39.54 to-19.10)] (Odum & Whaley-Connell, 2012).Similar findings were noted in a Brazilian quasi-experimental study where a pharmacist offered comprehensive medication management in two community primary care clinics which resulted in statistically significant reduction between baseline and post-intervention evaluation of defined clinical and laboratory parameters: HbA1c ($p<0.001$); systolic BP ($p= 0.020$); diastolic BP ($p= 0.020$); LDL cholesterol ($p<0.001$) and HDL cholesterol ($p<0.001$) (Neves, Nascimento, Silva & Ramalho-de-Oliveira, 2019). The effect of adding pharmacists to primary care teams in patients with type 2 diabetes management led to a statistically significant reduction in blood pressure mean decrease of 7.4 mmHg [95% CI 4.6 -10.2; $p<0.0001$) when compared to that of usual care, 2.5 mmHg [-0.1 to 5.2; $p=0.06$] (Simpson et al., 2011).

Unfavourable outcomes from pharmacist-led interventions have yet to be documented. Evidence from the literature clearly underpins the MTM role of trained pharmacists in a multidisciplinary team approach at the primary care level. With NCD's adding to South Africa's health burden, such an approach is yet to be tested for diabetes management in a public sector PHC facility, where the need is the greatest.

2.7 Medicine Therapy Management

2.7.1 The pharmacist's role in medicine therapy management

In South Africa, the prevalence of patients having a chronic condition with co-morbidities (Folb et al., 2015) has increased. Such a phenomenon imposes on an already burdened health care system, whereby inappropriate prescribing, poor detection of adverse drug reactions and sub-optimal adherence to medicine

regimens (Folb et al., 2015) may negatively affect patient's medicine use. In resource-constrained countries, pharmacists in primary care level are therefore required to engage in pharmacotherapeutic approaches to optimise chronic disease management. Following the quadruple burden of disease the government's PHC re-engineering strategy would enable pharmacists to form an integral part of the health care system, wherein their scope of practise entails the prevention and treatment of chronic conditions. The practise of pharmacovigilance, promotion of rational and cost-effective medicine use, therefore remains the pharmacist's core function (Bheekie & Bradley, 2016).

Pharmacists are trained to provide patient-centered pharmaceutical care (Kolar et al., 2017) by applying their pharmacotherapeutic knowledge and skills to identify patient medicine therapy needs. Therefore, pharmacists are in an ideal position to offer medicine therapy interventions by collaborating with other healthcare professionals (Blouin & Adams, 2017). By reviewing patient prescriptions, laboratory and clinical data, in accordance with therapeutic guidelines pharmacists could offer timeous therapeutic recommendations.

2.7.2 Definition of Medicine Therapy Management

In 1990, Douglas Hepler and Linda Strand changed the vision for the practice of pharmacy which they described as pharmaceutical care (Cipolle et al., 2012).Medicine therapy management (MTM) aligns with pharmaceutical care practice to optimize patient's medicine therapy and improve health outcome (Cipolle et al., 2012).

The framework within MTM is defined along five core elements: medicine therapy review, personal medication record, medication-related action plan, intervention and/or referral, and documentation and follow-up (Bluml, 2005). Such a process enables the pharmacist to provide an in depth medicine therapy plan. This entails, and is not limited to, monitoring and evaluating prescriptions, reviewing medication which adds no value and rationalising medicine use. MTM focuses on improving medication therapy problems that a patient may experience during the course of their treatment (Austin, 2017; Bluml, 2005).

2.7.3 Definition of Medicine Therapy Problems

A medicine therapy problem (MTP) is *"any undesirable event experienced by a patient that involves, or is suspected to involve, medicine therapy, and that interferes*

with achieving the desired goals of therapy and requires professional judgement to resolve." (Cipolle et al., 2012, p. 143)

MTPs are categorised into four medicine therapy needs classes (see Table 2.5) namely, indication, effectiveness, safety and adherence (Cipolle et al., 2012).

Table 2.5 Medicine therapy needs classes and the medicine therapy problems

Medicine therapy needs class	Medicine therapy problem categories
INDICATION	1. Unnecessary medicine therapy 2. Needs additional medicine therapy
EFFECTIVENESS	3.Ineffective medicine 4. Dosage too low
SAFETY	5. Adverse medicine reaction 6. Dosage too high
ADHERENCE	7. Nonadherence
Source: Cipolle et al., 2012	

MTPs are prioritized and addressed based on their urgency. Knowing how to prioritize MTPs is an essential skill for pharmacists to develop as patients will present with more than one problem. Each MTP is noted on the patients care plan including the interventions required to resolve the problem. The action taken to resolve the problem, which is also documented and added to the patient's records (Cipolle et al., 2012). Using the seven MTP categories enables the pharmacist to review patients' medicine regimens in a logical and rational manner.

2.7.4 The benefits of pharmacist-led medicine therapy management

Pharmacist-led MTM provides an opportunity for pharmacists to optimize medicine therapy and reduce health care costs (Ndefo, Moultry, Davis & Askew, 2017). Several studies support pharmacists' interventions as a means to improve biochemical markers, medication adherence, reduce MTPs in patients diagnosed with chronic diseases (Viswanathan et al., 2015; Simpson et al., 2011; Pousinho et al., 2016).

A systematic review of 21 studies assessed the effectiveness of pharmacists' interventions on diabetes management in an outpatient setting (Wubben & Vivian, 2008). Pharmacist-led interventions included MTM, lifestyle counselling and review of patient's glucose monitoring records. The primary outcome from the review demonstrated an overall reduction in Hb1Ac value for diabetic patients (Wubben & Vivian, 2008).

A Belguim study conducted at community pharmacies showed that a pharmacist-led intervention in the management of chronic asthma patients led to an improvement in asthma control, with reductions in the use of reliever medication and frequency of nocturnal awakening (Mehuys et al., 2008). The nature of interventions in asthma may be different to those for diabetes and the level of success in applying MTM may therefore vary across different chronic diseases of lifestyle.

A study conducted at an Indian tertiary hospital identified improper medicine selection among doctors. Following the pharmacist-led intervention, doctors' decision making on the patients medicine therapy was influenced, which led to improved patient clinical outcomes (Kumar, Kumar, Ahmad, Mohanta & Manna, 2012).In a similar approach to Kumar and colleagues, Bronkhurst and colleagues conducted a study at a South African tertiary hospital at the intensive care unit. The pharmacist reviewed patient prescription charts, vital signs and laboratory results. The pharmacist-led interventions identified untreated medical conditions and shortened the length or course of appropriate antibiotic therapy (Kumar et al., 2012; Bronkhorst, Schellack, Gous & Pretorius, 2014).

Based on the above-mentioned studies by Mehuys et al. (2008), Kumar et al. (2012) and Bronkhurst et al. (2014) it clearly demonstrates to varying degrees that pharmacist-led MTM produces better outcomes, both clinically and economically for patients with chronic disease conditions.

While both local and international studies focus primarily on hospital-based care, with South Africa's drive towards a district-based PHC system, the focus on chronic disease management has transitioned towards community-based care.

While numerous pharmacist intervention studies are conducted in hospital settings, pharmacist-led interventions on MTM among stable diabetic patients at a CDC in Cape Town are yet to be documented. Therefore, the focus of this thesis is to explore the potential role of the pharmacist in MTM among diabetic patients at the primary level of care.

Section C: Primary Health Care in the public health sector of South Africa

This section of the literature discusses the background to South Africa's primary health care system, the health policies and legislation aligned with the sustainable development goals and operational systems implemented within primary health care facilities.

2.8 Background to Primary Health Care in South Africa

Many countries have adopted primary health care (PHC) into their health systems to promote health and use the principles to gravitate towards achieving the Sustainable Development Goals and universal health coverage (WHO, n.d.). In 1978, an International Conference on PHC was held in Alma-Ata where the principles of PHC were outlined in the Alma-Ata Declaration and became a core concept for the World Health Organization (WHO) to achieve health for all people (WHO&Unicef, 1978). The WHO Alma-Ata declaration (WHO & Unicef, 1978) definition of PHC is as follows:

> *Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and the country can afford. It forms an integral part of the country's health system of which it is the nucleus and of the overall social and economic development of the country. It is the first level of contact of individuals, the family and the community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of continuing health care process.* (WHO & Unicef, 1978, p 3-4)

After more than two decades of democracy, South Africa has made gradual efforts to transform the health system towards accessible and affordable PHC. The White paper for the transformation of the health system in South Africa (DoH, 1997), the National Health Act (Parliament, 2003), and the PHC approach and development of the District Health System (Department of Health [DoH], 1997) provide a framework for the transformation of South Africa's National health system. The National Health Insurance white paper (NDoH, 2015), a form of universal health coverage, aims to provide access to quality and affordable health care services.

In 2015, South Africa's estimated population was 55 million people (Statistics South Africa, 2015), the majority of whom access the PHC system. South Africa's PHC

system is in the midst of facing a quadruple burden of disease characterised by communicable; non-communicable; maternal and perinatal; and injury and violence (Mayosi et al., 2009). In 2004, the WHO reported that 28% of the total burden of disease in South Africa, measured by disability-adjusted life years, was caused by NCD's (Mayosi et al., 2009). Furthermore, WHO estimates on the basis of the disability-adjusted life years per 100 000 population, placed South Africa burden of disease from NCD's at a higher position than that of developed countries (Mayosi et al., 2009).

A South African study reported that in 2000, diabetes accounted for an estimated 13 500 deaths (2.6%), positioning diabetes as the 10th leading cause of death amongst all age categories in South Africa (Bradshaw et al., 2007). An additional South African study highlighted that PHC in the public sector is sub-optimal in the management of diabetes and hypertension but steadily, progress has been made through government legislation, policies, STGs and EML to improve care of patients at a primary level (Steyn et al., 2008).

The public health care sector is accessed by 82.1% of South Africa's population while the remainder of the population utilise the private health care sector (Bidzha, Greyling,& Mahabir, 2017). South Africa's investment in health was 8.7% of its gross domestic product which was found to be more than other African countries (Kleinert & Horton, 2009). This gross domestic product figure in percentage was reported to be similar to the health expenditure in Sweden (8.9%) and also higher than that reported in Hungary (7.8%) (Kleinert & Horton, 2009). Since 2005/2006, the country's health expenditure has more than doubled (in real terms) in the public sector, PHC, from 443 South African rands (USD 2) per capita per year in 2005/2006 to 897 rands (USD 56) in 2014/2015 (Gray & Vawda., 2015), largely due to integration of expanding access of antiretroviral treatment for HIV into PHC system (Bidhza et al., 2017).

2.9 Health policies and legislation

South Africa's health policies are aimed at providing quality patient care through universal health coverage. Collaboration and support are required from different levels of government to effectively deliver health care services to patients in accordance with the Sustainable Development Goals (United Nations, n.d.). The Healthcare 2030 Strategy, the National Development Plan and the National Drug Policy are outlined to illustrate the health policy framework for the management of NCD's.

Millennium Development Goals towards Sustainable Development Goals

In 2000, South Africa signed the Millennium Development Declaration and committed to achieving the Millennium Development Goals (MDG's) to reduce poverty and meet the development needs of their people. The MDG's were eight goals with minimum standards that must be met by nations around the world (Motala et al., 2015). The eight MDG's were to:

1. Eradicate extreme poverty and hunger
2. Achieve universal primary education
3. Promote gender equality and empowerment of women
4. Reduce child mortality
5. Improve maternal health
6. Combat HIV and AIDS, Malaria and other disease
7. Ensure environmental sustainability
8. Develop a global partnership for development

To achieve these goals, South Africa's government has aligned its national development plans with MDG's. The MDG's relating to health includes child mortality; maternal health; and combating HIV and AIDS Malaria and other diseases, respectively. The Sustainable Development Goals were built on from the MDG's and a total of 17 Sustainable Development Goals were identified (2015) by the United Nations (United Nations, n.d.). South Africa is required to connect the MDG's with its policies as it moves towards Sustainable Development Goals (Motala et al., 2015).

Healthcare 2030 Strategy

In South Africa, the Sustainable Development Goal 3 is reflected in the *Healthcare 2030 Road to Wellness* document (Western Cape Government Health, 2014). The Health 2030 policy document, among others prioritised the burden of disease as one of its main objectives.

National Development Plan

In guiding the Health Care 2030 vision, the National Development Plan, focuses on improving health care management at an institutional level. In addition, it aims to reduce NCD's by 28%. In this regard, the 2030 strategic framework has structured health programmes to optimise and support the management of these conditions within the public sector (National Planning Commission, 2012).

Essential Medicines Programme

South Africa introduced the Essential Medicines Programme in 1998 as part of the National Drug Policy in 1996 (DoH, 1996). The National Drug Policy's health objectives clearly outlines that all South Africans are provided with access and availability of medicines through the Essential Medicines Programme. The Essential Medicines Programme encompasses the STGs and EML which forms part of an integral strategy to rationalize medicine use in the public sector.

> The WHO describes Essential medicines as those that satisfy the priority healthcare needs of the population. Essential medicines are intended to be available within health systems at all times in adequate quantities, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. (NDoH, 2014, p. xvi)

In the public health sector antidiabetic therapy for patients are categorised as essential medicines. Pharmacists form an integral part of the workforce to ensure that medicine therapy is accessible to diabetic patients to prevent complications.

2.10 Government circulars: a form of communication to healthcare professionals

A government circular conveys policy matters to healthcare providers (Law & Martin, 2009). Changes in policies and guidelines are due to dissemination of global evidence-based practices, and such information should be conveyed timeously to prescribers at health care facilities (Kapadia-Kundu et al., 2012).

Health information within government health systems flows through a link of channels which is initiated at a national level and then deployed to provincial, district and sub-district levels (Kapadia-Kundu et al., 2012; Bradley, Lehmann & Butler, 2015). At sub-district levels electronic health information is disseminated through circulars and/ or guidelines to promote uptake among staff. However, lack of access to computers, irregular updating of government websites, poor integration of information and fragmented communication across the health care levels (Kapadia-Kundu et al., 2012) limit timeous uptake among staff.

Medicine Use Evaluation results are shared with facility staff to promote rational prescribing through circularised updates as a strategy to curb the pharmaceutical

expenditure (Kapadia-Kundu et al., 2012; Bradley et al., 2015). Medicine Use Evaluations are conducted at facilities to determine reasons for high prescriber usage and high costs which affect pharmaceutical expenditure (Appendix 1). Irrational prescribing places a financial burden on South Africa's health budget (Isaacs et al., 2015). At a primary care level, the transfer of medicine therapy information to health care workers requires constant updating and reminding. In this regard, prescribers may also require pharmacotherapeutic support to implement rational prescribing. Trained pharmacists could therefore engage directly with prescribers within a facility on circularised medicine therapy updates. Therefore, along with guidelines, prescribers are also required to adhere to government circulars to optimise therapeutic approaches at primary care clinics.

2.11 Distribution of pharmacists within the public health sector

In South Africa, nurses make up the largest health profession in the country (Gray & Vawda, 2014). In 2015, 173 761 health professionals were working in the public health sector whereof, 77% were nurses, 10.8% were medical doctors, 2.9% were pharmacists and the balance was distributed amongst other health professionals (radiographers, occupational therapists, physiotherapists, dentists, psychologists, and environmental health practitioners) (Gray & Vawda, 2014).

There are large inequalities in the distribution of the health workforce across South Africa's health sectors. In 2014, over 41000 doctors were registered with the Health Professions Council and 45% worked in the public sector whereas a smaller number of pharmacists, over 13 000, were registered with the Pharmacy Council (2014)with only a third (34%) of pharmacists reported to be working in the public sector (Gray & Vawda, 2014). A similar figure was noted in Pakistan,where an estimated35% of pharmacists work in the public sector (2007) (Azhar et al., 2009). However, in Ghana, only 15% of the practicing pharmacists were reported to be working in the public sector (2005) (Chan &Wuliji, 2006).

2.12 Operational systems within Primary Health Care facilities

In South Africa, adult diabetic patients seek free access to PHC services in the public sector (Steyn et al., 2008). A community day centre (CDC) is a health facility that provides integrated primary health care services for 8 hours a day or more reflecting the needs of the community. A community health centre (CHC) is similar to a CDC however; the services are extended to 24 hour maternity and emergency services (KwaZulu-Natal Department of Health, 2001).

There are various types of systems operating within South Africa's PHC facilities and the manner in which these systems function may vary at each facility site. One of these systems include the chronic club system which has been implemented to improve patient adherence, educate patients about their condition, reduce patient load and waiting times at the CDC and the CHC (Slingers & De Villiers 2009; Frontières, 2012). Two types of chronic club services are rendered at PHC CDCs and CHCs, namely, chronic diseases of lifestyle clubs and the antiretroviral therapy adherence clubs. Implementation of health models to address the burden of disease and patient overload at health facilities through a centralised dispensing model has proven to be a solution to provide medicine to patients in a safe and affordable manner (Du Toit, Dames & Boshoff, 2008). These organisational systems are discussed below:

Chronic disease of lifestyle clubs

Patients who are diagnosed with an NCD for example, diabetes and when classified as "stable" are referred to the chronic diseases of lifestyle club. These patients need to see a clinician twice a year for a follow-up consultation at the primary care facility. Stability requires a patient to adhere to their medicine regimen accompanied by minimal change in the current disease status (Meintjies & Maartens, 2012).

Chronic diseases of lifestyle clubs at PHC facilities consist of basic functional characteristics, which are outlined as follows:

An appointment system is in place for patients, ensuring that they will be seen on the day. This also assists staff in organizing the club scheduled for the particular day. A club register records all patient particulars to facilitate strategic planning in the facility. At the patient's visit, a nurse performs basic observations and records these readings on the record sheet. The doctor assigned to the club will assess the patient's medical records and disease status. Either a nurse or a health promoter offers health education. The health promoter refers patients to other health care professionals if a problem or complication is identified requiring further assistance (Slingers & De Villiers 2009). Stable club patients receive their monthly medicine supply through the Chronic Dispensing Unit (CDU) system, a centralised dispensing intervention (Magadzire, Marchal & Ward, 2015).

Antiretroviral therapy adherence clubs

In contrast to the NCD club system, the HIV club system is organised by peer educators, also known as club facilitators at public sector facilities. The HIV club system also known as antiretroviral therapy adherence clubs consists of groups of approximately 30 patients. Firstly, the club patient will see an antiretroviral therapy club nurse at their clinical consultation visit and receive a two month supply of

medication (month1 to 2). For the next two months, the club facilitator offers group education on antiretroviral therapy adherence and medication is supplied for a further two months (month 3 to 4). At the next routine visit, patient adherence counselling is repeated, and antiretroviral therapy is supplied for another two months (month 5 to 6). At this visit, the patient's blood sample is required to determine their white blood cell count and viral load. The antiretroviral therapy adherence club system employs CDU services to supply pre-packed medication to antiretroviral therapy adherence club patients (Frontières, 2012).

Chronic medicine distribution model

The increasing number of patients diagnosed with HIV and chronic conditions (diabetes, hypertension, asthma, epilepsy, chronic obstructive pulmonary disease) caused tremendous strain on resources in the South African healthcare systems. In view of these constraints, the National Department of Health (NDoH) initiated the Central Chronic Medicine Dispensing and Distribution (CCMDD) programme to address challenges of overburdened health facilities, long waiting times and to reduce travelling costs for patients seeking to access medicines. The CCMDD programme offers alternative access to medicines for stable chronic patients, from a health facility-based model to a community-based model approach (Decroo et al., 2011).

The Western Cape Metro Distric Health Services contracted the chronic dispensing unit (CDU), to an external service provider for the purpose of pre-packing patients medication into ready to go parcels. The primary function of CDU services is to reduce the facility's pharmacy department workload. At the initial club visit, prescriptions are written for each club patient, which the facility's pharmacy department submits to the CDU. The CDU services pre-packs patient's chronic medication and delivers the patient medicine parcels timely to the facility's pharmacy department (Du Toit, et al., 2008).

2.13 Expanding access to chronic medicines in communities

In addition, to the facility-based CDU services, the Metro District Health Service has also contracted CDU in the implementation of the Western Cape's alternative chronic medicines distribution programme. This model aims to expand access to medicines, and is considered to be a PHC re-engineering approach which conforms to the vision of the National Health Insurance White Paper in December 2015 (Magadzire et al., 2015; NDoH, 2015). Stable chronic patients enrolled onto CDU have an option to collect their patient medicine parcel at their health facility or at an alternative collection site, which is much closer, at community-based venues such as

community halls and churches. This community-based model is also known as alternative distribution model are used for the distribution of medicines to chronic patients who are located in the community (Decroo et al., 2011). The community-based distribution model aims to minimize barriers to access chronic medicines (Decroo et al., 2011)

In summary, access to free PHC services and essential medicines in the public sector was made possible through the South African government's policy, legislation and Essential Drugs Programme (DoH, 1996). The reformed policy to strengthen and expand community-based services and PHC are in accordance with the Health 2030 strategy (Western Cape Government Health, 2014).

With expanded community-based services, stable patients are not at the health facilities every month. Inevitably, monitoring of patients becomes crucial, to ensure that complications are avoided.

2.14 Conclusion of the chapter

Diabetes is a complex metabolic disease which may be associated with hypertension and hyperlidaemia and if not managed appropriately can lead to diabetic complications. A multidisciplinary team approach especially at a PHC level is crucial to prevent escalation to secondary and tertiary level care. The pharmacist's potential role in MTM for stable chronic diabetic patients requires investigation at a primary care facility.

The next chapter of the thesis discusses the research design and methodology employed in the study.

CHAPTER 3: METHODOLOGY

This chapter provides an overview, description and discussion of the research design and methods used in the study. In addition, a description of the data collection methods, instruments and process are discussed.

3.1 Research design and methods approach

For this study, a quasi-experimental evaluation study design and case study approach was used. The research design is a procedural plan which a researcher uses to implement the research study in a logical way to address the research question(s). The research design is chosen that best fits the study investigated and is considered a blueprint for the collection, measurement and analysis of data (Cormack, 2000).

Quasi-experimental research methods may omit one of the other two properties that characterize a true experiment, that is, the researcher may omit a control group for comparison or the researcher may omit randomisation in sampling if a control group is used (Brink, Van der Walt & Van Rensburg, 2006). The quasi-experimental method used for this study is based on a time-series design (Brink et al., 2006). This method involves the researcher measuring and collecting quantitative data for a single group over a period of time, before and after introduction of treatment (Brink et al., 2006; Creswell, 2014). In this study, randomisation was not possible because patient folder selection was based purposively on 6 monthly clinic visits. Patient folders were retrieved from the reception department a week before patients were due for their follow-up visit. Data was collected retrospectively and prospectively from diabetic patient folders at a single primary care facility. The pharmacist reviewed prescriptions and pharmacist-led interventions were made in accordance with the PHC STGs and EML. Over an 8 month period, the pharmacist monitored and evaluated the prescriptions at baseline, post-pharmacist intervention and at 6-month follow-up visit.

Evaluation research design involves identifying and finding out how well a program, processes, policy or practices concerning an intervention is working. It evaluates how well the program is meeting its objectives and how useful it is. Evaluation research can often provide direction for making improvements in programmes that are found to be partially effective (Brink et al., 2006). In this study, a pharmacist-led MTM intervention for diabetes was evaluated at a primary care facility.

A case study research approach is used when there is a need to obtain an in-depth understanding of an individual, group, institution in its natural environment. The

researcher analyses and understands the data obtained in the field at the study site where the participant's problem occurs (Crowe et al., 2011). Data collected may often also include the participant's past experiences and environmental factors relating to the problem investigated. The researcher has face-face interaction, often over a period of time with participants (Brink et al., 2006). In this study, the case study approach was applied to collect data for the research problem investigated at the CDC, which was representative of a public primary level health care facility. The researcher engaged with the facility staff who were recruited during the course of the data collection phases.

Cormack (2000) defines retrospective and prospective studies as follows:
"Retrospective studies investigate events that have already happened in attempt to describe and understand those events whereas prospective studies investigate what might happen in the future." (Cormack, 2000)

These aspects are further described in the relevant sections of the thesis.

A mixed method approach was used for the study. This type of research method enables the researcher to combine quantitative and qualitative methods, techniques and approaches into a single research study. The principle of a mixed method approach is such that merging the two methods results in complementary strengths, and permits a more complete utilization of data once analysed (Creswell, 2014).

Quantitative research methods produce data that is objective, numerical and analysed through the use of statistics. This method measures data to formulate facts. It also aims to uncover cause-and-effect relationships among variables. The sample population is large and the data collection methods are more structured (Cormack, 2000). The quantitative aspects of this study included: patient demographics, co-morbidities, known allergies, and clinical and physical measurements; the number of interventions per patient, the type of intervention recorded, patient medicine therapy, outcome of pharmacist recommendation and indirect costs of medicine therapy.

Qualitative research methods are subjective and use human speech or writing as data (Cormack, 2000). It is used to gain insight and understanding of the underlying problem investigated. It provides an in-depth explanation of the target groups behaviour, experience, attitudes and intentions in terms of what people do and say. Some common methods include participant observation, focus groups and in-depth interviews. Compared to quantitative research methods, the sample size is smaller and the data collection methods vary using unstructured or semi-structured techniques (Cormack 2000). In this study, the qualitative aspects included: record of minutes kept during workshops with staff participants, completion of a semi-structured questionnaire by facility staff participants and the researcher journal entries recorded during the course of the research study period.

3.2 Study setting

The study was conducted at a CDC in Cape Town, South Africa which offers PHC services to the community. The staff complement at this CDC was 35(2016-2017). The facility renders chronic diseases of lifestyle club services under which the diabetic club operates.

Operational process at the CDC

Approximately 160 patients attended the diabetic club at the CDC every month. This system was introduced to improve patient flow, reduce patient load and waiting times at the CDC. Chronic club appointments were provided by the club doctor and clinical nurse practitioner (CNP) and recorded in the appointment registry. A reception clerk was assigned to have folders pre-drawn a day before the club appointment. On the day of the club, the staff nurse would begin preparatory work in which physical and clinical measurements of the diabetic patient were taken and recorded on the Metro District Health Service chronic disease record sheet for the doctor or CNP to review during the patient's consultation. The staff nurse checked and recorded the patient's physical measurements (weight, height) and clinical measurements (blood pressure, FPG, dipstick urinalysis). A health promoter and nutritional specialist offered health talks to educate patients in sessions covering lifestyle changes. The doctor or CNP would then examine the patient, draw blood sample to examine the blood lipid panel, HbA1c, kidney function and prescribe the necessary medicine. Blood results were discussed with the patient two weeks later after the initial clinic visit. Prescriptions were written up for a period of 6-months and patients only received their initial one month supply of antidiabetic medication from the pharmacy. Blood test results were obtained within 3 days, depending on the location and the resources available at the CDC. This government facility had access to the laboratory services and their database whereby theclinicians could access and view patient's laboratory results. Stable patients were requested to return for their6-month clinical follow-up appointment. The preceding months before the 6-month follow-up club appointment, stable patients were required to obtain their antidiabetic medication through the CDU system.

The researcher was a South African Pharmacy Council registered pharmacist and master's student. Thus, the researcher's role as a pharmacist, served a dual purpose throughout the study period. The researcher who was conversant with the facility's operational procedures both within the pharmacy and the rest of the facility, monitored, evaluated and documented data from diabetic club patient folders which were retrieved from the reception department. In order to work within routine operational procedures of the CDC, pharmacists usually do not often have direct interaction with patients, only at the point of dispensing. Therefore, the MTM data

collection process for this study took into consideration the contextual factors at the facility. This meant that in designing the intervention, the key criteria was that it had to be non-invasive to routine pharmaceutical and clinical practice patterns at the facility. This meant that the researcher would be required to undertake her routine pharmaceutical duties and responsibilities as a dispensing pharmacist, whilst undertaking the intervention, at the facility. Therefore the intervention was designed to follow an integrated process into the operational procedures of the facility.

3.3. Sample population selection and recruitment

The target population for this study included two groups of participants, namely stable diabetic patients who attended the diabetic club and facility staff that were involved in managing these patients. It should be noted that, diabetic club patients were not actively or physically recruited during the course of study.

According to Brink and colleagues (2006), a population is defined as the entire group of individuals or objects that meet the sample criteria for inclusion in the study (Brink et al., 2006). In this case study, the population included facility staff members from the CDC. Facility staff members from different service categories involved in the diabetic care process within the CDC was approached to participate in the study. These staff members consisted of doctors, CNP's, a health promoter, a dietician, a qualified post-basic pharmacist assistant, an occupational therapist, a nutritional specialist and reception clerks. The researcher monitored, evaluated stable diabetic club patient folders medicine therapies and prescriber patterns in accordance with recommended guidelines.

A sample refers to a selected group of elements that the researcher selects from a portion of the population with the intention of obtaining information about the entire population of interest (Cormack, 2000). For this study, the researcher approached facility staff members involved in diabetes care to partake in the study. Those facility staff members who agreed to partake in the study and conformed to the study criteria were included. They attended the pharmacist-led workshops and completed a semi-structured questionnaire. To eliminate researcher bias of the selection of diabetic club patient folders, the folder selection process is outlined in Section 3.3.3.The researcher selected the diabetic patient folders from the reception department, which met the study's inclusion criteria (outlined below).

3.3.1 Selection of staff members and diabetic club patient folders

Selection of facility staff members and diabetic club folders were determined by inclusion and exclusion criteria. Below is the criteria used for the study:

A. Inclusion and exclusion criteria for facility staff recruitment:

Inclusion criteria:

(i) All facility staff members involved in diabetes management at the CDC, who were willing to participate in the study.

Exclusion criteria:

(i) Staff involved in the management of conditions other than diabetes mellitus, namely family planning, tuberculosis, paediatrics.

(ii) Those who were not interested in participating in the study, or who declined to participate in the study, or who did not give informed consent.

B. Inclusion and exclusion criteria for patient folder selection

Inclusion criteria:

(i) The inclusion criteria that were applied during the patient folder selection noted all of the following:

- Adult patients (>18 years of age),
- Be of either sex,
- Diagnosed with type 2 diabetes mellitus,
- Categorised as a *'stable' diabetic patient who were attending the Thursday diabetic club, and
- Had a valid 6 month prescription inside the folder.

*Patients who are diagnosed with an NCD for example, diabetes and when classified as "stable" are referred to the chronic diseases of lifestyle club. These patients need to see a clinician twice a year for a follow-up consultation at the primary care facility.

Exclusion criteria:

(i) Patients diagnosed with type 1 diabetes mellitus as the focus of the study was adult type 2 diabetes mellitus, due to the high prevalence of type 2 diabetes mellitus in the community who attend the CDC.

(ii) Patients folders indicating other chronic disease clubs (e.g. epilepsy, asthma) at the CDC for folder review.

3.3.2. Sample method and sample size for folder review

For the purpose of this evaluation study, a non-probability sampling technique was used, specifically convenience sampling (Brink et al., 2006). Thereafter, the sample size was calculated, that is the estimated diabetic club folders, required for data collection.

Non-probability sampling is a technique wherein, it is not known which individuals from the population will be selected as a sample. Individuals are selected on the basis of their accessibility or require subjective judgment by the researcher (Brink et al., 2006). Convenience sampling is a non-probability sampling technique that entails selecting subjects or objects that are readily accessible to the researcher (Brink et al., 2006). For this study, the following was considered when applying convenience sampling:

(i) Only one researcher was responsible for collecting the data at the facility within the study time-frame, and,

(ii) The researcher was familiar with the operational procedures at the facility and could easily retrieve the diabetic club folders from the reception department, and,

(iii) The researcher was familiar with the role of the facility staff and had established a cordial working relationship with them.

Approximately 40 diabetic club patients attended the CDC on a Thursday and were seen by either a doctor or CNP. The minimum number of stable diabetic club patient folders (**n=109**) needed for the study was calculated using the following equation (Larson & Marx, 1986):

$$n = \frac{z^2 p(1-p)}{d^2}$$

where n = estimate of sample size

z = 1.96 for 95% confidence level

d = distance between true and estimated proportion i.e. 0.05

p = proportion i.e. prevalence of diabetic population, assumed = 7%, i.e. 0.07

$$n = \frac{z^2 p(1-p)}{d^2}$$

$$= \frac{1.960*1.960*[0.07\ (1-0.07)]}{(0.05*0.05)}$$

= 100.04

= 100

To accommodate for missing or incomplete data the sample size was increased by 10% and a minimum of 110 folders were required for review. However, a sample of **109** stable diabetic patient folders was obtained from the reception department and reviewed. It should be noted that stable diabetic club patients were not actively involved, only patient data extracted from folders were reviewed for this study.

3.3.3 Selection of patient folders for pharmacist's review

A total of 109 diabetic club folders were reviewed for data collection. Even though convenience sampling method was used for the study, diabetic patient folders were selected by systematic random selection of folders to reduce bias in this study (Brink et al., 2006; Maree, 2007). The number of folders required to be reviewed each week was approximately 9. Folders were obtained from the reception department.

The total sample of folders expected for the Thursday diabetic club was approximately 40. The patient folder number was written on an individual slip of paper, that was folded neatly to hide the patient folder numbers and placed in a box. One folder number was drawn from the box and this was the start folder in the stack of folders that were collected. Thereafter every n^{th} folder was selected, that is, every 4^{th} folder was reviewed for the study.

The calculation was as follows:

(i) Divide the total number of folders collected for the week by 10 which will give an answer (n).

(ii) Then every n^{th} folder is reviewed

(iii) A sample of 40 folders was collected for the week, and 9 folders are required for pharmacist's review.

Therefore, 40÷9= 4.4 (n)

The pharmacist reviewed every 4^{th} folder.

3.4 Pilot study period

A pilot study also referred to as a preliminary study, is a small-scale study conducted by the researcher prior to the main study. The purpose of conducting a pilot study is to evaluate the feasibility, time, costs of the proposed study and to improve upon the study design and data collection instruments (Brink et al., 2006).

The diabetic patient folders reviewed during the pilot study period was excluded from the main study using identifier codes. After completion of the pilot study, 109 diabetic patient folders were monitored and evaluated over an 8 month period (December 2016 to July 2017).

3.5 Data collection process

The researcher used a mixed method approach and collected quantitative and qualitative data pertaining to this research study at the CDC. The researcher who was a pharmacist trained in pharmacotherapeutics, attended the *Integrated Applied therapeutics: Fundamentals of Rational Prescribing course* which was offered in 2015 by Pharmacy Education International (Perkin, 2014). One of the skills acquired were MTM for NCD's using the PHC STGs and EML.

The PHC STGs and EML (NDoH, 2014) and a government circular were used as reference guides for the researcher during the data collection process. The researcher began collecting data from 2016. Subsequent to the data collection process, the circular, "*H141/2017: Aspirin Medicine Use Evaluation Feedback*", was released later in 2017 (Appendix 1). The researcher used the reference guides to promote rational medicine prescribing of aspirin during the data collection process. The aspirin Medicine Use Evaluation 2017 circular reinforced the prescribing criteria of aspirin as per STGs (2014). Even though circulars are available to staff, there is

no mechanism at the facility whereby it is not explicitly communicated (direct face-to-face engagement) with prescribers.

Quantitative data was collected using the pharmacist MTM data forms (Appendix 2). Qualitative data was obtained by administering a semi-structured questionnaire (Appendix 3), keeping a record of minutes from facility staff workshops and the pharmacist's journal.

Figure 3.9 provides an outline of the 7 phase approach to the pharmacist-led medicine therapy management data collection process.

3.5.1 Data collection instruments

Quantitative data collection tools used for the study was the pharmacist MTM data tools (Appendix 2) which comprised of the following:

(i) Pharmacist medicine therapy management data forms (pharmacist's patient data sheet, pharmacist assessment worksheet, pharmacist intervention log sheet)

(ii) Pharmacist intervention label

(iii) Reminder prompt cover page for the stable diabetic patient folder

The pharmacist rendered MTM whilst documenting data using the above three sheets.

The qualitative data collection instrument was a semi-structured questionnaire. These were administered to staff participants to gauge their experiences regarding pharmacist MTM recommendations in diabetes management (Appendix 3).

3.5.1.1 Medicine therapy management forms

The Pharmacotherapy Workup tool created by Strand and colleagues (1988) was used as a guide for the researcher to develop a set of MTM tools (Appendix 2) for the data collection process (Strand, Cipolle & Morley, 1988; Cipolle et al., 2012).

Pharmacist's patient data sheet

The researcher completed the patient's demographic information on the top section of the first sheet of the pharmacist MTM data forms. This is illustrated in Figure 3.1.

This sheet enabled the researcher to monitor and evaluate the stable diabetic patient data at baseline (pre-intervention), assessed prescriber uptake of pharmacist-led interventions (post-intervention) and also obtain data at 6-month club follow-up visit at the facility.

Demographic information	***Patient folder number:*** *AB12551733*		***Gender:*** ***Male*** ❑	***Female*** ☒	
	Date of Birth/Age: *1955/10/29*		***Allergies:*** *None*		
Condition	Diabetes Mellitus Type 2 ☒				
Co-morbidities	Hypertension ☒	Asthma ❑	Epilepsy❑	COPD❑	
	Other co-morbidities not listed: specify *None*				

Figure 3.1: Demographic section of the pharmacist patient data sheet

For the purpose of this study, the researcher recorded physical, clinical, and biochemical parameters to make appropriate therapeutic recommendations to prescribers. These recommendations were in accordance with the PHC STGs and EML (NDoH, 2014) measures for the management of type 2 adult diabetics.

The physical measurements recorded were weight, height and BMI. As illustrated in Figure 3.2 the diabetic club patient's height was recorded once and the weight was recorded at each clinical visit. From these two measurements, the BMI was recorded.

	BASELINE DATA		**POST-PHARMACIST INTERVENTION**		**6-MONTH FOLLOW-UP DATA**	
PHYSICAL MEASUREMENT	**DATE**	**RESULT**	**DATE**	**RESULT**	**DATE**	**RESULT**
Wight (kg)	*01/09/2016*	*92*	*26/01/2017*	*94*	*27/07/2017*	*94*
Height (m)	*21/10/2014*	*1.56*				
Body Mass Index (BMI) kg/m^2	*21/10/2014*	*36*	*26/01/2017*	*38*	*27/07/2017*	*No record*

Figure 3.2: Physical measurements

The clinical parameters which were recorded as illustrated in Figure 3.3 were blood pressure, FPG and urine test for glucose, ketones and proteins.

	BASELINE DATA		POST-PHARMACIST INTERVENTION		6-MONTH FOLLOW-UP DATA	
CLINICAL MEASUREMENT	**DATE**	**RESULT**	**DATE**	**RESULT**	**DATE**	**RESULT**
Blood pressure (mmHg)	*20/10/2015; 07/04/2016 01/09/2016*	*124/65; 131/78; 158/94*	*26/01/2017*	*138/77*	*27/07/2017*	*136/83*
Fasting Plasma Glucose (mmol/L)	*20/10/2015; 07/04/2016 01/09/2016*	*8.0; 9.4; 7.6*	*26/01/2017*	*6.6*	*27/07/2017*	*7.8*
Glucose	*01/09/2016*	**NAD*	*26/01/2017*	**NAD*	*27/07/2017*	*NAD*
Ketones	*01/09/2016*	*NAD*	*26/01/2017*	*NAD*	*27/07/2017*	*NAD*
Proteins	*01/09/2016*	*NAD*	*26/01/2017*	*NAD*	*27/07/2017*	*NAD*

*NAD=No Abnormalities Detected

Figure 3.3: Clinical measurements

The researcher recorded laboratory tests results namely, HbA1c, serum creatinine and total cholesterol (refer to Figure 3.4). The eGFR was calculated to determine the renal function of the diabetic club patient and the Cockroft-Gault equation (Rossiter et al., 2016) was used in this study. The equation is provided below:

$$\textit{estimated}\ \text{GFR (mL/min)} = \frac{(140\text{-age}) \times \text{weight (kg)} \times \text{constant}^*}{\text{serum creatinine (umol/L)}}$$

where the *constant is 0.85 for females.

The researcher accessed the patient's laboratory tests results online from the laboratory service database, to determine if blood samples were drawn. This information enabled the researcher to refer to the PHC STGs in offering the prescribers a therapeutic recommendation if deemed necessary.

	BASELINE DATA		POST-PHARMACIST INTERVENTION		6-MONTH FOLLOW-UP DATA	
LABORATORY TESTS	**DATE**	**RESULT**	**DATE**	**RESULT**	**DATE**	**RESULT**
HbA1c (%)	*20/10/2015*	*6.9*	*26/01/2017*	*7.8*	*27/07/2017*	*Bloods to be drawn 2018*
Serum Creatinine (µmol/L)	*20/10/2015*	*61*	*26/01/2017*	*61*	*27/07/2017*	*Bloods to be drawn 2018*
GFR (ml/minute)	*20/10/2015*	*129*	*26/01/2017*	*131*	*27/07/2017*	*Bloods to be drawn 2018*
Total cholesterol (mmol/L)	*20/10/2015*	*4.46*	*26/01/2017*	*4.10*	*27/07/2017*	*Bloods to be drawn 2018*

Figure 3.4: Laboratory tests

The researcher recorded the patient's medicine therapy on the bottom section of the pharmacist's patient datasheet as indicated on the patient's prescription. This is illustrated in Figure 3.5. The date of patient's clinical visit and details of prescription was written on the datasheet.

	BASELINE DATA	POST-PHARMACIST INTERVENTION	6-MONTH FOLLOW-UP DATA
PATIENT MEDICINE THERAPY			
Date of prescription	*01/09/2016*	*26/01/2017*	*27/07/2017*
Name/Dose/Route			
1.	*Metformin 1g 8hrly p.o*	*Metformin 850mg 8hrly p.o*	*Metformin 850mg 8hrly p.o*
2.	*Hydrochlorothiazide 12.5mg daily p.o.*	*Hydrochlorothiazide 12.5mg daily p.o.*	*Hydrochlorothiazide 12.5mg daily p.o.*
3.	*Enalapril 5mg 12hrly p.o.*	*Enalapril 5mg 12hrly p.o.*	*Enalapril 5mg 12hrly p.o.*
4.	*Simvastatin 10mg daily p.o.*	*Simvastatin 10mg daily p.o.*	*Simvastatin 10mg daily p.o.*
5.	*Aspirin 75mg daily p.o.*		

Figure 3.5: Transcription of prescribed patient's medicine

Pharmacist intervention log sheet

Pharmacists are responsible for providing medication related care to improve patient health and clinical outcomes. Part of the MTM process allows pharmacists to review prescriptions and when necessary, suggest a pharmacist intervention. Pharmacist interventions focus on improving patient safety, efficacy, or cost-effectiveness of medication. These interventions demonstrate the importance of the pharmacist's role in MTM in order to optimize patient care with the collaboration of other health care professionals.

In this study, the term pharmacist intervention addressed a wide array of potential medicine therapy issues. Once the medicine therapy issue was addressed the pharmacist made a recommendation to the prescriber. Therefore, for the purpose of this study, the recommendations formed part of the pharmacist intervention (Sartore, Ehman & Good, 2014).

All pharmacist interventions were documented using the pharmacist intervention log sheet in which the pharmacist describes the intervention and makes a recommendation to the prescriber. Refer to Figure 3.6 for an excerpt of the form.

The interventions were classified according to 8 MTP categories and 35 MTP types. The MTP categories and types which are listed on the pharmacist intervention log sheet (refer to Appendix 2), were adapted from Cipolle and colleagues (2012)

Pharmacotherapy Workup Notes. A short description of the MTP categories is provided below:

A- The medicine therapy that the patient is taking is unnecessary because there is no clinical indication stated.

B- The patient requires additional medicine therapy to meet their health condition needs.

C- The medicine product chosen is ineffective and inappropriate in treating the medical condition

D - The prescribed medicine dosage regimen is too low to produce a desired pharmacological result.

E - The medicine product that the patient is taking is causing an adverse medicine reaction.

F - The prescribed medicine dosage regimen is too high, resulting in undesired pharmacological results.

G -The patient is not adhering to taking medicine therapy as directed.

H- Failure to draw patient bloods for biochemical evaluation and recording of physical measurements to calculate the patients BMI.

Date	Medicine therapy problem category	Medicine therapy problem type	Pharmacist intervention description	Pharmacist recommendation
11/01/2017	*A*	*1*	*No indication noted for aspirin as indicated in STGs and EML*	*Remove aspirin from regimen as per circular.*
11/01/2017	*F*	*23*	*Dose of metformin is too high, 1g 8rly p.o.*	*Review regimen, STGs and EML, maximum dose of metformin 850mg 8hrly p.o.*
11/01/2017	*H*	*34*	*No laboratory tests results for HbA1c, total cholesterol and serum creatinine*	*Draw patient bloods for following tests: HbA1c, total cholesterol and serum creatinine*
11/01/2017	*H*	*35*	*BMI not calculated*	*Calculate BMI. Calculation provided:* $BMI\ (kg/m^2) = \frac{mass\ (kg)}{height\ (m^2)}$

Figure 3.6: Pharmacist intervention data

Pharmacist assessment worksheet

The MTP types, pharmacist intervention description and recommendation were transferred to the pharmacist assessment worksheet. This was to determine if the club doctor or club CNP accepted the proposed pharmacist's recommendation. Their response was recorded as either '*accepted*', '*partially accepted*' or '*rejected*' on the data sheet. Figure 3.7 is an excerpt of the pharmacist assessment worksheet.

The MTP types, pharmacist intervention description and recommendation that had been identified in the *Pharmacist Log Sheet* (Appendix 2) were transferred to the pharmacist assessment worksheet. The purpose was to determine the outcome of the proposed pharmacist recommendation that were offered to the club prescribers.

Interventions which the researcher recorded as being *accepted*, *rejected* or *partially accepted* were compared between the club doctor and CNPs. An intervention was considered *accepted* if the prescriber agreed to and noted the pharmacist's recommendation on the prescription. If the recommendation was *rejected*, that meant it was not accepted. *Partially accepted* interventions were recommendations made by the pharmacist that were not completely rejected by the prescriber.

The researcher recorded an indirect cost of medicine therapy for a month's supply in the last column of the pharmacist assessment sheet. This was calculated and analysed as secondary data. This is further discussed in Chapter 4: Results and Discussion. The Western Cape Master Procurement Catalogue-November 2016 was used to calculate an indirect cost of a patient's medicine therapy over a period of 28 days (one month) in the public sector versus costs over a 6 month period. The catalogue provides the medicine item price.

Date	Medicine therapy problem type	Pharmacist intervention description	Pharmacist recommendation	Outcome: Accepted (A), Partially Accepted (PA), or Rejected (R)	Club doctor (CD) or Clinical Nurse Practitioner (CNP) whom intervention was recommended to	Indirect cost per month of medicine therapy
09/02/2017	*1*	*No indication noted for aspirin as indicated in STGs and EML*	*Remove aspirin from regimen*	*A*	*CNP*	*R2,69*
	23	*Dose of metformin is too high, 1g 8rly p.o.*	*Review regimen, STGs and EML, maximum dose of metformin 850mg 8hrly p.o.*	*A*	*CNP*	*R6,45*
	34	*No laboratory tests results for HbA1c, total cholesterol and serum creatinine*	*Draw patient bloods for following tests: HbA1c, total cholesterol and serum creatinine*	*A*	*CNP*	----

	35	BMI not calculated	Calculate BMI. Calculation provided: $BMI\ (kg/m^2) = \frac{mass\ (kg)}{height\ (m^2)}$	A	CNP	-----

Figure 3.7: Pharmacist assessment worksheet

3.5.1.2 Pharmacist intervention label

Reminder prompts are effective in alerting clinicians to a clinical intervention and in doing so minimizing medical errors (Balas et al., 2000). The literature discusses various reminder prompting tools that are used in many health care settings (Balas et al., 2000; Dexheimer, Talbot, Sanders, Rosenbloom & Aronsky, 2008).

In a systematic review of literature on reminder prompting strategies towards clinicians, Dexheimer et al. (2008) classified reminder methods as either "paper-based", "computer-generated" or "computerized". Paper-based reminders include prompting stickers, memos or cards; checklist attached to patient chart; and tagged note attached to the patient chart. Computer-generated reminders include encounter forms which are printed and attached to the patient chart to prompt clinicians. Computerized reminders are electronic prompts which are incorporated in the computer software, and are displayed as pop-up boxes or are inserted into the software and require the clinician to acknowledge reading the information presented (Dexheimer et al., 2008; Evidence Centre, 2012). The study done by Dexheimer et al. (2008) found that paper-based reminder methods were more commonly used (31%) to prompt clinicians as opposed to computerized methods (13%) (Dexheimer et al.,2008). Paper-based reminder methods can easily be implemented into the clinical workflow and where there are limited information systems within the infrastructure (Dexheimer et al., 2008).

Implementation of reminder prompt techniques has found to improve clinician compliance with guidelines and also improve patient outcomes (Schwann et al., 2011; Tierney et al., 1995). In light of this development it is important to understand that pharmacists' play an active role in alerting clinicians to medicine related information.

In this study, a paper-based reminder prompt was used. Folders were obtained at the reception department within the facility and a reminder prompt such as a cover sheet (Appendix 2) was attached onto the cover of the patient folder. For prescribers, this aided in easily identifying the study folder. The researcher wrote a brief description of the intervention and made recommendations on the intervention label which also served as a reminder to prompt clinicians. The information was printed on

a sticky label which was then attached to the existing prescription for the doctor or clinical nurse to consider. The pharmacist intervention label was used as a reminder prompt as illustrated in Figure 3.8.

The pharmacist-led MTM for diabetes was systematically co-ordinated to avoid interruption of routine operational procedures. Since this preliminary pharmacist intervention required engagement from staff within the facility, a qualitative evaluation was thus deemed necessary.

Figure 3.8: Pharmacist intervention label

3.5.1.3 Questionnaire

For this part of the study a semi-structured questionnaire consisting of 4 open-ended questions was used (Appendix 3) to determine whether the facility staff involved in diabetes management would benefit from having the pharmacist as part of the diabetes multidisciplinary team. A questionnaire is a research form consisting of a list of questions for the purpose of collecting specific information through the written responses from the subjects (Cormack, 2000). Open-ended questions allow subjects to express their opinions through written responses to questions (Polit & Hungler, 1987). The open-ended questions used for this study were:

1. *In your opinion, how did the pharmacist contribute to diabetes management at this Community Day Centre?"*

2. In what way has your management of the diabetic patient changed following the involvement of a pharmacist?

3. From your experience, should a pharmacist be part of the team in diabetes management at facilities?

4. Would you recommend a pharmacist in the diabetes management team at other community day care centres?

An independent assessor distributed the questionnaires to the group of staff participants at a feedback workshop at the CDC. Staff participants completed the semi-structured questionnaire at the same time allowing the independent assessor to clarify any misunderstandings of the instrument.

3.5.2 Workshops

A workshop is a teaching and learning program for a small group of participants that is provided in a short space of time. A workshop can introduce a new concept to participants and enable them to acquire skills, test techniques or ideas which they can use in a practice setting (Community Tool Box, 2013). The researcher encouraged staff participants to discuss their role in diabetes management at workshops conducted during the research study period.

3.5.3 Pharmacist Journal

The researcher maintained a journal during the research study period. Diaries and journals are used as a source of documenting data over the research study period. Participants or researchers are required to diarise their thoughts and experiences (Moon, 2006., Polit & Hungler, 1987). The journal entries provided insight into the researcher's experiences during the study period.

3.5.4. Preliminary research planning

The researcher had preliminary discussions with the staff during the study's planning phase: the Director of Pharmacy Services, the responsible pharmacist at the facility, pharmacy support personnel, the facility manager and operational manager. Monthly meetings were scheduled with heads of departments to discuss the progress of the project. The research method, design and data collection instruments in relation to the facility's operational procedures, had to be non-invasive, not compromise any staff member's duties and be integrated into routine practice pattern. Consequently, the researcher's flexibility, in adapting data collection times was essential to prioritize the operational procedures of the facility.

The researcher's planning entailed:

- Notifying staff participants of the workshop via electronic communication (email),
- Sending a reminder text message of the scheduled workshop dates,
- Inviting a staff participant to present a topic at the workshop, and,
- Arranging food snacks for participants.

3.5.5 Data collection phases

The pharmacist collected quantitative and qualitative data retrospectively and prospectively and followed a phased approach during the data collection process. Figure 3.9 depicts the data collection process.

The framework for the pharmacist MTM data collection process consisted of seven phases:

Phase 1: Introductory workshop- staff recruitment

Phase 2: Pilot study with facility staff

Phase 3: Baseline data (pre-intervention)

Phase 4: Pharmacist-led interventions (intervention)

Phase 5: Assess prescriber uptake (post-intervention)

Phase 6: Diabetic patient 6-month club follow-up

Phase 7: Feedback workshop

Quantitative data was collected from Phase 2 to Phase 6. Qualitative data was collected at Phase 7.

An outline of each phase is presented below:

Phase 1: Introductory workshop for staff recruitment into the study

The pharmacist approached facility staff members who were involved in diabetes management to participate in the research study. An introductory workshop was conducted at the facility to inform facility staff participants of the purpose of the study. This part of the data collection process was done prospectively. Participants who agreed to partake in the study received a study information leaflet (Appendix 4) and signed an informed consent form (Appendix 5).

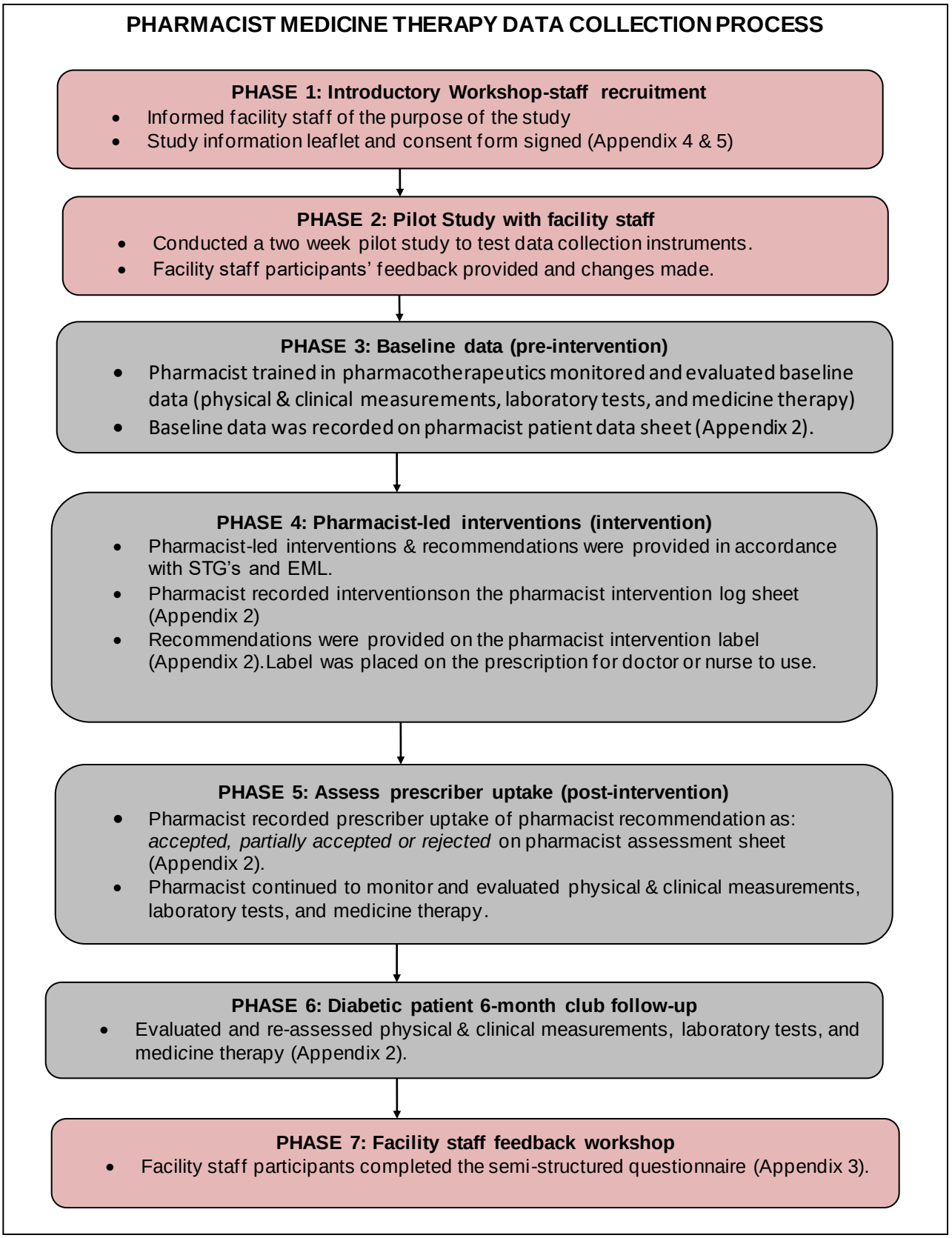

Figure 3.9: The outline of the pharmacist medicine therapy management data collection process.

Staff participants were informed of the data collection process in which the pharmacist incorporated the MTM process into the operational framework of the facility. These staff participants were also informed that they were required to complete a semi-structured questionnaire at the end of the study period.

Phase 2: Pilot study with facility staff

The pharmacist carried out a two week pilot study to identify problems, especially to test the pharmacist MTM tools, address problems, and make the necessary changes. Facility staff participants were given an opportunity to raise questions at a feedback workshop. Hence, feedback was obtained to test the data collection instruments. Phase 2 was conducted prospectively.

From **Phase 3** to **Phase 4** the pharmacist monitored and evaluated stable diabetic club patient folders (n=109) over an 8 month period.

Phase 3: Baseline data (pre-intervention)

Due to workload constraints encountered at the clinic, the pharmacist was unable to review the diabetic patient folders on the Thursday appointment club date.

A list of the club patients attending the Thursday diabetic club was recorded by the club CNP in a club register. The pharmacist obtained permission to acquire the patient list from the club CNP to retrieve diabetic patient folders from the reception department on a weekly basis. The pharmacist used a random method of selection for reviewing the folders of stable diabetics retrospectively.

The pharmacist trained in pharmacotherapeutics monitored and evaluated baseline data of stable diabetic patient folders (n=109). Baseline data was recorded on the pharmacist patient data sheet (Appendix 2).

Phase 4: Pharmacist-led interventions (intervention)

A framework for pharmacist-led interventions was used so that medicine regimens and doses could be adjusted in accordance with the recommended guidelines. The pharmacist intervention and recommendation was recorded on the pharmacist intervention log sheet (Appendix 2). The pharmacist also recorded the MTP category and type under which the intervention was classified on the log sheet.

The pharmacist recommendation to the prescribers was provided on a pharmacist intervention label (Appendix 2). The pharmacist intervention label was attached to the patient's prescription inside the folder for the club doctor or club CNP to consider,

and to minimize direct interaction with the prescribers. The pharmacist's recommendations were offered before the diabetic club patient returned for their follow-up appointment at the club within 6 months of their previous appointment.

During the course of the study period, the researcher arranged workshops with facility staff participants to create an opportunity for facility staff participants to discuss their role in diabetes management and to elucidate their understanding of the pharmacist's role. The researcher initiated and facilitated the workshops which were approximately 30 minutes in duration and held on a Friday afternoon at the CDC to ensure that services at the facility were not disrupted. The workshops formed the qualitative evaluation arm of the study.

Phase 5: Assess prescriber uptake (post-intervention)

The researcher obtained the stable diabetic club folders from the reception department and reviewed them retrospectively. From the post-pharmacist interventions, data were extracted from the folders on physical, clinical and biochemical parameters and recorded on the pharmacist patient data sheet (Appendix 2).

Although the predicted sample size was 109 diabetic club folders, only 104 diabetic patients adhered to their club appointment date at the facility.

The outcome of the intervention which the pharmacist had recommended to either the club doctor or club CNP was recorded as "accepted", "partially accepted" or "rejected" on the pharmacist assessment worksheet (Appendix 2).

An indirect cost of medicine therapy was calculated and analysed as secondary data. For this study the pharmacist continued to re-evaluate the stable diabetic patient folders as described in phase 6.

Phase 6: Diabetic patient 6-month club follow-up

The researcher evaluated and re-assessed the stable diabetic patients' (n=104) 6-month follow-up physical and clinical parameters, and laboratory data. This data was recorded on the pharmacist patient data sheet (Appendix 2).

The researcher compared data obtained pre- and post-intervention, in terms of prescriber practices and patient data during the three phases, that is, phase 3, phase 5 and phase 6 of the data collection process.

Phase 7: Facility staff feedback workshop

In an attempt to reduce study bias during the study, a non-practising pharmacist was recruited to independently assess participant feedback during the workshop. The independent assessor had the training, skills and experience in conducting workshops.

A semi-structured questionnaire (Appendix 3) was administered at the end of the study period to facility staff participants at the CDC. For this part of the study the data was collected prospectively.

The semi-structured questionnaire consisted of open-ended questions which enabled participants to respond in their own words. The purpose of the questionnaire was to gain insight into the facility staff participant's experiences, attitudes and perceptions of the potential benefits and role of the pharmacist in diabetes management.

The independent assessor used neutral probes during the workshop to refrain from influencing the participant's response to the questions. The purpose of a probe is to elicit more useful and in-depth information by the participant when questions are not fully understood during the first reply (Polit & Hungler, 1987).

Each participant's response offered a unique perspective which enabled the pharmacist to reflect on the information provided.

3.6 Data analysis

The researcher analysed quantitative data, producing a summary of descriptive data from the folders that were reviewed of stable diabetic patients and from the pharmacist-led interventions. Qualitative data analysis involved identifying common themes from the semi-structured questionnaire, the researcher's journal entries and audio recordings transcribed from workshops.

(a) Quantitative analysis:

The researcher captured quantitative data on a MS Excel® spreadsheet. The computer software program used to analyse this data was IBM SPSS Statistics, Version 24 and consisted of descriptive and inferential statistics.

Descriptive statistics was used to describe and summarise the data collected. Data were organized, analyzed and visually represented by the researcher so that the data may have some clear meaning to the audience reading the research report

(Brink et al., 2006). A summary of descriptive data consisted of averages, frequencies and percentages of categorical data. This included:

- Patient data: gender, co-morbidities, known allergies
- Prescriber data: types of pharmacist-led interventions encountered and the prescribers' acceptance of the pharmacist-led interventions
- Estimated medicine costs

These were graphically presented in tables and bar graphs. Baseline demographic data was summarized using mean, standard deviation, minimum and maximum figures.

Coding is a process used to organize data collected for analysis. The coding process involves using symbols to categorize information (Polit & Hungler, 1987). Data was captured and coded on an MS Excel® spreadsheet for analysis. An example of one of the variables coded for this study was the pharmacist intervention outcome: coded 0 for accepted, 1 for partially accepted and 2 for rejected (Appendix 6).

Inferential statistics is a type of statistics that provides a means of drawing conclusions about the population, on the basis of analysis and observation (Brink et al., 2006). In an inferential approach, data was analysed using means, standard errors, 95% confidence intervals, P-value or significant level at 0.05. The outcome (accepted, partially accepted and rejected) of the pharmacist intervention were all included in the data analysis. *"The P-value is the probability that the outcome is owing to chance-are used to communicate the significance or lack thereof of the data."*(Brink et al., 2006)

Paired sample t-test was applied to compare data obtained from folders of stable diabetic patients at baseline (pre-intervention), post pharmacist-led intervention (post-intervention) and at 6-month club follow-up. Comparisons were made between the pre- and post- prescriber practice as well as changes in biochemical markers to determine the stability of the diabetic club patients. A P-value $p<0.05$ was considered statistically significant.

(b) Qualitative Analysis

The researcher analysed the qualitative data to determine if any common themes emerged across all qualitative data. These consisted of:

- Staff participant responses to the open-ended questions,
- Transcribed audio recordings from workshops as written words to analyse, and
- Journal entries maintained by the researcher to identify the researcher's experiences and feelings during the study period.

The qualitative data analysed in written form was interpreted and represented in a meaningful way to determine common themes during the study. In addition, the researcher also determined overlapping of the quantitative and qualitative data during analysis of this mixed method research study.

3.7 Reliability and Validity

Reliability and validity of the data collection instruments and process are fundamental, upon which the research findings are judged in a research study (Cormack, 2000).

Validity refers to the extent to which a research instrument measures what is intended to be measured. Reliability refers to the consistency with which the research instrument measures if the same study were repeated under similar conditions (Cormack, 2000).

Reliability and validity of the data collection instruments were tested during the pilot study to recognise and address any problems encountered. The pharmacist MTM forms (Appendix 2) was adopted from the Pharmacotherapy Workup document developed by Strand and colleagues (1998). The pilot study measured the internal consistency of the data collection instruments for this study setting.

The researcher collected data retrospectively and prospectively. This enabled the researcher to commence with a description of the patient's history from the folder and attempt to identify previously occurring causative factors. A unique code was assigned to each pharmacist's patient data sheet (Appendix 2) to enable the researcher to verify, cross-reference and link patient information from the diabetic folder.

The independent pharmacist who had administered the semi-structured questionnaire validated themes from the qualitative data.

3.8 Bias

In this evaluation study, concerted efforts were made to control for bias during the data collection process.

The researcher did not physically hand over the diabetic patient folders containing the pharmacist intervention label (Appendix 2) to either the doctor or CNP. This approach was adopted to reduce bias and ensure that the routine prescriber consultation practice pattern at the facility was not disrupted. The pharmacist provided medicine-related recommendations and re-evaluated diabetic patient

folders while obtaining the laboratory results. The pharmacist used the STGs and EML as a reference tool to evaluate the patient folders.

Convenience sampling method was used to conduct the study at the selected primary care facility to enable the researcher to access patient folders. However, to reduce bias, a random method for the selection of patient folders was used.

The researcher recruited an independent pharmacist assessor to engage with facility staff participants in administering the semi-structured questionnaire (Appendix 3) during the workshops and to assess their feedback about the pharmaceutical care process.

3.9. Ethical consideration

The data collection process commenced once ethical approval was obtained from the Biomedical Science Research Ethics Committee of the UWC (Ethic Reference Number: BM/16/4/11) (Appendix 7) and the Western Cape Department of Health (Reference: WC_2016RP43_75) (Appendix 8). The researcher wrote a letter of intent to the Facility Manager at this CDC to request permission to conduct the study at the health facility (Appendix 9). During the study, confidentiality was maintained for (a) diabetic patient folder data and (b) facility staff participants.

Informed consent was obtained from facility staff members who agreed to partake in the research study. An introductory workshop was provided and permission to audiotape the session was obtained before the start of the workshop. Staff members who agreed to participate in the study were given an informed consent form to sign (Appendix 5) and provided with an information leaflet (Appendix 4) of the study. Participants were also informed that they were required to complete a questionnaire at the end of the study period.

A pharmacist trained in facilitating workshops was approached to be an independent assessor for the feedback workshop at the end of the study period (Phase 7). The pharmacist administered a semi-structured questionnaire (Appendix 3) to facility staff participants to complete.

The researcher assured strict confidentiality by not discussing any of the patients information and data with anyone other than the staff at the CDC in a professional manner in the clinical setting. Only information from facility staff members who gave informed consent was used in the data transcription and analysis. The semi-structured questionnaire (Appendix 3) had a unique code that linked staff responses. Unique codes were also assigned on the pharmacist MTM forms (Appendix 2) used for the collection of quantitative data. The codes were only known to the researcher.

All data obtained and analyzed for the study was kept in a locked cupboard and was only accessible to the researcher to ensure confidentiality.

There were no direct risks and benefits anticipated for participants in this study. Participation was voluntary and participants were not paid for their time.

Informed consent was not taken from patients as the researcher monitored and evaluated patient data directly from diabetic patient folders, withoutany contact with the patients at the facility.

3.10. Conclusion of the chapter

This chapter described the research design and methods, the study setting, selection and recruitment of sample population, data collection process, analysis of quantitative and qualitative data, reliability and validity, and ethical consideration were discussed.

The next chapter describes and discusses the findings from the data obtained and analysed using the research methods described and discussed in this chapter.

CHAPTER 4: RESULTS AND DISCUSSION

This chapter presents and discusses the findings obtained from this study conducted during December 2016 to July 2017. An evaluation research design was used and the researcher collected quantitative and qualitative data at the CDC. The quantitative data analysis (Section A) discusses Phase 2 to Phase 6 (Figure 3.10) of the study. The qualitative results (Section B) discusses key findings from the workshops facilitated by the researcher and analyses of the responses from facility staff from the semi-structured questionnaire. In addition, an outline of the researcher's journey is provided.Lastly, limitations and challenges (Section C) encountered during the research study is discussed.

4.1 Section A: Quantitative results

The quantitative data in this sub-section discusses:

- Baseline demographics of stable diabetic patients,
- Physical measurements (BMI),
- Clinical measurements (blood pressure,fasting plasma glucose, urine dipsticktest analysis),
- Laboratory tests results (HbA1c, cholesterol, serum creatinine, and GFR),
- Description of the types of pharmacist-led interventions, outcomes and,
- Estimated costs associated with irrational prescribing

4.1 Demographic and pharmacological treatment of type 2 diabetic patients at baseline

For this study, the researcher recorded demographic data and pharmacological treatment on the pharmacist MTM data forms (refer to Appendix 2). Baseline data was analysed and the results are discussed and presented below.

4.1.1 Demographicdata of stable chronic diabetic patients

For this study, 104 diabetic club foldersof stable patients were reviewed, monitored and evaluated at a single CDC in Cape Town. The demographic characteristics

wereextracted from patient files and are summarised in Table 4.1 and discussed hereafter.

From the 104 diabetic patients files reviewed for this study, two thirds (67.3%) were females and a third (32.7%) were male patients (refer to Table 4.1). The global prevalence for diabetes (2017) was recorded to be slightly higher in men (8.9%) than in women (8.4%) (Cho et al., 2018). In a one-year study review conducted at a KwaZulu-Natal hospital the authors found that the prevalence of diabetes is higher in females (63.8%) than in males (36.2%) (Govender et al., 2017), which is reflective of the gender-based difference for diabetes among participants in this study.

Table 4.1: Baseline demographics of stable diabetic patients (n=104)

Baseline Demographics and Parameters	Number of Patients n (%)	Mean± Standard Deviation	Minimum-Maximum	Target Range
Demographics				
Gender *Male* *Female*	 34 (32.7%) 70 (67.3%)			 N/A N/A
Medicine allergies *Known#* *No known*	 10 (9.6%) 94 (90.4%)			N/A
Age in years *21-30* *31-40* *41-50* *51-60* *61-70* *71-80*	104 1 (1) 3 (2.9) 18 (17.3) 38 (36.5) 39 (37.5) 5 (4.8)	57.7 ± 9.22	26-80	N/A
Stable patients *Diabetes only* **Stable patients with co-morbidities** *Diabetes, Hypertension,Others* *Diabetes, Hypertension, Cholesterol, Others* *Diabetes, Hypertension*	 2 (1.9) 30 (28.8) 27 (26) 22 (21.2)			N/A

Diabetes,Hypertension, Cholesterol	16 (15.4)			
Diabetes, Others	3 (2.9)			
Diabetes,Cholesterol	2 (1.9)			
Diabetes,Cholesterol, Others	2 (1.9)			
Physical Parameters				
Height	102 (98.1)	1.614 ± 0.083	1.45-1.84	N/A
Weight	102 (98.1)	82.2 ± 18.5	52-148	N/A
BMI	94 (90.4)	32.3 ± 9.07	18.5-86	18.5-24.9kg/m^2
Clinical Parameters				
Systolic blood pressure	104 (100)	144 ± 19	100-187	<140mmHg
Diastolic blood pressure	104 (100)	82.8 ± 9.92	47-108	<90mmHg
Fasting plasma glucose *Acceptable* *Additional action suggested*	103 51 (49) 52 (50)	8.26 ± 3.14 5.759 ± 1.56 5.759 ± 2.218	2-16.6 2-7.9 8-16.6	N/A <8mmol/L >8mmol/L
Biochemical markers				
HbA1C (%) (2015) *Optimal* *Acceptable* *Additional action suggested*	43 (41.3) 9 (8.6) 6 (5.8) 28 (26.9)	8.64 ± 1.81 6.39 ± .04 7.57 ± 0.233 9.6 ± 1.47	5.7-14.2 5.7-6.9 7.2-7.9 8.2-14.2	 <7% 7-8% >8%
HbA1C (%) (2016) *Optimal* *Acceptable* *Additional action suggested*	54 (51.9) 12 (11.5) 12 (11.5) 30 (28.9)	8.59 ± 1.92 6.29 ± 0.43 7.43 ± 0.36 9.88 ± 1.37	5.5-12.8 5.5-6.9 7-8 8.1-12.8	 <7% 7-8% >8%
Total cholesterol (2015) **Total cholesterol (2016)**	44 (42.3) 54 (51.9)	4.35 ± 0.91 4.79 ± 1.18	2.67-6.71 2.58-8.69	<4.5mmol/L <4.5mmol/L
Serum Creatinine (2015) **Serum Creatinine (2016)**	43 (41.3) 58 (55.8)	68.8 ±27.2 67 ± 25.6	40-145 34-172	49-90umol/L 49-90umol/L
eGFR (2015) **eGFR (2016)**	42 (40.4) 59 (56.7)	130 ± 68 121 ± 57	31-353 32-386	>60 mL/min >60 mL/min

[#]Known medicine allergies of patients= enalapril, metformin, glimepiride, penicillin, co-trimoxazole, aspirin
Others=Osteoarthritis, Chronic obstructive pulmonary disease, Ischaemic heart disease, Gout.
BMI=Body Mass index
eGFR indicates estimated Glomerular Filtration Rate

Diabetic patients were categorized according to age range depicted in Table 4.1. with the mean age of 57.7± 9.22 years. The minimum and maximum ages of the diabetic patients were 26 and 80 years old, respectively. More than a third of the diabetic patients were found between the ages of 51 to 60 years (36.5%) and 61 to 70 years (37.5%). Only 1% of the patients were between 21-30 years of age. In 2017, global diabetes estimates by IDF were most prevalent in adults aged between 18-99 years with 451 million diabetes cases (Cho et.al, 2018). In 2009, approximately 2 million (9%) South Africans aged 30 years and older had diabetes, concurring with the findings from this study (Bertram et al., 2013).

Of the 104 diabetic folders reviewed, almost 10% (n=10) of the patients were noted to have medicine allergies (refer to Table 4.1). The known medicine allergies consisted of enalapril, metformin, glimepiride, penicillin, co-trimoxazole and aspirin. This figure is slightly lower than that reported in a Hong Kong study (Chung et al., 2017) which found that 14.2 % of patients had known medicine allergies at the diabetes clinic.

A total of 8 co-morbidities were recorded from the 104 diabetic patient folders that were reviewed. The average co-morbidities were 1.2 per patient. Over a quarter (28.8%) of diabetic patients were noted to have more than one co-morbidity namely, hypertension and other chronic conditions (28%) and, hypertension, cholesterol and other chronic conditions (26 %). Table 4.1 outlines a breakdown of the co-morbidities noted during this study. Werfalli et al. (2018) found that at least twofold of South Africans had higher rates of coexisting chronic conditions with diabetes than those without diabetes. The study also found that diabetes was associated with poor quality of life and disability in older South African adults (Werfalli et al., 2018). In this study, 1.9% of patients were identified with only type 2 diabetes. In comparison, higher figures were reported in studies conducted in Malaysia and at primary care health centers in Cyprus: 9.4% and 23%of patients who had only type 2 diabetes; 20,8% and 21.6% patients had type 2 diabetes, hypertension and cholesterol; and 18.4% and 10.5% had diabetes and cholesterol , respectively (Chua et al., 2012; Zachariadou et al., 2006)

The mean ± standard deviation BMI (kg/m^2) reported in this study was 32.3 ± 9.07. This is slightly higher than that found in a Western Cape study which reported the mean BMI of 32 ± 7.3 in a diabetes group (Folb et al., 2015). The main factors causing obesity are high fat foods, large portion size and low physical activity (Yumuk et al., 2015). Overweight and obesity are recognized as the main risk factors for the emergence of non-communicable diseases such as type 2 diabetes (Kengne et al.,2013). In 2000, the study by Joubert and colleagues (2007) found that 87% of type 2 diabetes cases were attributed to excess body weight (Joubert et al., 2007).

The mean ± standard deviation systolic blood pressure (mmHg) and diastolic blood pressure (mmHg) in this study was 144 ± 19 and 82.9 ± 9.92. The mean systolic

blood pressure is slightly above the target range as indicated in the PHC STGs and EML (NDoH, 2014). The findings of blood pressure for this study concur with the findings reported in a KwaZulu-Natalstudy which reported that the mean ± standard deviation systolic blood pressure and diastolic blood pressure to be 146 ± 22.4 and 82.7 ± 12.6 respectively in type 2 diabetes mellitus patients at the first visit (Govender et al., 2017). Despite these findings, a cross-sectional cohort study conducted by Amod et al. (2012) in South Africa found the blood pressure of South African patients' were relatively controlled who had a mean ± standard deviation systolic blood pressure 131 ± 17.3 and a mean diastolic blood pressure of 79.4 ± 10.2 in comparison to studies done elsewhere in the world.

The mean HbA1c (%) for this study was 8.64% and mean fasting plasma glucose was 8.26 mmol/L which is above the recommended target ranges. The mean HbA1c for this study concurs with the findings of a cross-sectional study conducted at three academic teaching hospital diabetic clinics in Gauteng, where the mean HbA1c was noted at 8.7% (Klisiewicz & Raal, 2009). These findings are higher than those found in anAmerican study that reported a mean HbA1c of 7.43% (Coon & Zulkowski, 2002). An audit study conducted at two Maltaprimary healthcare centres found a higher mean fasting plasma glucose of 9.56 mmol/L (Cutajar, 2008)than that reported in this study. The findings from this study and international studies demonstrate that diabetes management is sub-optimal as the recommended target ranges are not being achieved (Klisiewicz & Raal, 2009;Cutajar, 2008).

The mean ± standard deviation measurement for total cholesterol (mmol/L) at baseline for the diabetic patients in the year 2015 and 2016 was 4.35 ± 0.91and 4.79 ± 1.18 respectively. The findings for 2016 are notably above the recommended target levels of less than 4.5mmol/L. Both the figures are lower than that reported in a Cape Town randomized controlled trial study, where the mean ± standard deviation for total cholesterol for the diabetes intervention group was 5.7 ± 1.4 (Steyn et al., 2013). For this study almost half of the diabetic patient folders reviewed, that being forty-seven (45.2%), had high cholesterol.In comparison to international studies performed in Czech (2005) and Norway (2008) which consisted of large diabetic study groups showed poor achievement of cholesterol control (Škrha& Ambos, 2005; Jenssen et al., 2008). Hence, developed and developing countries are affected by the global challenge of managing the complex combination of diabetes and dyslipidemia (Daya et al., 2017).

For the type 2 diabetic patients folders reviewed, the mean ± standard deviation serum creatinine (umol/L) reported for 2015 and 2016 was 68.8 ± 27.2 (minimum-maximum range 40-145) and 67 ± 25.6 (minimum-maximum range 34-172). The mean ± standard deviation (60 mL/min) for 2015 and 2016 was 130 ± 68 and 121 ± 57. The findings of this study are comparable to the study conducted by Steyn, et al. (2013) in Cape Town who reported a higher mean ± standard deviation serum creatinine for the diabetes intervention and control group which was 84.2 ± 37.7 and 87.8 ± 63.2 respectively. In contrast, a cross-sectional study at two Abu Dhabi

tertiary hospitals for type 2 diabetic patients also reported higher figures for the mean ± standard deviation serum creatinine, 92.63 ± 84.43 (Jelinek et al., 2017). However, the eGR mean ± standard deviation documented by Jelinek et al. (2017) was reported to be lower, 81.09 ± 28.26, than that found in this study. The diabetic complication, nephropathy, can be determined by the marker eGFR (Jelinek et al., 2017). A meta-analysis study suggested low eGFR(less than 60 mL/min) may be an independent risk factor for mortality in type 2 diabetic patients (Toyama et al., 2013).

4.1.2 Pharmacological treatment of type 2 diabetic patients at baseline

The pharmacological treatment prescribed for stable type 2 diabetic patients at baseline are shown in Table 4.2.

From the 104 diabetic folders reviewed, metformin was the most commonly prescribed antidiabetic agent in 93 (89.4%) of the patients, either prescribed as monotherapy or in combination. This findings concur with international and South African guidelines, where the biguanide, metformin, is the recommended first-line pharmacological treatment for type 2 diabetic patients (ADA ,2013; NDoH, 2014). Approximately 63% of patients were prescribed only one or more oral agents, while 39.4% were prescribed insulin with or without an antidiabetic oral agent. The findings of this study are slightly higher than that found in a Cape Town study which found 60% of diabetic participants were prescribed an antidiabetic agent (without insulin) and 32% were prescribed insulin (with or without antidiabetic agents) (Folb et al., 2015).

Diabetic patients who were hypertensive, were most commonly prescribed angiotensin-converting enzyme inhibitors (62.5%) and calcium channel blockers (62.5%). In this study, a higher percentage, that is, 80% were prescribed more than one antihypertensive medicine while a lower percentage, 60% was noted in the Cyprus study (Zachariadou et al., 2006).

For this study, at baseline, 90 (86.5%) patients were prescribed a statin, namely, simvastatin. Despite the use of simvastatin, the baseline results indicate that the current PHC STGs recommended targets for total cholesterol are still not being met in diabetic patients. Aspirin was prescribed in more than three quarters (79.8%) of the patients and medicines for co-morbid conditions was prescribed in two-thirds (66.3%) of diabetic patients. In comparison to this study, a Greek study showed that fewer diabetic patients were prescribed a statin and aspirin, 76.5% and 15.4%, resepctively (Zachariadou et al., 2006).

Table 4.2: Pharmacological treatment in type 2 diabetic patients at baseline

Medicine treatment	Number of patients n (%) n=104
Antidiabetic medicine	
Biguanides –(Metformin oral)	93 (89.4)
Sulphonylureas (Glimepiride oral)	45 (43.3)
Insulin	38 (36.5)
Number of antidiabetic medicine	
1 oral medicine	33 (31.7)
2 oral medicines	32 (30.8)
Insulin and 1 oral medicine	27 (26.0)
Insulin and 2 oral medicines	7 (6.7)
Insulin alone	7 (6.7)
Anti-hypertensive medicine	
Angiotensin-converting enzyme inhibitors	65 (62.5)
Calcium channel blockers	65 (62.5)
Thiazide diuretics	56 (53.8)
Beta blockers	25 (24.0)
High-ceiling diuretics	27 (26.0)
Angiotensin receptor blockers	1 (1)
Number of antihypertensive medicines	
1	10 (9.6)
2	32 (30.8)
3	43 (41.3)
4	10 (9.6)
5	1 (1)
Statin (simvastatin)	90 (86.5)
Aspirin	83 (79.8)
Other medicines	69 (66.3)

4.2 Physical, clinical and biochemical parameters

The researcher recorded physical, clinical and biochemical parameters on the pharmacist MTM data forms (refer to Appendix 3). During the three phases of the data collection process, namely, baseline, post-pharmacist intervention, and 6-month follow-up, the results extracted for these parameters are discussed below.

4.2.1 Body Mass Index

The BMI readings recorded of the diabetic patients folders reviewed at baseline, post-pharmacist intervention and at 6-month clinic follow-up are shown in Table 4.3).The diabtetic patient's BMI was calculated using the Quetelet's formula: weight (kg)÷ height (m^2) (SEMDSA, 2012). This was important to make dosage adjustments to patients

Table 4.3: Body Mass Index recorded from diabetic patient folders

Record of BMI (kg/m^2) in diabetic patient age groups (years)	Number (%) of diabetic patients		
	Baseline data (n=104)	Post-pharmacist intervention (n=104)	6-month-follow up (n=104)
21-30 (years)			
No record of BMI reading	0	1 (1)	1 (1)
*BMI record *18.5-24.9*	0	0	0
BMI record *25.0-29.9	0	0	0
BMI record *30.0-34.9	0	0	0
BMI record *35.0-39.9	0	0	0
BMI record *>40	1 (1)	0	0
31-40 (years)			
No record of BMI reading	0	2 (1.9)	3 (2.9)
18.5-24.9	0	0	0
25.0-29.9	0	0	0
30.0-34.9	1 (1)	1 (1)	0
35.0-39.9	0	0	0
>40	2 (1.9)	0	0
41-50 (years)			
No record of BMI reading	2 (1.9)	15 (14.4)	18 (17.3)
18.5-24.9	1 (1)	1 (1)	0
25.0-29.9	6 (5.8)	1 (1)	0
30.0-34.9	5 (4.8)	5 (4.8)	0
35.0-39.9	0	0	0
>40	4 (3.8)	1 (1)	0
51-60 (years)			
No record of BMI reading	3 (2.9)	25 (24)	36 (34.6)
18.5-24.9	3 (2.9)	0	0
25.0-29.9	12 (11.5)	4 (3.8)	0
30.0-34.9	4 (3.8)	4 (3.8)	0
35.0-39.9	4 (3.8)	2 (1.9)	0
>40	3 (2.9)	0	0
61-70 (years)			
No record of BMI reading	5 (4.8)	35 (33.6)	41 (39.4)
18.5-24.9	3 (2.9)	0	0
25.0-29.9	15 (14.4)	1 (1)	0
30.0-34.9	6 (5.8)	0	0
35.0-39.9	7 (6.7)	1 (1)	0
>40	3 (2.9)	0	0
71-80 (years)			
No record of BMI reading	0	4 (3.8)	5 (4.8)
18.5-24.9	1 (1)	0	0
25.0-29.9	3 (2.9)	1 (1)	0
30.0-34.9	1 (1)	0	0
35.0-39.9	0	0	0

>40	0	0	0
Total: no record of BMI reading	***10 (9.6)***	***82 (78.7)***	***104 (100)***
Total: record of BMI reading	***94 (90.4)***	***22 (21.3)***	***0***
BMI= Body Mass Index; ** 18.5-24.9 kg/m^2=normal; 25.0-29.9 kg/m^2=overweight; 30.0-34.9 kg/m^2=mildly obese; 35.0-39.9 kg/m^2=moderately obese; >40 kg/m^2=extremely obese*			

considered obese with a BMI of more than 30kg/m^2(Rossiter et al., 2016). Findings were grouped according to the BMI category (18.5-24.9, 25.0-29.9, 30.0-34.9, 35.0-39.9 and >40 kg/m^2), as listed in the PHC STGs and EML (NDoH, 2014) and age groups (21-30, 31-40, 41-50, 51-60, 61-70 and 71-80) for this study.

At baseline, only 8 (7.8%) of diabetic patients were noted to have a normal BMI reading (18.5-24.9 kg/m^2) between the age groups, 41-50 years (1%), 51-60 years old (2.9%), 61-70 years old (2.9%) and 71-80 years old (1%). Documented BMI showed that 36 (34.6%) of the diabetic patients were overweight (25.0-29.9 kg/m^2), while 41 (39.4%) were above 30kg/m^2 and considered obese. Furthermore, 14 (13.4%) of those diabetic patients had a BMI reading of more than 40, a category classified in the PHC STGs and EML as extremely obese (NDoH, 2014). A cross-sectional study conducted at a public tertiary hospital in Johannesburg in type 2 diabetic patients reported that 15.5% of patients had a normal BMI reading, 20.5% were overweight and 61.5% were obese (Daya et al., 2017). The problem of obesity was also observed in other South African studies conducted in the Gauteng province by Webb et al. (2015) and Klisiewicz & Raal (2009), who reported obesity in 51% and 37.3% in diabetic patients, respectively. Similarly in an international study done by Jelinek et al. (2017) in Abu Dhabi, more than half of the diabetic patients (58.47%) were reported to be obese.

At post-pharmacist intervention, only 1 patient (1%) from the diabetic folders reviewed had a normal BMI reading (18.5-24.9 kg/m^2), while 7 (6.7%) diabetic patients were overweight (25.0-29.9 kg/m^2) and 14 (13.6%) were obese (above 30 kg/m^2). Unaccounted BMI readings at post-pharmacist intervention were 82 (78.7%) and at patients 6-month follow-up clinic visit it was 104 (100%). According to Table 4.1, at baseline 102 (98.1%) diabetic patients height was recorded. If the diabetic patient's weight or height is not recorded in their folder, as reported in this study, consequently the researcher was unable to calculate the BMI. In comparison to this study, an audit study conducted at four health clinics and hospital in Porchefstroom, North-West Province, reported that a height measurement was checked and BMI calculation was done in 57% of patients, which is lower than that reported at baseline in this study (Siko & van Deventer, 2017).The BMI findings of this study's post-pharmacist intervention are similar to that of an American study in which the researchers had noted poorly documented BMI readings and missing height information in clinical records with only 60.5% of patients having had their BMI

recorded in the study (Rose et al., 2009). The BMI findings of this study at 6-month follow-up clinic visit concur with the findings from a Kwazulu-Natal study which highlighted that in almost all (99%) patients, their BMI readings were not recorded (Igbojiaku et al. 2013).

BMI is an important physical measurement that should be part of the prescriber's assessments during all chronic patient clinic visits at the primary care level. The calculation is simple and inexpensive. The calculated BMI readings can be categorized to assess obesity status and cardiovascular risk factors (Rose et al., 2009). Further, the omission of physical measurements during routine clinic visits, compromises timeous adjustments to medicine doses or alternative regimens being prescribed (Rose et al., 2009; Igbojiaku et al., 2013).

4.2.2 Clinical parameters and laboratory tests

The clinical parameters considered for this study was blood pressure (mmHg), fasting plasma glucose (mmol/L), and urine dipstick testing (glucose, ketones, and proteins). These are summarised in Table 4.3. These tests should be performed at each clinic visit as part of the routine examination.

For this study, the systolic and diastolic blood pressure was recorded in all patients at baseline and post-pharmacist intervention. At baseline, of the 104 patients folders reviewed, 44.2% of patients had systolic blood pressure at or below 140 mmHg and 82.7% had a diastolic pressure at or below 90 mmHg, respectively. At the 6-month follow-up, there was an improvement in systolic blood pressure control in 50% of patients, but a reduction to 74% of patients was noted in diastolic blood pressure control. These results are comparable to studies done by Igbojiaku et al. (2013) in Kwa-Zulu Natal and Akel & Hamadeh (1999) in Lebanon. Igbojiaku et al. (2013) reported poor blood pressure control in type 2 diabetic patients, in which only 39.6% and 38.7% of patients had met the systolic blood pressure and diastolic blood pressure targets respectively. Akel & Hamadeh (1999) found optimal or acceptable blood pressure control for both systolic (84.5%) and diastolic (74.8%) readings. Blood pressure was recorded for 104 (100%) patients at baseline and post-pharmacist intervention. The findings of this study are similar to a Saudi Arabian study which noted that, blood pressure measurements were recorded in almost all diabetic patients (98.7%) at a PHC centre (Al-Musa, 2013). At the 6-month follow-up, 90 (86.5%) patients' systolic and diastolic blood pressure readings were recorded. In contrast, a South African study in the Tshwane district recorded blood pressure readings for two-thirds (66.8%) of patients (Webb et al., 2014). Blood pressure control for the management of type 2 patients is recommended in the PHC STGs and EML (<140/90mmHg) as the risk factor, hypertension, is a predictor for the incidence of microvascular and macrovascular complications (Jelinek et al., 2017).

Table 4.4: Summary of clinical and laboratory parameters analysed at baseline, post-pharmacist intervention and at 6-month follow-up in type 2 diabetic patients

Parameter	Number (%) of clinical, physical and laboratory tests		
	Baseline data n=104 (100%)	**Post-pharmacist intervention n=104 (100%)**	**6-month-follow up n=104 (100%)**
Clinical parameters			
Systolic blood pressure			
No record of test performed	0	0	14 (13.5)
Test performed:>140 mmHg	58 (55.8)	48 (46.2)	38 (36.5)
Test performed:<140 mmHg	46 (44.2)	56 (53.8)	52 (50)
Diastolic blood pressure			
No record of test performed	0	0	14 (13.5)
Test performed: >90 mmHg	18 (17.3)	20 (19.2)	13 (12.5)
Test performed:<90 mmHg	86 (82.7)	84 (80.8)	77 (74)
Fasting plasma glucose			
No record of test performed	1 (1)	0	14 (13.5)
Test performed: >8mmol/L	50 (48.1)	58 (55.8)	56 (53.8)
Test performed:<8mmol/L	53 (51.9)	46 (44.2)	34 (32.7)
Urine dipstick test analysis			
No record of test performed	0	0	14 (13.5)
Test for glucose Normal/Negative Positive	 64 (61.5) 40 (38.5)	 64 (61.5) 40 (38.5)	 54 (51.9) 36 (34.6)
Test for ketones Normal/Negative Positive	 103 (99) 1 (1)	 103 (99) 1 (1)	 89 (85.5) 1 (1)
Test for proteins Normal/Negative	 89 (85.6)	 96 (92.3)	 76 (73)

Positive	15 (14.4)		8 (7.7)	14 (13.5)
Biochemical parameters	**Baseline data n=104 (100%)**		**Post-pharmacist intervention n=104 (100%)**	**6-month follow-up n=104 (100%)**
Glycosylated Haemoglobin (%)				
No record of test performed	7 (6.7)		71 (68.3)	79 (76)
	Year 2015	**Year 2016**	**Year 2016**	**Year 2017**	**Year 2017**
Test performed: <7% Optimal	9 (8.7)	12 (11.5)	4 (3.8)	2 (1.9)	5 (4.8)
Test performed: 7-8% Acceptable	5 (5.8)	12 (11.5)	0	3 (2.9)	4 (3.8)
Test performed: >8% Additional action suggested	28 (26.9)	30 (28.9)	3 (2.9)	21 (20.2)	16 (15.4)
Total cholesterol mmol/L					
No record of test performed	6 (5.8)		71 (68.3)		83 (79.8)
	Year 2015	**Year 2016**	**Year 2016**	**Year 2017**	**Year 2017**
Test performed:< 4.5 mmol/L	27 (26)	23 (22.1)	0	10 (9.6)	11 (10.6)
Test performed:>4.5 mmol/L	17 (16.3)	31 (29.8)	9 (8.6)	14 (13.5)	10 (9.6)
Serum Creatinine					
No record of test performed	3 (2.9)		71 (68.3)		79 (76)
	Year 2015	**Year 2016**	**Year 2016**	**Year 2017**	**Year 2017**
Test performed:<49 umol/L	6 (5.8)	13 (12.5)	2 (1.9)	5 (4.8)	2 (1.9)
Test performed: 49-90 umol/L	33 (31.8)	39 (37.4)	5 (4.8)	15 (14.4)	21 (20.2)
Test performed: >90 umol/L	42 (40.4)	6 (5.8)	0	6 (5.8)	2 (1.9)
Glomerular Filtration Rate (mL/minute/1.73m²)					
No eGFR calculated	3 (2.9)		71 (68.3)		79 (76)
Stages and Kidney function	**Year 2015**	**Year 2016**	**Year 2016**	**Year 2017**	**Year 2017**
eGFR:>90 mL/min (normal)	33 (31.8)	42 (40.4)	6 (5.8)	16(15.3)	17 (16.3)
eGFR: 60-89 mL/min (mild)	4 (3.8)	12 (11.5)	1 (1)	3 (2.9)	6 (5.8)
eGFR: 30-59 mL/min (moderate)	5 (4.8)	5 (4.8)		4 (3.8)	2 (1.9)
eGFR: 15-29 mL/min (severe)				3 (2.9)	

The FPG mean at baseline was slightly above the target value of 8mmol/L for this study. From the baseline results, 54 (51.9%) patients were within the target range, whereas more than half of the patients (55.8%) had an uncontrolled FPG reading at post-pharmacist intervention and at 6-month follow-up (53.8%) which was above the recommended target value. The findings of this study show improved fasting plasma glucose control in comparison to international studies done in the United Arab Emirates (Shehab et al., 2012) and Cyprus (Zachariadou et al., 2006) which found 45.7% of patients at baseline and 44.6% of patients, respectively were within the target range. For this study, at the 6-month follow-up visit, 90 (85.5%) patients had their fasting glucose recorded. In contrast to a Cape Town study(98.9%) and a Malaysian study(97.2%), the fasting glucose readings had been recorded in more diabetic patients , respectively (Steyn et al., 2008, Sazlina et al., 2010) than that noted in this study. The fasting plasma glucose test is important as the test can detect diabetes and prediabetes stages, diagnose diabetes and predict early mortality and high risk of microvascular and cardiovascular complications (Alberti & Zimmet et al., 1998).

The urine dipstick test analysis for glucose, showed a slight decrease amongst patients analyzed at pharmacist post-intervention (38.5%) when compared to 6-month follow-up (34.6%) in this study. However, for proteins, the results were found to be similar at baseline (14.4%) and at 6-month follow-up (13.5%), while the percentage of patients who had ketones (1%) present, remained unchanged. In this study, the urine dipstick test analysis figures for the presence of glucose was notably lower at baseline (38.5%), post-pharmacist intervention (38.5%) and 6-month follow-up (34.6%), than that reported in aCape Town study which reported glucose present in most (88.9%)of the patients (Levitt et al., 1996).More patients were identified with proteinuria in this study at baseline (14.4%), at post-pharmacist intervention (7.7%) and at 6-month follow-up(13.5%), than that compared to a Malta study which reported proteinuria in 3% of patients (Cutajar, 2008).Urine dipstick analysis was performed in all 104 (100%) patients at baseline and at post-pharmacist intervention and in 90 (85.5%) patients at 6-month follow-up. A Lebanese study showed similar findings to this study in which almost all patients (88.7%) had a urinalysis test performed (Akel & Hamadeh,1999), while a Gauteng study conducted in the Tshwane district showed a poor urinalysis record for 60% of patients in the preceding year of the study (Webb et al.,2015). Persistent proteinuria was not considered for this study. Persistent proteinuria occurs in patients with an underlying condition such as diabetes whereupon testing urine dipstick proteins are present on three or more consecutive occasions over an 18 month period (Motala et al., 2001). A retrospective analysis study done in Kwa-Zulu Natal, reported that 25% of type 2 diabetes patients who have had diabetes for longer than 10 years had persistent proteinuria (Motala et al.,2001). It is rare and thus performing a urine analysis test can detect early signs of diabetic nephropathy (Tumbo & Kadima, 2013).

Reviewing the clinical parameters (blood pressure, FPG, and urine analysis) for this study at 6-month follow-up found that 14 (13.5%) patients did not attend their follow-up club visit. Possible causes for the lack of attendance could be due to long waiting times, a reflection of poor patient management of the condition or travelling costs to the facility (Levitt et al., 1996). In contrast to this study, a Cape Town study noted poor clinic attendance patterns, as only a third (35%) of patients attended all clinic visits (Levitt et al., 1996).

Table 4.5: Emergency cases reported (2016-2017) for uncontrolled blood pressure and uncontrolled fasting plasma glucose amongst stable diabetic patients for this study

		n (%)
Reason for emergency case	**Date of admission**	**Number of patients from study sample (n=14)**
Uncontrolled blood pressure (mmHg)		4 (3.8)
	14 June 2016 19 January 2017 26 January 2017 09 February 2017	
Uncontrolled fasting plasma glucose (mmol/L)		10 (9.6)
	10 March 2016 07 December 2016 15Decemeber 2016 12 January 2017 19 January 2017 21 January 2017 27 January 2017 03 February 2017 10 February 2017 23 February 2017	

Diabetic patients who were considered stable were included in the study sample. Of the 104 patient folders reviewed, 14 (13.5%) patients were admitted to the emergency unit at the CDC for uncontrolled blood pressure (n=4) and uncontrolled fasting glucose (n=10) as shown in Table 4.5. The findings of emergency admissions are much higher than that reported in a Cape Town audit study, whereby 5 (0.2%) emergency admissions were due to the presence of ketones (n=2) and non-diabetes-related conditions (n=3) (Levitt et al., 1996). Regular follow-up visits which

record patient's vital readings such as blood pressure, fasting glucose and urine dipstick analysis are crucial in preventing emergency admissions. In addition, such clinical measurements enable healthcare providers to institute appropriate therapy, aimed at minimizing diabetic complications (Steyn et al., 2008)

The primary objective of this study was to measure the change in the biochemical marker, HbA1c at baseline, to post-pharmacist intervention and at 6-month follow-up. Additional laboratory tests included total cholesterol, serum creatinine and following calculation of eGFR. Table 4.4 contains the number of recorded laboratory data for diabetic patient folders reviewed for this study at baseline (2015-2016), post-pharmacist intervention (2016-2017) and at 6-month follow-up (2017). The primary measurement was determined from the 2016-2017 dataset.

Biochemical markers enable health care professionals like pharmacists to make timeous therapeutic recommendations and absence of laboratory data impedes the decision to respond appropriately to abnormal results which could lead to uncontrolled diabetes (Igbojiaku et al., 2013). Therefore, pharmacists working in PHC facilities who are trained in interpreting laboratory results can work closely with clinicians to make appropriate therapeutic recommendations (Sazlina et al., 2010).

For this study, from baseline (20.2%), post-pharmacist intervention (5.7%) to 6-month follow-up visit (4.8%), only 32 patients had optimal HbA1c values of less than 7%, while 24 (17.3%, 2.9% and 3.8%) patients had acceptable Hba1c values at or between 7% to 8%, and poor glycaemic control was noted in 98 patients (55.8%, 23.1% and 15.4%) who had an HbA1c value of more than 8%, respectively. Acceptable HbA1c values obtained in this study are lower than that reported among patients in the Gauteng study (30.7%) (Klisiewicz & Raal, 2009) and in Lebanon(28.4%) (Akel & Hamadeh, 1999). The findings from this study are comparable to international studies wherean American study, found that 30% of patients required additional action for their diabetic condition, based on HbA1c values of more than 8% (Coon & Zulkowski, 2002), while higher figures were reported in a Cyprus study that found 77.4 % of patients with poor glycemic control, withHbA1c levels recorded at or above 8% (Zachariadou et al., 2006). At baseline, almost all 97 (93.3%) patients had their HbA1c performed and recorded while only a third, 33 (31.7%) were noted atpost-pharmacist intervention and only a quarter 25 (24%) had a recording done at 6-month follow-up. The findings from this study at baseline are similar to that reported at the Rustenburg provincial Hospital in the North West Province (Tumbo & Kadima, 2013) who found 95.6% of patients had their HbA1c checked. Post-pharmacist intervention and at 6-month follow-up results are consistent with the findings from studies conducted in the Eastern Cape (Erasmus & Blanco-Blanco, 2000) and in Malaysia at a primary care clinic (Sazlina et al., 2010) who reported 24% and 27% of diabetic patients respectively had their HbA1c recorded. The results from this study suggest that glycemic control in diabetic patients is sub-optimal and there is poor compliance with the performance of HbA1c testing. HbA1c measurement is a useful investigation to determine the development

of undesirable macro-and micro-complications in diabetic patients (ADA, 2013). The PHC STGs and EML recommend that the HbA1c test be done annually in diabetic patients. Patients who are unstable should have the test performed 3 to 6 monthly (NDoH, 2014). Alternative cost-saving glucose measurements are undertaken from finger-prick blood glucose levels or urine dipstick analysis, but HbA1c is identified as the most reliable tool to date. Such a biochemical marker would serve as a useful reference tool for pharmacists to evaluate prescribed medicine therapy in accordance with guideline recommendations.

In this study, 71 diabetic patients total cholesterol from baseline up to 6-month follow-up (48.1%, 9.6% and 10.6% respectively), met the target range of less than 4.5mmol/L. However, poor control (more than 4.5mmol/L) was noted in 48 (46.1%) patients at baseline, 23 (21.1%) at post-pharmacist intervention and 10 (9.6%) at 6-month follow-up, respectively. The baseline findings for this study are similar to other South African studies where a Kwazulu-Natal study found that 44.2% of patients had normal total cholesterol values (Igbojiaku et al., 2013) whilst a North West Province study reported 25.6% of patients total cholesterol results were not within the recommended range (Tumbo & Kadima, 2013).The total cholesterol measured in patients from baseline (94.2%), post-pharmacist intervention (31.7%) and at 6-month follow-up (20.2%) clinic visit in this study, showed a gradual decline in accountable readings. The latter two figures are very low when compared to aBosnia and Herzegovina study conducted at primary health centers where almost three-quarters (72.9%) of diabetic patients had their total cholesterol test performed. (Novo & Jokić, 2008). Yet, the finding from a Western Cape study conducted at CHCs noted that only 6.4% of diabetic patients had a total cholesterol measurement recorded (Steyn et al., 2008). The PHC STGs and EML recommend total cholesterol be performed annually in diabetic patients (NDoH, 2014).

In this study, at baseline, over two-thirds (69.2%) of the diabetic patients'serum creatinine levels were within the range of 49 to 90µmol/L during the period 2015 to 2016. These findings concur with the findings from a Malta study in which 60.9% of the study participants were within the target range (Cutajar, 2008). An increased serum creatinine level was found in this study for 48 (46.2%) patients at baseline during 2015 to 2016, 6 (5.8%) at post-pharmacist intervention and 2 (1.9%) at 6-month follow-up clinic visit, respectively. A UK study performed in four general practices in Newcastle, noted a lower figure of increased serum creatinine levels among 11% of diabetic patients (Tunbridge et al., 1993). Inconsistent recording of serum creatinine tests performed for patients in this study was observed from baseline to 6-month follow-up visit (97.1%, 31.7% and 24%). Similar to the baseline results obtained from this study were found in other studies which reported consistent serum creatinine tests performed (86.8% and 75%, respectively) amongst diabetic patients (Akel & Hamedeh,1999; Tunbridge et al., 1993).

For this study, the eGFR was calculated using the Cockroft-Gault equation (Rossiter et al., 2016) in this study. Poor eGFR (less than 90mL/min) was found in almost a

quarter (24.9%) of patients at baseline (period 2015 to 2016), 10.6% at post-pharmacist intervention and 7.7% at 6-month follow-up visit, which is much lower than that reported in a South African study and United Emirates study who found poor estimated GFR (42% and 53.58%) in type 2 diabetic patients, respectively (Motala et al., 2001; Jelinek et al., 2017). In this study, a poor record of eGFR calculation was found at post-pharmacist intervention (68.3%) and at 6-month follow-up (76%), while a study by Jelinek et al. (2017), reported an eGFR record in 91.02% of patients. Diabetes remains the leading cause in end-stage kidney failure which has necessitated the need for screening for chronic kidney disease in diabetics (Kramer & Molitch, 2005). Therefore, measurement of eGFR to determine kidney function should be done regularly in diabetic patients at clinic visits (Rossing et al., 2006). The PHC STGs and EML recommends that an annual laboratory investigation for serum creatinine be performed and eGFR be calculated for diabetic patients (NDoH, 2014).

The facility's staff nurse consistently recorded the clinical parameters which are noted in Table 4.4.However, laboratory tests were not requested routinely by clinicians at the patient's clinic visits, and such incomplete information obscures prescribing staff from detecting abnormalities timeously in diabetic patients, inevitably leads to inappropriate prescribing and predisposes patients to diabetic complications. This study demonstrated the incompleteness of medical records in diabetic patient folders (refer to Table 4.4) and concurs with other South African studies. A Kwa-Zulu Natal and Cape Town study have shown that laboratory tests were seldom requested (Igbojiaku et al., 2013; Levitt et al.,1996), whilst studies in the Cape Town Metropole and Ugu district of Kwa-Zulu Natal encountered poor record keeping at the health facilities (Isaacs et al., 2015; Govender et al., 2017). Performing and recording a diabetic patient's physical measurements, clinical and laboratory tests are crucial to enable pharmacists to assess the effectiveness and safety of medicine therapy prescribed in accordance with the PHC STGs and EML recommendations.

One technological barrier encountered at the CDC was intermittent network access to laboratory services which prevented prescribers and pharmacists to assess laboratory tests to make timeous adjustments to the patient's medicine therapy during club visits. Findings from another study attested that staff working in public sector facilities were exposed to high volume patients, limited equipment and budgetary constraints for laboratory testing (HbA1c) (Steyn et al., 2013). A Gauteng study revealed that nursing staff expressed their need to have all computer programs connected at the clinic for improved patient management at the primary care level (Xaba et al., 2012).

4.2.3 Statistical analysis of study findings using sample t-test

The prescribing cohort consisted of doctors (n=2) and CNP's (n=2). The comparison of acceptance and rejection of pharmacist-led interventions between the two cohort groups could not be statistically analysed. Details of the overall acceptance and rejection of the pharmacist-led interventions is discussed in Section 4.3.2.

No statistical significant correlation between the pharmacist intervention and any of the clinical parameters and laboratory tests were found when using the Paired sample t-test, consequently, resulting in no conclusive findings. An example illustrating the statistical testing done for the clinical parameters, systolic blood pressure, diastolic blood pressure, fasting glucose and urine dipstick analysis was analyzed for the MTP *Synergistic/potentiating effects of medicines* and the outcome. The paired sample t-test was applied, indicating a significance of $p<0.05$ and is tabulated in Appendix 10.The complete data set (65 pages) for the specified clinical parameters are available on request.

4.3 Pharmacist-led interventions in medicine therapy management

During the research study period, the researcher identified several medicine-related concerns while reviewing the diabetic patient folders. The MTM data collection process enabled the pharmacist to optimize patient care through the pharmacist-led interventions and provide medicine therapy adjustments in accordance with the guidelines (recommendation) to the prescribers. This sub-section describes and discusses the results analyzed during phase 4 and phase 5 of the pharmacist MTM data collection process as shown in Figure 3.9 of Chapter 3. Table 4.6 provides details of the pharmacist-led interventions of MTM performed and analyzed.

4.3.1 Description of types of medicine therapy problems encountered by the pharmacist

Of the 104 folders reviewed, 453 interventions were identified, resulting in an average of 4 interventions per patient. Similarly, a high intervention average per diabetic patient (4.1) was achieved in a Denmark study (Haugbølle & Sørensen, 2006), but a much lower average (1.9) was noted in a Malaysian study (Huri & Wee, 2013).

From the 35 MTP types used for this study, only 11 MTP types (refer to Table 4.6) were identified by the pharmacist during phase 4 of the data collection process. The

Table 4.6: Summary of medicine therapy problems identified and prescriber response to pharmacist's recommendations

Medicine therapy problem type	Medicine therapy Problem description	Number (%) of interventions (n=453)	Doctors			Clinical Nurse Practitioners		
			Accepted n (%)	Partially accepted n (%)	Rejected n (%)	Accepted n (%)	Partially accepted n (%)	Rejected n (%)
35	Lack of physical measurements recorded	102 (22.5)	7 (1.5)	1 (0.2)	47 (10.4)	11 (2.4)	0	36 (8)
1	No medical indication noted	87 (19.2)	16 (3.5)	0	31 (6.9)	12 (2.6)	0	28 (6.2)
34	Laboratory tests not undertaken	83 (18.3)	7 (1.5)	0	38 (8.4)	19 (4.2)	0	19 (4.2)
8	Synergistic/potentiating effects of medicines	64 (14.1)	9 (2)	1 (0.2)	23 (5.1)	4 (0.9)	1 (0.2)	26 (5.7)
13	Wrong dose(dosage too low)	43 (9.5)	6 (1.3)	3 (0.7)	11 (2.5)	9 (2)	2 (0.4)	12 (2.6)
23	Wrong dose (dosage too high)	36 (7.9)	6 (1.3)	1 (0.2)	14 (3.1)	1 (0.2)	4 (0.9)	10 (2.2)
6	Untreated medical condition	17 (3.8)	6 (1.3)	0	3 (0.7)	2 (0.4)	1 (0.2)	5 (1.2)
7	Lack of preventative/prophylactic	12 (2.6)	2 (0.4)	0	2 (0.4)	4 (0.9)	0	4 (0.9)
22	Contra-indications	5 (1.1)	1 (0.2)	1 (0.2)	2 (0.5)	0	1 (0.2)	0
19	Medicine interaction	3 (0.7)	1 (0.2)	0	2 (0.5)	0	0	0
24	Medicine frequency inappropriate	1 (0.2)	0	0	0	0	0	1 (0.2)
Total interventions		***453 (100)***	***61 (13.2)***	***7 (1.5)***	***173 (38.5)***	***62 (13.6)***	***9 (2)***	***141 (31.2)***

MTP types and categories listed on the pharmacist intervention log sheet were adapted from Cipolle and colleagues (2012) Pharmacotherapy Workup Notes. The researcher thus identified the MTP from the diabetic patient folder with reference to the STGs and EML. Other studies have used a different classification system of MTPs for their study. The study by Haugbølle & Sørensen (2006) used the Problem Intervention Documentation coding system whereas Huri & Wee (2013) used the Pharmaceutical Network Care Europe tool version 5.01 to classify and categorize MTPs.

The highest number of pharmacist-led interventions identified from the MTP types was:

- Lack of physical measurements for BMI calculation: n=102 (22.5%)
- No medical indication noted in the patient folder: n=87 (19.2%)
- Laboratory tests not undertaken: n= 83 (18.3%)

Lack of physical measurements for BMI calculation (22.5%) was the most common MTP observed in this study. The patients' weight and many of the patients BMI was not calculated and recorded in the patient folders by prescribers. Despite more than a third of patients being obese at baseline (n=36) (refer to Table 4.2)for this study, physicians did not document and assess BMI during the patient clinic visits. Therefore, assessment and calculation of BMI, understanding the BMI category and the complications of obesity are important in diabetic patients to have medicine therapy recommendations made to manage the condition (Rose et al., 2009). Medicines prescribed with no medical indication (19.2%) were the second most common MTP observed. The medicines prescribed with no indication included aspirin, furosemide and vitamin C. Laboratory tests not undertaken accounted for 18.3% of thetotal MTPs observed in this study. At baseline, many of the stable diabetic patients did not have a record of laboratory data in their folders, indicating a lack of blood tests requested. Typically, laboratory tests are routinely requested in the PHC environment, however, there is usually no well established system to review and file these accordingly. The tests which lacked laboratory data was HbA1c, total cholesterol and serum creatinine

The lowest number of pharmacist-led interventions that were identified included:

- Contraindications n=5 (1.1%);
- Medicine interactions n=3 (0.7%);
- Frequency inappropriate of medicines prescribed n=1 (0.3%).

Findings from this study are comparable to that of an Indian study (Shareef et al. 2016) conducted at a tertiary hospital who found that the following MTP types "no medical indication noted" was slightly lower (18.0%) than this study (19.2%) and "laboratory tests not undertaken" in diabetic patients was found to be much lower (2.1%) than this study (18.3%). With regard to MTP types, "medicine frequency inappropriate" (3.17%) and "medicine interaction" (5.8%) the figures were found to be much higher in the Indian study (Shareef et. al 2016) than that noted for this study, 0.3% and 0.7% respectively. The findings from this study concur with those from a Hong Kong study where the least identified MTPs were "contraindications" (1.2%), "medicine interactions" (1%) and "medicine frequency inappropriate" of medicines prescribed (0.5%) in diabetic patients (Chung et al., 2017). However, the most common MTPs identified from the sub-categories by Chung et al. (2017) were "medicine dose too low or dosage regimen insufficient" of medicines prescribed (23.3%), medicine dose too high or dosage regimen too frequent" of medicines prescribed (16.5%), and allergic reaction" (15.6%) experienced from medicines.

related to MTP "medicine dose too low or dosage regimen insufficient" (43.9%), untreated medical condition (17.3%) and allergic reactions (15.6%) caused by medicines.

4.3.2 Prescriber uptake (acceptance or rejection) towards pharmacist-led recommendations

One of the key objectives of the study was to determine the uptake (acceptance and rejection) of the pharmacist-led interventions amongst prescribing staff at the facility. Both the doctors and CNP's seemed to have accepted more than a quarter (27.2%) of the pharmacist-led interventions whereas, only a few 16 (3.5%) were partially accepted. However, doctors rejected almost 40% of the pharmacist-led interventions as opposed to clinical nurse practitioners who rejected less than a third (31.2%) of the interventions.

The total number of accepted pharmacist-led interventions that were recommended to prescribers was 123 (27.2%). Figure 4.1 depicts the acceptance and rejection of the pharmacist-led interventions amongst the doctors at the facility while Figure 4.2 depicts the acceptance and rejection of pharmacist-led interventions amongst CNP's.

Doctors were more accepting towards the following pharmacist-led interventions than CNP's:

- No medical indication noted n= 16 (3.5%);
- Synergistic/potentiating effects of medicines n= 9 (2%);
- Wrong dose (dosage too high) n= 6 (1.3%);

- Untreated medical condition n= 6 (1.3%).

In contrast, CNP's were highly accepting of the pharmacist-led interventions relating to the following MTP types:

- Laboratory tests not undertaken n= 19 (4.2%);
- Lack of physical measurements recorded n=11 (2.4%);
- Wrong dose (dosage too low) n= 9 (2%).

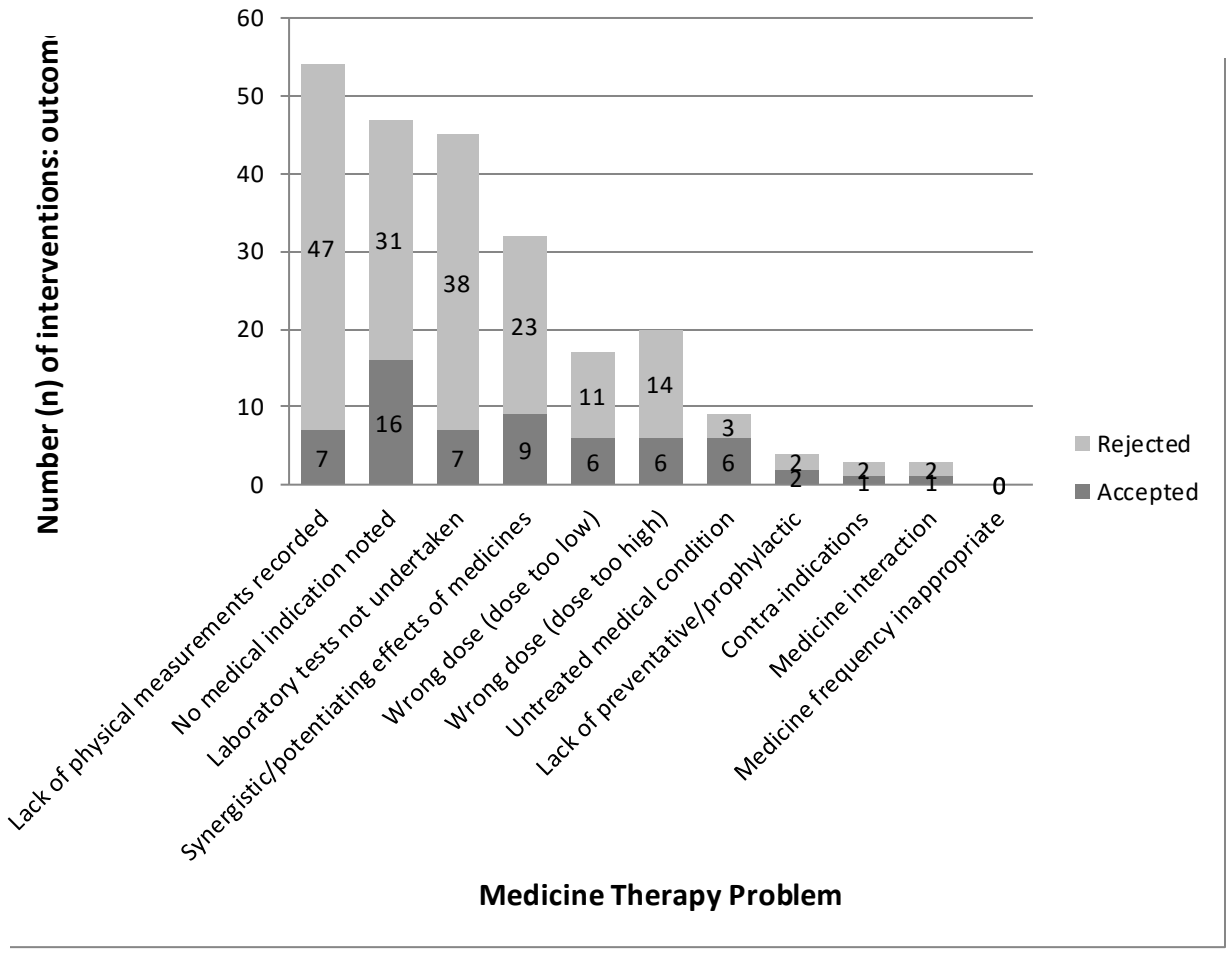

Figure 4.1: Doctors acceptance and rejection of recommendation from pharmacist-led interventions identified

A total of 314 (69.7%) pharmacist-led interventions were rejected amongst prescribers. Doctors mainly rejected pharmacist-led interventions in the following MTP types:

- Lack of physical measurements recorded n= 47 (10.4%);

- Laboratory tests not undertaken n= 38 (8.4%);
- No medical indication noted n=31 (6.9%).

While, CNP's rejected pharmacist-led interventions relating to the following MTP types:

- Synergistic/potentiating effects of medicines n= 26 (5.7%);
- Untreated medical condition n= 5 (1.2%).

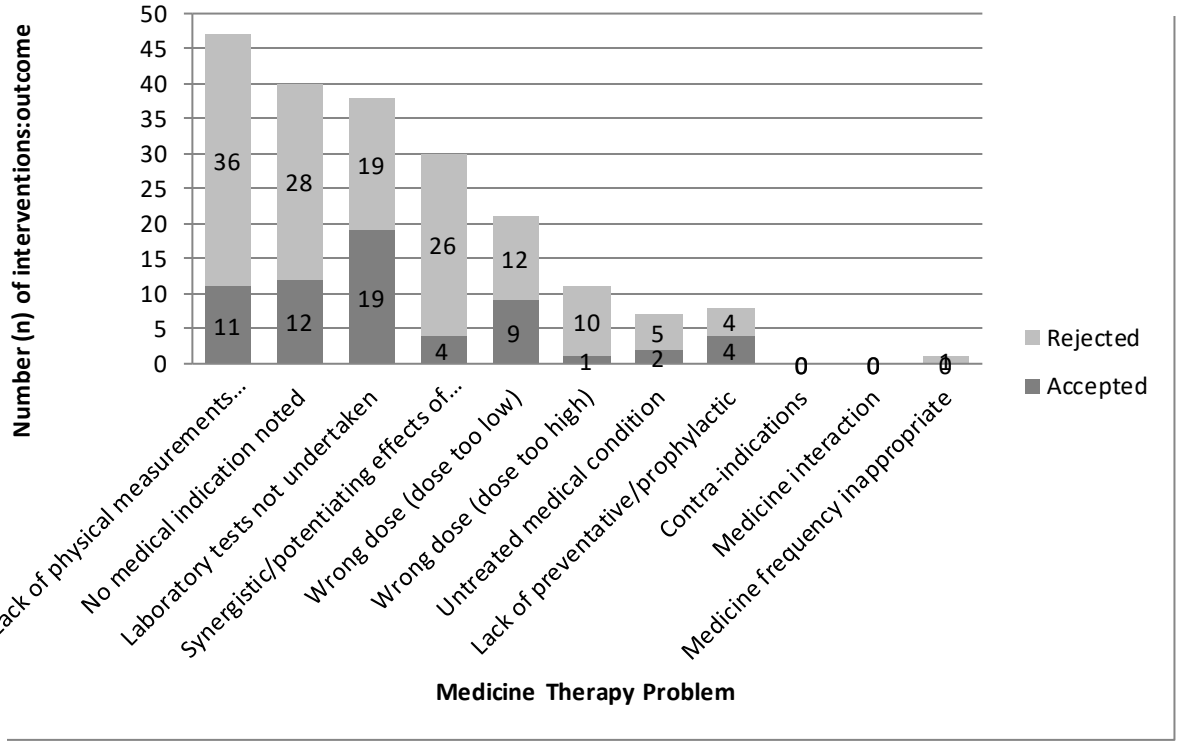

Figure 4.2: Clinical Nurse Practitioners acceptance and rejection of recommendation from pharmacist-led interventions identified

From the MTP type "laboratory tests not undertaken", the pharmacist's recommendation that doctors and CNP's consider calculating the diabetic patient's BMI was essential towards clinical and therapeutic-decision-making. Refer to sub-section 4.1.2.1 for the importance of BMI as a physical measurement. In this study prescribing staff were noted to have rejected 83 (18.4%) of the pharmacist-led interventions. At the facility, the staff nurse is expected to measure and record the patient's height and weight, and essentially it is the prescriber's responsibility to

calculate and record the patient's BMI in the patient folder, a protocol which forms part of sound medical record keeping (Rose et al., 2009).

The pharmacist plays a pivotal role in early identification of MTPs in diabetic patients who may have more than one medical condition and can thus assist in medicine therapy adjustments. Other contributing factors to MTPs include renal impairment, multiple medicine therapies and age-related factors in diabetic patients (Huri & Wee, 2013). The study by Chan et al. (2017) demonstrated the importance of the pharmacist's role in collaboration with other health care professionals by identifying, resolving and preventing MTPs which improved diabetic patients' clinical outcomes (Chan et al., 2017).

The pharmacist identified 453 interventions and the prescribers rejected more than two-thirds (69.7%) of the pharmacist's recommendations. One possible explanation could be "clinical inertia". Clinical inertia in diabetes is the failure to act on a recognized problem and modify a patient's treatment (Strain et al., 2014). According to Strain et al. (2014), the factors contributing to clinical inertia can be categorized as follows:

- Physician barriers: limited time spent to assess treatment; patients referred from tertiary hospital to primary care clinic and reluctance to change or stop medication on the prescription; lack of knowledge of the chronic disease,
- Patient factors: medication non-adherence; resistance to change in treatment therapy; denial of chronic disease, and,
- Environmental setting: poor communication amongst healthcare professionals; lack of time.

Strain et al. (2014) further explains that physicians tend to work in isolation especially at PHC facilities. In this study prescriber inertia could possibly be induced by high patient loads at PHC setting; age difference of prescribers; limited prescribing staff; locums; time constraints; and lack of resources in the facility. Even though the pharmacist intervention label was visible for prescribing staff to consider, it was not perceived to be worthy. The high patient load at the facility may have led to newly qualified doctors following prescriptions written out by their predecessors, where they had directly transcribed those prescriptions by default, and may have overlooked the pharmacist-led recommendations.

Strategies to maintain glycemic control in patients through a multidisciplinary team is lacking as physicians will only request for further assistance from other health care professionals once glycemic targets are not met and diabetic complications arise (Strain et al., 2014). Therefore, the high patient load and time constraints at public sector primary care facilities, requires a multidisciplinary team approach to converge the scope of practice among facility staff to optimise chronic disease management.

4.3.3 Estimated costs associated with irrational prescribing of aspirin

During the study period, an aspirin circular, namely, "*H141/2017: Aspirin Medicine Use Evaluation Feedback*" endorsed the need for prescribers to promote rational prescribing. The director of pharmacy services approved and signed a circular (26 October 2017) which was subsequently circulated to pharmacy support personnel (Appendix 1). The circular is synonymous with the STGs and EML (NDoH, 2014) which stipulated that aspirin be prescribed for the following indications: atherosclerotic peripheral arterial disease, ischemic heart disease (angina), myocardial infarction (heart attack), pre-eclampsia, systemic lupus erythematosus and cerebrovascular accident (stroke).

In this study, from a total of 87 pharmacist-led interventions reported for the MTP "no medical indication noted", 70 (15.4%) of these were directly related to irrational prescribing of aspirin. Such prescribing practice contributes to unnecessary pharmaceutical expenditure as shown in Table 4.7. In contrast to this study, a Cyprus study found that aspirin was under prescribed in 15.9% of study participants (Zachariadou et al., 2006). The researcher made the recommendation for prescribers to consider removing aspirin from the diabetic patients regimen of which 53 (75.7%) pharmacist-led interventions were rejected by prescribers (refer to Table 4.7). Prescriber adherence to aspirin guidelines was therefore found to be poor in this study.

Table 4.7: Prescriber acceptance and rejection of pharmacist-led intervention for aspirin

Prescribing staff		**Number (%) of Pharmacist Recommendation**	
		Accepted	**Rejected**
Doctors (n=2)		11 (15.7)	27 (38.6)
Clinical nurse practitioner (n=2)		6 (8.6)	26 (37.1)
Total of:	***4***	***70***	

Table 4.8 demonstrates the rational and irrational prescribing of aspirin including other medicines over 28 days and over a 6 month expenditure period at the CDCs pharmacy. Only pharmacist-led interventions that were accepted by prescribers and resulted in medicine adjustments were found to achieve an estimated cost saving.

Acceptance of the pharmacist-led aspirin recommendation depicts a cost saving of R53,80 for 28 days, and R322,80 over 6 months at post-pharmacist intervention. Consequently, where doctors and CNPs rejected the pharmacist recommendation, irrational prescribing expenditure of aspirin was estimated at R196,37 over 28 days and R1178,22 over 6 months. An estimated three-fold saving could have been possible resulting from irrational aspirin prescribing at the facility. The authors of a Cape Town district-based study found that while there was no association between quality of care and cost of prescriptions for diabetic and hypertensive patients, they attested that the increasing costs were rather due to the number of co-morbidities rather than the quality of care provided at the facility(Isaacs et al., 2015). Isaacs et al. (2015) thus recommends assessing prescribing patterns for chronic diseases, particularly diabetes mellitus and hypertension, in relation to the PHC STGs and EML.

Table 4.8: Estimated costs associated with rational and irrational prescribing during medicine therapy management of pharmacist-led intervention

Category		Cost of Medicine (Rands)	
		28 day supply	6 month supply
Rational prescribing	Aspirin	R53,80	R322,80
	Other medicine agents *	R49,77	R298,62
Irrational prescribing	Aspirin	R196,37	R1178,22
	*Other medicine agents	R107,19	R643,14
*Other medicine agents= furosemide, vitamin C			

4.4 Section B: Qualitative results

The qualitative data in this sub-section discusses:

- Themes obtained from role-clarification workshops (researcher-facilitated)
- Staff participants' feedback workshop on pharmacist-led intervention (independent assessor)
- The researcher's experience during the study

4.4 Workshops in management of diabetes

Role clarification workshops in the management of diabetes were scheduled to take place every alternate week on a Friday afternoon as this was the most appropriate day for the researcher to facilitate the workshops for staff participants. However, poor staff availability due to work schedules, leave absence and festive holiday periods led to only two role clarification workshops that were conducted with the study participants on the 24 February 2017 and 03 March 2017. The purpose of the workshops was to provide an opportunity for facility staff to elucidate their respective role and responsibility in diabetes management. In essence, such an engagement would attain collective understanding that could materialise towards the formation of a multidisciplinary team at the primary care level at a public sector facility.

Study participants' profile for the workshop is outlined in Table 4.9. A description of the data collection process is discussed in sub-section 3.5.4 of Chapter 3. In preparation for the first workshop, the researcher invited the staff to present their respective role in diabetes management. The occupational therapist and dietician opted to make their presentations at the workshops respectively, using a case study approach to engage the participants.

Table 4.9: Profile of study participants (n=11) at role clarification workshops

	n
Profile	**Number of participants**
Doctors	2
Clinical nurse practitioner	2
Occupational therapist	1
Health promoter	1
Dietician	1
Nutritional specialist	1
Administrative clerks	2
Qualified post-basic pharmacist assistant	1

Table 4.10 provides the profile of staff participants who were present at each of the two workshops.

Table 4.10: Attendance of staff participants at each of the two role clarification workshops

			n
Workshop	**Presenter**	**Professional Role**	**Number of attendees**

Workshop 1 (February 2017)	Occupational therapist	• Clinical nurse practitioner • Nutritional specialist • Administrative clerk • Pharmacist/Researcher	5

During both workshops staff engaged positively with each other, and obtained a clearer picture of the presenter's roles in diabetes management. Key findings which had emerged from both workshops, were that staff participants were not cognizant of each other's role in diabetes management. They felt that the workshops provided an opportunity to discuss their respective roles and experiences and exchange knowledge, demonstrating convergence towards a holistic approach to diabetes management. Following the first workshop, which the occupational therapist had facilitated, the researcher noted the following journal entry (24 February 2017)

"…..the occupational therapist presented an insightful topic titled: Occupational therapy and diabetes. I learnt a great deal at this workshop. It is astounding how we as healthcare professionals can become so focused in our own profession that we do not realise that we should work together as a team and learn from one other. I feel that study is creating that opportunity. We are acknowledging each professionals skills and qualities in diabetes care." – Pharmacist/Researcher

In primary care practice, to optimize patient care in the management of chronic diseases, coordination of each health care professional's role within a multidisciplinary team is crucial (Wagner, 2000). There should be a clear understanding of each professional's role and skills to improve patient care (Pearson & Jones, 1994). This might not always be possible in a primary care setting as health care professionals often function independently in different departments within the facility. Diabetes is recognised as one of the diseases belonging to a disease cluster, classified as 'metabolic syndrome', therefore adopting a multifaceted approach with other health care workers to optimise management at the primary care level was essential for the arm of this study.

4.5 Staff participant's feedback workshop to pharmacist-led interventions

An independent assessor facilitated the feedback workshop with facility staff participants. During phase 7 of the data collection process, an independent assessor (refer to sub-section 3.5.4 of Chapter 3) administered a semi-structured questionnaire to facility staff participants. Participants were not identifiable by name, as their coded responses were only known to the researcher. Study participants who were able to attend the feedback workshop are outlined in Table 4.11.

Table 4.11: Attendance of staff participants at facility staff feedback workshop

Workshop	Facilitator	Professional Role	n Number of attendees
Feedback workshop (March 2017)	Independent assessor	• Doctor • Clinical nurse practitioners • Nutritional specialist • Administrative clerk • Qualified post-basic pharmacist assistant • Occupational Therapist	8

The semi-structured questionnaire consisted of 4 questions, and participant responses were transcribed and analysed thematically. The semi-structured questionnaire consisted of the following 4 open-ended questions:

1. *In your opinion, how did the pharmacist contribute to diabetes management at this Community Day Centre?"*

2. In what way has your management of the diabetic patient changed following the involvement of a pharmacist?

3. From your experience, should a pharmacist be part of the team in diabetes management at facilities?

4. Would you recommend a pharmacist in the diabetes management team at other community day care centres?

Based on responses obtained from the staff participant feedback, there was clear support for the pharmacist-led intervention. All ten health care professionals found that the pharmacist's role made a positive contribution towards diabetes management at the facility. Deductive themes that emerged were the pharmacist's prominent role in medicine management at the facility (Table 4.11). These are discussed below:

Theme 1: Pharmacist's review of prescribed medicines in accordance with guidelines

All ten health care professionals found that the pharmacist's role made a positive contribution towards diabetes management at the facility. The positive contribution was attributed to an increased awareness of the pharmacist's role, by alerting staff to medication use as evident from the notes and label included in the patient folder,

reviewing patient medication profiles, and suggesting adjustments to medicine therapies.

"The notes from the pharmacist made you more alert regarding medication." - Clinical nurse practitioner 1

"The removal of aspirin from the regime." - Clinical nurse practitioner 2

Findings from a systematic review showed that nurses identified breakdown in communication as the most significant factor related to medication error in the exchange of medication information within an interdisciplinary team (Sassoli &Day, 2017).In a Netherlands study, Doekhie et al. (2017) investigated primary care professionals' perceptions of teams, and found that they had expressed a desire for more proactive communication between disciplines and knowing other professionals involvement in patient care. In addition, primary care professionals acknowledged the importance of regular and structured knowledge exchange between them and believed in the added value for patients of working in a team.

Theme 2: Pharmacist's use of objective assessments to rationalise therapeutic recommendations to prescribers

The findings suggest that all participants felt that the pharmacist's contribution was made through timeous therapeutic recommendations to prescribers using objective assessment to rationalise therapy adjustments in accordance with practice guidelines.

> "... emphasis on guidelines and potential drug interactions." Doctor 1

Sassoli and Day's (2017) systematic literature review found that in the medication management cycle, a structured communication tool is required to communicate the patient's clinical information effectively with nurses and doctors to avoid preventable medication errors. The review further highlighted that pharmacists indicated the importance of effective medication communication during the transfer of care, as the consequences of poor communication could be fatal.

Theme 3: Pharmacist's timeous therapeutic intervention

All participants felt that their management of a diabetic patient changed following the involvement of a pharmacist. This finding seemed evident from the faster retrieval of patient folders at reception, and from the CNP's perspective, the pharmacist's recommendations to prescribe appropriate dosages for diabetic patients.

Table 4.12:Themes which emerged from the staff feedback workshop on the pharmacist-led medicine therapy management of diabetes at the community day centre.

Theme	*Summary of staff participant responses*
1. Pharmacist's review of prescribed medicines in accordance with guidelines	• Created awareness and the opportunity to engage directly with the pharmacist about medicine-related queries • Offered valuable adjustment to prescribed medicines e.g. identifying drug interactions, contra-indications, advise on new medicine therapy, Alerted prescribers to removal of inappropriate prescribing of aspirin • Avoided indiscriminate prescribing among prescribers for repeat prescriptions • Identified as a resource for new prescribing staff e.g. doctors, clinical nurse practitioners • Prescribers welcomed continued prescription feedback with recommendations
2. Pharmacist's use of objective assessments to rationalise therapeutic recommendations to prescribers	• Recommendations were based on objective data • Offered detailed explanations of inappropriate medicine use
3. Pharmacist's timeous therapeutic intervention	• Offered early intervention / therapy adjustments/ recommendations to medicine-related problems • Patient waiting time reduced
4. Systematic folder management at reception desk	• Folders retrieved from desk beforehand in preparation for club visit • Diabetic folders were marked, therefore club folders, easily identified at reception desk • Warning sign on patient file helpful
5. Practice-based intervention that is suitable for primary care level	• Practical approach to disease management • Intervention could be applied to other primary care facilities
6. Pharmacist recognised as member of a multidisciplinary approach to diabetes management	• Pharmacist a resource for offering guidance to new prescribing staff eg. doctors, clinical nurse practitioners • Role clarification workshops using patient cases stimulate collective discussions among staff on optimising diabetes management. • Request that the 'forums' continue to help manage patient cases among different health care workers at the facility

"It made valuable contributions with respect to adjustment of meds." – Clinical nurse practitioner 2

"Time management was very helpful, patient wouldn't wait longer. Waiting period was plus minus 10 to 15 minutes waiting." – Reception clerk 1

One of the factors which patients tend to value at facilities is faster access to health care services (Hindi et al., 2019). Therefore a trained pharmacist's MTM services, would consequently free up the time for clinical practitioners to focus their attention on more complex patient cases (Hindi et al., 2019).

Theme 4: Systematic folder management at reception desk

Participants re-iterated the pharmacist's positive role at the facility such as retrieval and identification of club folders at the reception desk.

"Club folders are easily identified and pulled two days before the visit or appointment."- Reception clerk 1

The results obtained from a focus group discussions with patients, pharmacists and general practitioners revealed that all stakeholder groups believed that pharmacists required more access to patient medical records to have a better overall understanding of the patients' condition, as lacking full patient information deters pharmacists from engaging with clinical data to make timeous therapeutic recommendations (Hindi et al., 2019). Findings from a Canadian qualitative study which had investigated pharmacists identity development within the multidisciplinary team, attested that pharmacists who had access to patient medical records and interacted daily with team members, had acquired a better understanding of relationships with primary care staff (Pottie et al., 2009).

Theme 5: Practice-based intervention that is suitable for primary care level

Our findings suggest that this intervention could be applied to other primary care facilities as expressed in the comment:

"*... what she did is very practical and will make a difference at other facilities."* - Reception clerk 2

The practice-based research that was conducted at the CDC served as an additional "laboratory" apart from the basic science laboratory work and biomedical research required for clinical practice (Westfall et al., 2007). While treatment guidelines are constantly updated and distributed, the key question about how to implement such recommendations at the primary care level remain unresolved (Westfall et al., 2007). In this study, an attempt was made to address common clinical and therapeutic

concerns using a pharmaceutical perspective to bridge the gap between recommended guideline-based care and actual practice.

Theme 6: Pharmacist recognised as member of a multidisciplinary approach to diabetes management

All ten participants were in agreement that a pharmacist should form an integral part of a multidisciplinary diabetes management team at a facility. These findings were confirmed by comments made by participants:

> *"... they were beneficial because they acted as reviewers of the patient's medication and in a sense of their condition/illnesses, which benefits and protects the patients in the end. It helps having someone review your work and advise you on new medicines and drug interactions."- Doctor 2*

> *"Yes, their input will assist and guide the way we prescribe."*- Clinical nurse practitioner 2

Costa et al. (2019) conducted a comprehensive review of sixteen policy papers and ten studies to analyse pharmacy-based diabetes interventions that were developed in Portugal. They found positive interventions related to screening individuals at risk for diabetes, monitoring diabetic patients and referring patients to a practitioner (Costa et al., 2019). The authors concluded that development of integrated programmes with primary care, such as medication therapy management to patients on multiple medications, would be a valuable contribution from pharmacists in assessing therapeutic outcomes.

Similar to this study, Wagner (2000) found that multidisciplinary teams were more effective with the addition of a pharmacist (Wagner, 2000). In the study done by Stading et al. (2009), pharmacists involved in diabetes care helped patients to improve their HbA1c values (Stading et al., 2009). In contrast to a Northern Ireland qualitative study, Millar et al. (2015) identified perceived lack of medication knowledge among health care workers, and medication reviews were not conducted unless explicitly requested, which endorsed a need for the pharmacist's medicine management services within the existing multidisciplinary team (Millar et al., 2015). Further, the health care workers had lacked awareness of the pharmacist's role which was identified as a barrier to the pharmacist's integration in the team (Millar et al., 2015).

Qualitative findings from the two role clarification workshops and the staff participant feedback workshop clearly underpin the importance of pharmacist-led intervention on optimising MTM for diabetes in accordance with guideline recommendations.

The immediate access to consult with a pharmacist on medicine related queries is currently lacking in PHC, as doctors seem to be the first point of reference for such information, which adds (unnecessarily) to their intense workload. On the contrary trained pharmacists or could serve as a verification resource to optimise medicine therapy. CNP's also felt that the intervention was valuable in promoting rational prescribing making it a possible intervention applicable at other public sector primary health care facilities, thereby alluding to its sustainability. The workshops could be formalized as a means to promote good clinical and pharmacotherapeutic practice at the facility.

4.6 Participation of staff participants during the research study

Staff participation and their attendance at workshops during the research study were documented using attendance registers and through audio recordings.

The administrative clerks were asked to assist the researcher in the retrieval of folders during the MTM process. During the MTM pharmacist-led intervention phase, that is Phase 4, the club doctors and CNP's could consider the intervention made by the pharmacist and make the necessary medicine adjustments on the patient prescription. The other health care professions (staff participants) were invited to present their role in diabetes management at the two role clarification workshops held at the facility. The occupational therapist presented at the first role clarification workshop and the dietician at the second workshop. Attendance of staff participants at the workshops held are shown is shown in Table 4.9, Table 4.10 and Table 4.11. The most consistent attendees amongst the staff participants were there *Clinical Nurse Practitioner 2* and the *Nutritional Specialist* who attended all the workshops held during the study.

A timeline of the research study period from November 2016 to July 2017 is illustrated in Figure 4.3.

4.7 Researcher's journey during the study

In my dual role as the pharmacist and researcher in this study, I provide background to my professional training and research journey.

As a pharmacist working in the public health care sector for 8 years, I am passionate about improving the quality of pharmaceutical care by promoting rational medicine use in chronic disease management. Having reached a saturation point with routine

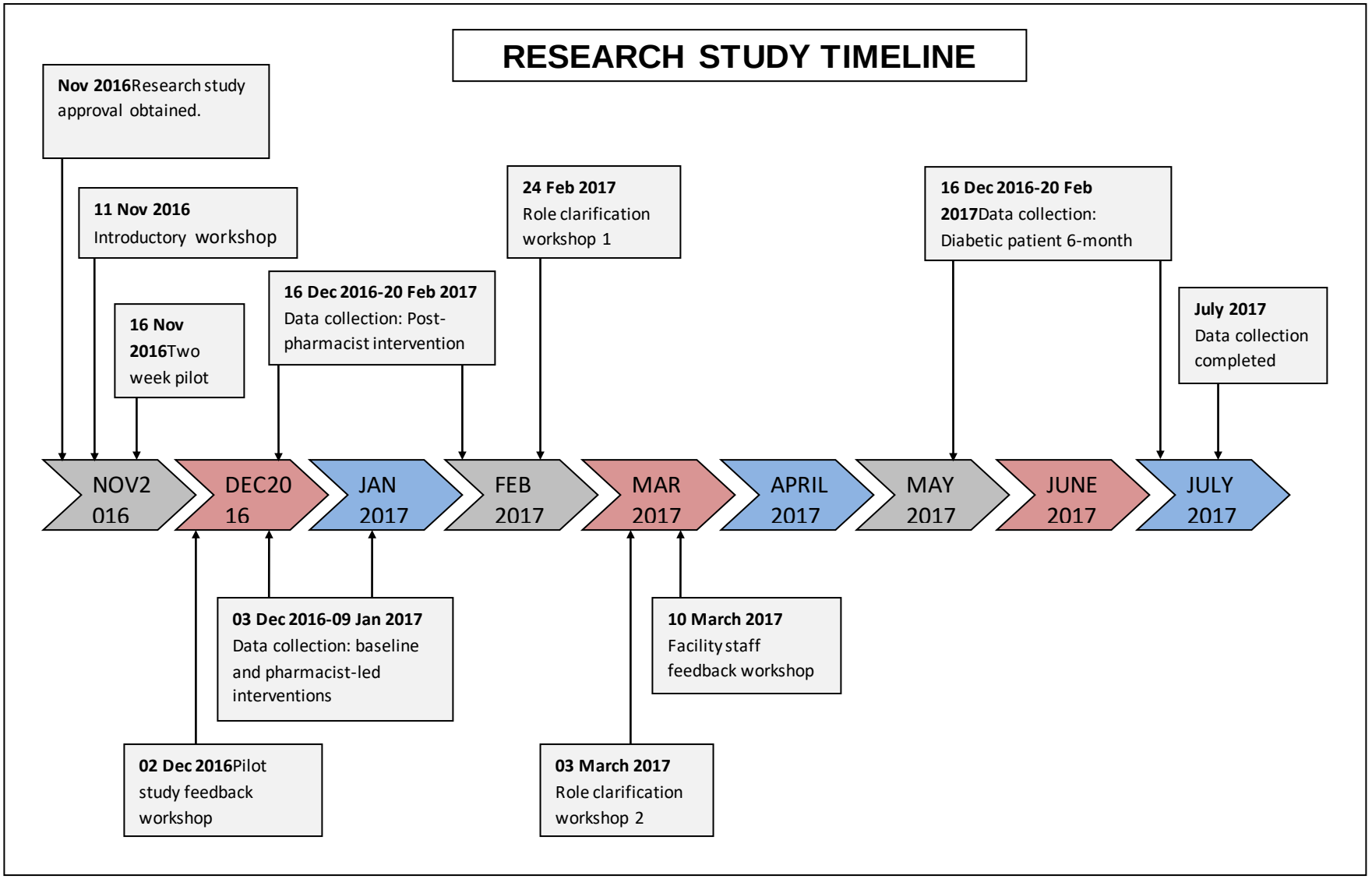

Figure 4.3: Research study time from November 2016 to July 2017

mechanical dispensing, I participated in a therapeutics training course, titled "Integrated applied therapeutics: fundamentals of rational prescribing" (2014) which was offered by a designated service provider (Pharmacy Education International) to health professionals employed in the public sector in Cape Town. This course not only augmented my theory-based knowledge but drew my attention to the practice based application of pharmacotherapeutic principles in chronic disease management.

I realized that if I could apply my newly acquired skills in a systematic way I would be able to identify enabling and inhibitory factors for practice-based implementation research at the facility. In this way, I could maximize my potential at the primary care level where the need is the greatest. I was familiar with the routine operational framework and had established a cooperative relationship with facility staff from different professional roles during the Service Learning in Pharmacy, an experiential learning program developed by the School of Pharmacy at UWC (Bheekie et al., 2015). For the Service Learning in Pharmacy program, I served as a student facilitator and realized the importance of teamwork in trying to expand experiential learning opportunities across the facility. The confidence I had gained in building a professional working relationship with the staff and my applied pharmacotherapeutic skills served as a catalyst to implement the research project at the facility where I was employed.

My introduction to the research terminology, plan and design began at UWC's Division for Postgraduate Studies research workshops (2016), where I realized the importance of systematic data collection procedures. From the literature review process, I decided that by designing, testing and implementing a tool for MTM in diabetes at the facility where I was established as a pharmacist, it would give me the confidence to improve pharmaceutical care, crafting my attempt to make a meaningful contribution to quality service delivery.

As I embarked on my research project, I felt overwhelmed when I encountered several challenges during the unpredictable data collection process. Insight from an entry in my journal is shared below.

22 November 2016

"I went to the reception department to place the pharmacist intervention label inside the folder. When I got to the reception, it was a mess and my diabetic patient study folders were not in the "UWC lin bin". I had to search and retrieve them again as they were filed. Eventually, I found the study folders and stuck the cover sheet onto the cover of each folder and placed the label with pharmacist recommendation onto the last available prescription inside the folder." - Researcher

In retrospect, I realized that I had to manage operational challenges such as poor filing of the patient folders single-handedly in order to make progress in the data collection process. I had to plan ahead, to secure early retrieval of the required patient folders, analyze the prescribed therapy in accordance with guideline recommendations, and offer therapeutic recommendations timeously before the patient's designated clinic day.

Overall, I've learned that a positive attitude and that perseverance, hard work and commitment are essential qualities to achieve the research goal.

Section C: Limitations of this study

The researcher's challenges of implementing MTM at a primary care clinic and the study limitations are discussed in this sub-section.

4.8 Study limitations

Data was collected at only one health care facility in Cape Town. Therefore, the findings from this study cannot be generalized to other PHC facilities. Limitations of this study include the following:

Lack of laboratory and clinical data

As the pharmacist evaluated the patient folders, she discovered incomplete medical records which consisted of poor medical notes and a lack of completeness of clinical information in the folders. Pertinent physical (weight and height), clinical (blood pressure, FPG, urine dipstick testing) and laboratory (HbA1c, total cholesterol, serum creatinine) data which was either not recorded or performed (unaccounted data) during routine practice. This resulted in incomplete therapeutic assessments, thereby reducing the rigor of the study findings. Furthermore, individual patient clinical parameters and biochemical markers led to varied outcomes which could not be statistically analyzed, leading to inconclusive findings.

Operational limitations during the practice-based research process

- The research pharmacist served as both "researcher' and "pharmacist" who was fully immersed in the operational procedures at the facility and in various phases of the MTM data collection process (see figure 3.9). Bias in such a

situation is inevitable. An independent evaluation of the research pharmacist's therapeutic recommendations and random checks in the data extraction would have strengthened the internal validity of the study

- Patient interviews at baseline and at 6-month follow-up were not included in this study. Patient data would have verified the baseline data and provided a holistic assessment of health outcomes at 6-month follow-upstudy phase.

- Staff participant attendance for the workshops varied due to time constraints at the facility. Therefore, the qualitative component required further in-depth probing especially with prescribing staff with an independent researcher to understand clinical and therapeutic decision-making.In addition, due to the limited time in which the project was conducted at the facility, the facility staff feedback workshop had to be conducted before the diabetic patient 6-month club follow-up (Phase 6 of data collection process) and therefore a follow-up workshop with staff participant's was not possible.

- Response from the Biomedical Ethics Committee of UWC was obtained in October 2016 resulting in data collection being initiated during the festive season (2016) which was not ideal as patients are not present at the facility.

Institutional (health system-based) challenges during the data collection process

Some of the system challenges experienced at the facility included:

- Due to staff constraints at the facility's reception department, the researcher was required to retrieve patient study folders for review. The folders were either misplaced or not chronologically arranged making it difficult to access folders timeously. On average, the researcher retrieved 20 folders per week in preparation for the patient's Thursday diabetic club visit at the clinic.

- Inadequate staffing, high patient volume and workload encountered at the clinic, limited the time for the research pharmacist to evaluate the diabetic folders on the designated day (Thursday) on which the diabetic club was scheduled. In an attempt to maintain operational flow of the activities to continue, the researcher proactively reviewed baseline data and prepared the pharmacist intervention label (Appendix 2) with recommendation, four days prior to the patient's appointment date. This meant that prescription analyses by the researcher required dedicated time. This was time-consuming and therefore, it was done after hours. The intention was to ensure that

prescribers were alerted to medicine therapy recommendation timeously during the patient's club visit.

Laboratory data was obtained electronically at the facility, but limited network access led to insufficient laboratory data being collected. Furthermore, additional time was spent accessing and obtaining patient information (laboratory results and medicines dispensed) using different electronic systems in government health facilities to evaluate chronic prescriptions.

The high patient load at the facility may have led to newly qualified doctors following prescriptions written out by their predecessors, where they had directly transcribed those prescriptions by default, and may have overlooked the pharmacist-led recommendations.

Others

- This study lacked comparison between a control group to ascertain the impact on outcomes of the MTM intervention with a non-intervention group.

- In this study, it would be difficult to determine whether the label had any influence on prescribing behavioural change. In addition participants were aware of the study following the five workshops (refer to Figure 4.3) which could have sensitized staff towards the study. Therefore, one cannot elucidate there was a clear cut behaviour change due to the pharmacist-led interventions.

4.9 Conclusion of the chapter

The quantitative and qualitative findings elucidated the pharmacist's role in integrating an MTM process for diabetes management during routine service delivery at a primary care facility. The availability of physical and biochemical data, evidence-based pharmacotherapeutic decision-making to rationalise therapy in accordance with the guidelines, prescriber uptake of pharmacist-led interventions and the estimated costs associated with irrational prescribing was discussed. The pharmacists attempt to engage with a multidisciplinary team and her research journey was also described.

Findings from the quantitative study illustrated the pharmacist's retrospective analysis of stable diabetic patients (n=104) where the baseline data was noted. Co-morbidities (n=8) were identified and the mean BMI was 32.3±9.07 kg/m^2 indicated overweight and obesity in the study sample. The mean ± standard deviation was noted for key cardiovascular parameters namely: BP 144±19 and 82.9±9.92 mmHg, FPG 8.26mmol/L, HbA1c of 8.64%, total cholesterol of 4.79± 1.18 (2016) which were found to exceed the target values. The mean ± standard deviation recorded (2016) for serum creatinine was 67±25.6 umol/L (minimum- maximum range 34-172), while the eGFR was 121±57 (60mL/min).

The clinical parameters which were monitored from baseline, post-pharmacist intervention and at 6 month follow-up included BP and FPG along with the laboratory tests for glucose, ketones and proteins, HbA1c, total cholesterol, serum creatinine and eGFR, (numerical values recorded in Table 4.4). In addition, the pharmacist noted poor recording of the four latter biochemical parameters at post -intervention and at 6-month follow-up. From the study sample (n= 104), the pharmacist identified diabetic patient cases who were identified for emergency care due to uncontrolled BP (n= 4; 3.8%) and uncontrolled fasting glucose (n=10; 9.6%).

Eleven types of MTPs were identified from the 104 folders that were analysed. From a total of 453 pharmacist-led interventions that were identified, an average of 4 interventions per patient was noted. Figure 4.4 illustrates the key MTPs identified in stable type 2 diabetic patients during the study. A quarter (27.2%; n=123) of the interventions were accepted among the prescribers, with 69.7% that were rejected. The high rejection rate towards the pharmacist-led interventions could be related to clinical inertia (Strain et al., 2014). Eighty-seven pharmacist-led interventions were identified from the MTP no medical indication, of which 70 interventions were related to poor prescriber adherence to aspirin guidelines as per PHC STGs and EML for which the pharmacological agent was prescribed. The pharmacist's recommendation were rejected equally among the doctors (38.6% n=27) and CNPs (37.1%, n=26). Such irrational prescribing for aspirin per patient is estimated to cost R 1178, for a 6 month supply, thereby imposing a strain on the Department of Health's budget, signifying a potential wastage which could be projected to R2400 per annum.

Key themes from the qualitative study underpinned the non-dispensing role of the pharmacist in the management of diabetes at the facility. Staff feedback focused on the pharmacist's application of pharmacotherapeutic skills in promoting rational medicine use in accordance with guideline recommendations. Examples included medicine therapy adjustments, drug interactions, contra-indications, inappropriate prescribing and offering updates on guidelines. The pharmacist's use of objective clinical and laboratory data to justify the therapeutic recommendation seemed evident. In addition, the timeous therapeutic intervention was noted among the prescribing staff. From an operational perspective, the systematic folder retrieval, and the tagged folders seemed an acceptable strategy to alert facility staff about the diabetic cases that required imminent pharmacotheraputic attention. Overall, the

pharmacist seemed to be recognised as an integral member of the PHC team for MTM in chronic stable diabetic patients.

Based on the quantitative and qualitative findings, the pharmacist-led medicine therapy management for chronic stable diabetic patients at the primary care facility meet the research objectives of this exploratory study.

In the next chapter, conclusions to the study findings and recommendations are discussed.

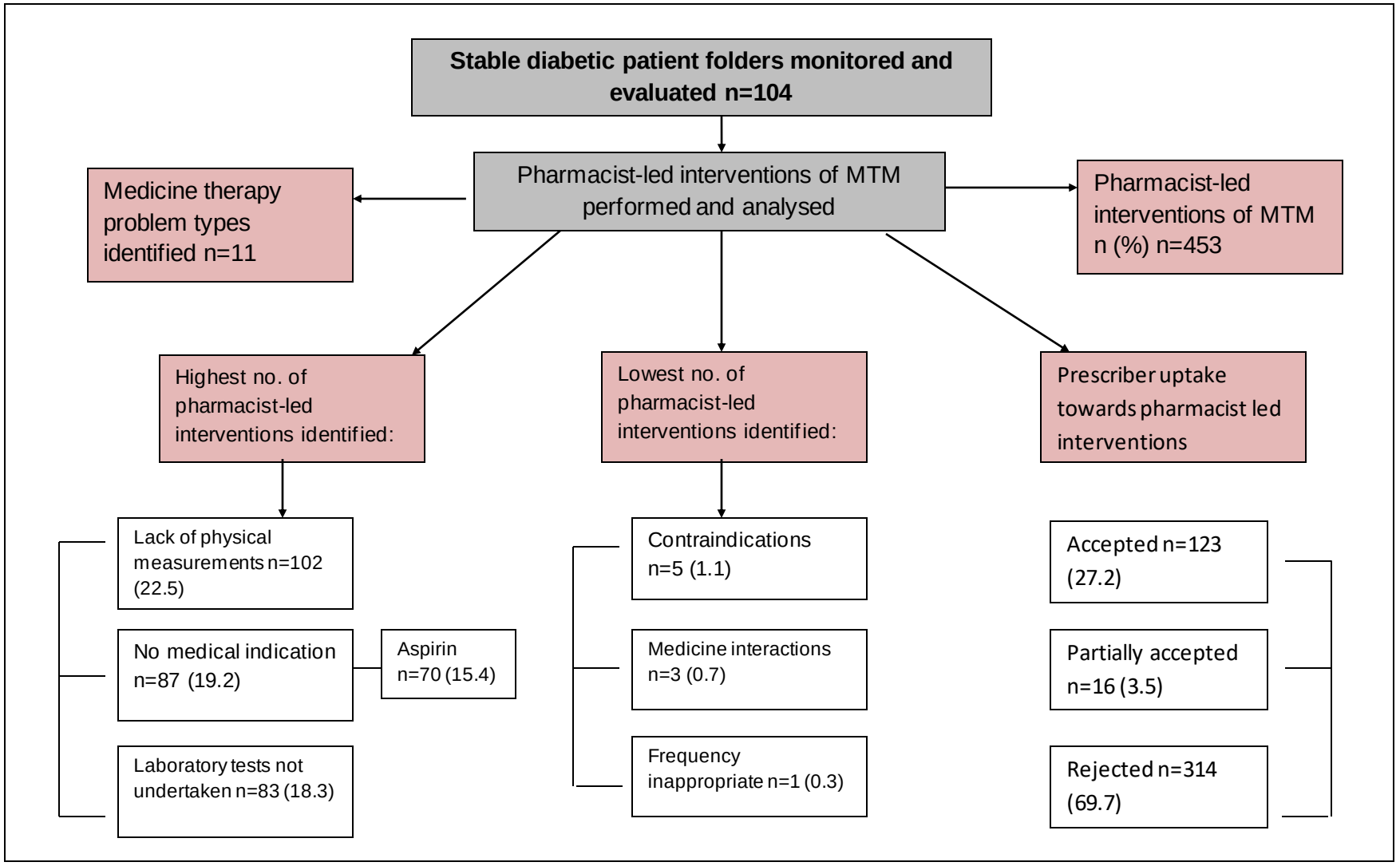

Figure: 4.4: Key medicine therapy problems identified in stable diabetic patients

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

This chapter concludes by summarizing the study and its findings, and proposes recommendations according to the research findings.

This research study aimed to determine the pharmacist's role in optimising MTM of stable diabetic patients attending a PHC clinic in the Western Cape. Based on the quantitative and qualitative data analysis of the pharmacist-led interventions and responses from staff participants to the semi-structured questionnaire, it can be concluded that the appropriately trained pharmacist plays an active role in a multidisciplinary team in diabetes management at a PHC facility through optimising MTM in type 2 diabetic patients, by alerting prescribers to perform diabetic investigations, for example,HbA1c test, encouraging rational medicine use in an attempt to reduce health care expenditure in diabetes care.

5.1 Summary of findings

The research study conducted, demonstrated that a pharmacist's role has shifted beyond mechanical dispensing in pharmacies but rather towards addressing a public health concern such as the management of type 2 diabetes mellitus at a public health CDC.

Literature states that diabetic patients seek access to over burdened public health facilities (Mash et al., 2008; Mayosi et al., 2009). However, through the chronic disease of lifestyle clubs and CCMDD programme, these offer alternative solutions to alleviate the strain encountered at CDCs. Patients who are considered stable are referred to the facility's club system. The baseline data gathered from the 104 stable diabetic patient folders and folder review by the researcher showed suboptimal glucose control despite these patients being classified as stable at the CDC. In addition, almost three-quarters of type 2 diabetic patient group were considered overweight or obese.

One aspect of the analysis of the diabetic patient folders in this study depended on the review of physical, clinical and laboratory records.The quantitative data collected during the data collection phases at baseline, post-pharmacist intervention and 6-month follow-up identified poor record keeping and performance of laboratory investigations (HbA1c, total cholesterol and serum creatinine) by prescribers. However, FPG, blood pressure and urine dipstick tests were performed by the staff nurse as this was part of the routine operational procedure at the facility.

The pharmacist identified 453 interventions in optimising MTM and made medicine therapy recommendations in accordance with PHC STGs and EML. One-fifth of the prescribers did not record the BMI (22.5%), tended not to request laboratory tests (18.3%); whilst three-quarters of them prescribed aspirin (75.7%) irrationally.The high occurrence of MTPs identified by the pharmacist in this study reflects a lack of pharmacological and non-pharmacological measures for achieving optimal glycemic control in the management of diabetes in clinical practice at a public setting. More than two-thirds (69.7%) of the pharmacist-led interventions were rejected by doctors and CNP's. Despite this high figure, findings from the qualitative data demonstrated that the intervention alerted prescribers to irrational prescribing and also to make appropriate medicine adjustments.

In contrast to the quantitative findings, the qualitative findings lacked rigour in understanding the factors contributing to prescriber inertia to the pharmacist's recommendations in optimising the management of diabetic patients. The absence of the doctors from the workshop and the lack of structure in the workshop could have negatively influenced the qualitative component of the study. Since most PHC facilities employ community service doctors who work for a limited time at facilities, establishing an inter-professional relationship to consolidate a multidisciplinary team, is a challenge. As such a semi-structured questionnaire, and deploying an independent facilitator to engage the participants should be considered to eliminate bias.

5.2 Conclusion

Management of NCD's requires clinical assessments, lifestyle adjustments, and prescriber and pharmacist interventions to maintain control of the disease. Diabetes mellitus is a complex metabolic syndrome, which requires a multidisciplinary team approach to optimise patient care in diabetes management at a PHC facility. Overall, this study demonstrates that pharmacist-led interventions are needed to improve prescriber practices and adherence to STGs and EML within South Africa's PHC system. Therefore, a trained pharmacist could be utilised for their pharmacotherapeutic skills to monitor and evaluate the MTM of chronic diseases at PHC clinics.

5.3 Recommendations

Based on the findings of this study, the following recommendations pertain to classification of stable diabetic patients, pharmacist-led workshops to promote

rational prescribing, dismantling silo's between institutions and outlining approaches to improve record keeping of patient information within the primary care facility.

a) Classification of "stable" diabetic patient

Emergency admissions which resulted from uncontrolled diabetes among patients classified as stable (were noted in section 4.2.2) is a major concern to health care professionals and planners. Such emergency admissions add a huge burden to the health care budget. The key questions which arise are: How do clinicians classify patients as "stable"? What criteria are used to classify a patient as "stable"?

b) Pharmacist-led workshops at the facility

This study highlights the irrational usage of aspirin (see Section 4.1.3.4), which begs the question: How effectively are government circulars being disseminated among healthcare personnel at facility level?

Pharmacists are ideally placed to intervene at prescriber level to encourage rational prescribing of medicines which are in accordance with the STGs and the EML. Relationships amongst prescribers and pharmacists could be improved through regular facility-based pharmacist-led workshops to promote rational prescribing practices, for example, presenting diabetes prescription monitoring and evaluation data to prescribers.

Although it was not evident in the study, maintaining a co-operative relationship with doctors is essential to strengthening teamwork. If community service doctors are deployed to a primary care facility, this would mean that new relationships would have to be forged annually, and a designated slot in the operational system to conduct weekly workshops would serve as a mechanism for constructive engagement among staff to collectively optimise patient health outcomes.

c) Dismantling silo's between institutions

i) Inter-professional Education

The healthcare strategy framework for human resources advocates that healthcare professionals need to work as a multidisciplinary team to address the burden of NCD's (Western Cape Government Health, 2014; Bradshaw et al., 2011).

Institutional barriers between the healthcare system and pharmacy training schools must be dismantled to promote teamwork amongst healthcare professionals (Frenk et al., 2010).

Experiential learning programs conducted at primary care facilities could be fully integrated into the health system, to promote team-based learning. To this end, pharmacy schools have incorporated inter-professional education into their curriculum (Brock et al., 2016) where students from different professional backgrounds are trained to work together and learn from each other's professional role to solve a common problem. The reconceptualization framework for South Africa's health professional training further endorses incorporated inter-professional education into the undergraduate curriculum. Initiating such collaboration at undergraduate training can strengthen multidisciplinary teams at health facilities and improve patient care (Nuffer et al., 2012).

Trained pharmacy students could have been a valuable resource to the data collection process, as they would have obtained first- hand experience of the MTM monitoring and evaluation process required in the management of diabetic patients. Since chronic disease management requires ongoing monitoring and evaluation to determine the effectiveness of the pharmacist-led intervention on population health outcomes, a sub-structure based longitudinal study in the Western Cape would be required to test the effectiveness of a pharmacist MTM intervention program.

ii) Continuous Professional Development for pharmacists

Diabetes is one of the quadruple disease forms in South Africa (Mayosi et al., 2009), therefore engaging trained pharmacists to apply their pharmacotherapeutic knowledge and skills to optimize diabetes management at a primary care level is crucial.By interpreting the physical measurements, clinical and laboratory data pharmacists would be able to offer recommendations directed at making timeous adjustments to diabetic medicine therapy. In this regard, the health system and pharmacy training schools are required to work collaboratively to offer continuous professional development courses to upskill practicing pharmacists in the application of pharmacotherapeutic principles and concepts to improve diabetes management.

iii) The dual role of a pharmacist and researcher in practice-based research

Two key questions arise from this project:

- Would a MTM study for diabetes be possible for an independent researcher to undertake at a PHC facility?

- If the study was mandated by the Provincial Department of Health, with full institutional support, would the research process have been any different?

Schematic representation of the planning process for a practice-based research project on MTM (Figure 5.1).

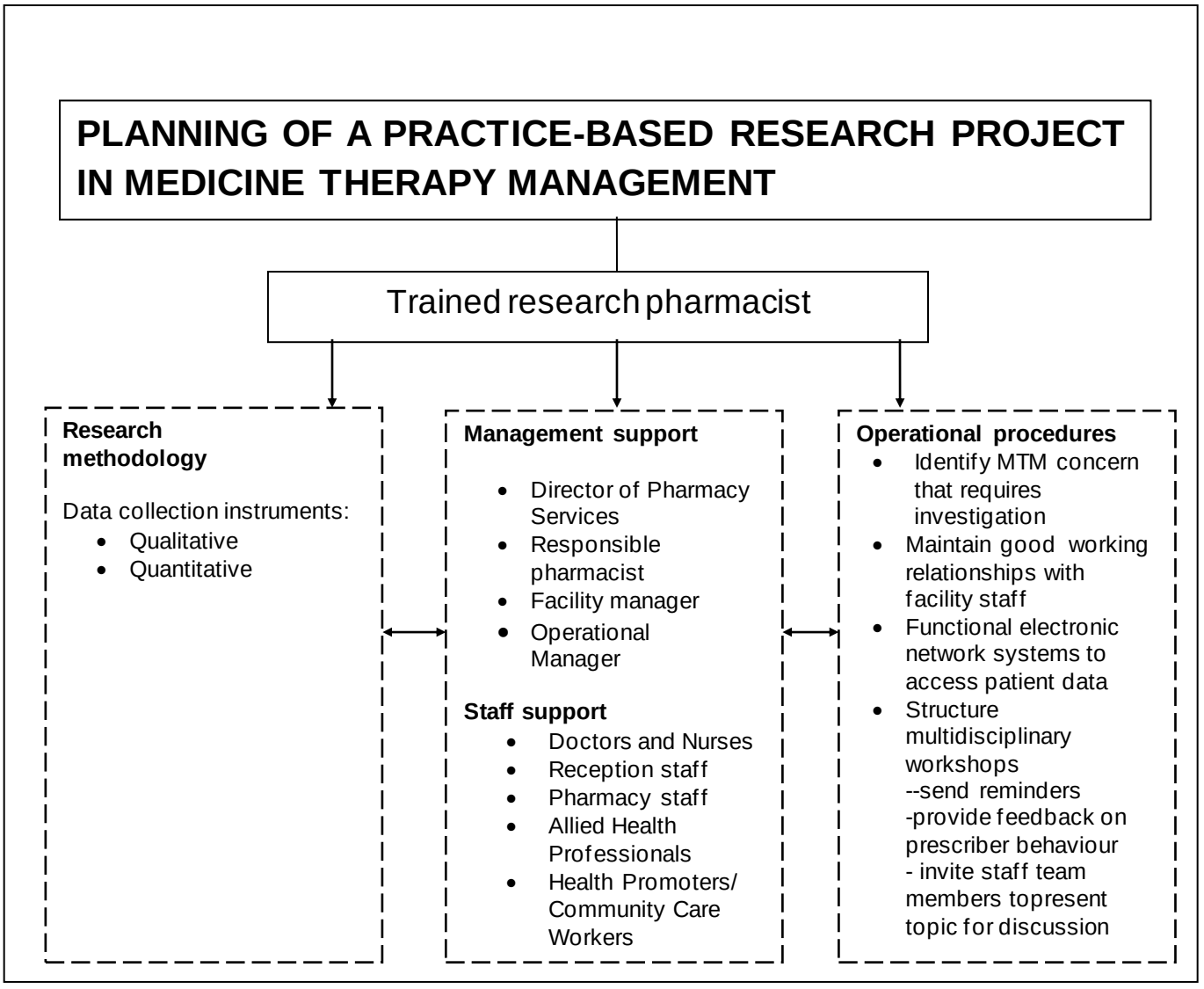

Figure 5.1: Preliminary planning of practice-based research

This exploratory study provides a roadmap to operationalize implementation research for optimising chronic disease management at the primary care level in the

public health sector. Planning a monitoring and evaluation research project on MTM in a practice setting requires the following:

- Establish a good working relationship with staff,
- Understand the operational procedures in the facility,
- Set realistic objectives which can be implemented within the study time-frame
- Identify data collection times in accordance with patient attendance at the facility,
- Update management and facility staff regularly on research progress, and,
- Garner Institutional support is crucial to ensure smooth data collection.

d) Approaches to improve operational challenges

(i) Electronic record keeping

In view of the increasing demand on the public health sector, it is important for the government to consider investing in computerizing patients records in which all programs are linked to one system and database. This will improve record keeping by reducing time spent retrieving records, ease extraction of patient information and improve the completeness of medical records by staff.

ii) Recording of required patient data

From the prep room all physical, clinical data and prior laboratory tests performed by prescriber needs to be recorded onto the MDHS chronic disease record sheet so that any missing data can be identifed and tracked as soon as possible.This is important when diabetic patient presciptions are analysed having the full dataset available to check appropriateness, effectiveness and safety of medicine therapy.

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APPENDIX 1: ASPIRIN CIRCULAR H141/2017

Western Cape Government
Health

DIRECTORATE: PHARMACY SERVICES

Reference: 18/2/18/7
Enquiries: Y Johnson
Yasmina.Johnson@westerncape.gov.za

CIRCULAR NO: H 141 /2017

TO: **DDG: CHIEF OF OPERATIONS**
CHIEF DIRECTORS
DIRECTORS
HEADS OF INSTITUTIONS
DEPUTY DIRECTOR: CAPE MEDICAL DEPOT
HEAD OF HEALTH: CITY OF CAPE TOWN
RESPONSIBLE PHARMACIST: CHRONIC DISPENSING UNIT UTI

N.B. **FOR CIRCULATION TO ALL MEDICAL, PARAMEDICAL, PHARMACEUTICAL AND NURSING PERSONNEL**

ASPIRIN MEDICINE USE EVALUATION FEEDBACK

Medicine use evaluation (MUE) is a systematic, criteria-based evaluation of medicine use that will ensure that medicines are used appropriately; ultimately improving patient outcomes[1]. MUEs focus on areas that show the most potential for improvement for appropriate, safe and effective use of medicines. The selection of a medicine for conducting an MUE is based on high use (impacts on large populations), high cost (impacts on expenditure), and high risk (impacts on safety) or is problem prone (inappropriate use)[1].

The province's expenditure on aspirin for a 6-month period (01 April 2014 to 30 September 2014) was R 3 628 154,00. Furthermore, usage statistics of aspirin suggested that approximately 170 000 patients per month receive aspirin in the province. Long-term use of aspirin is associated with increased risk of non-trivial bleeds[2] and a pilot investigation conducted prior to the MUE reflected that prescribing of aspirin was often not according to the national guidelines[5, 6]. With this in mind, the Western Cape Pharmacy and Therapeutics Committee requested that an MUE be conducted for aspirin in 2015.

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The impact of the MUE was assessed in terms of the reduced usage of aspirin in 2016. Aspirin usage reduced from 2 742 650 packets (14's) in 2015 to 1 787 700 packets (14's) in 2016 i.e. a reduction of 954 950 packets (14's); which translated into a savings of R5, 4 million in 12 months.

Background:

The aspirin medicine use evaluation was conducted in 2015 with the following objectives:

- To determine whether aspirin is prescribed for chronic indications as set out in the Standard Treatment Guidelines and Essential Medicines List for Primary Health Care 2008[3] as well as Adult Hospital Level 2012[4]. These recommendations for aspirin are in line with the updated Standard Treatment Guidelines and Essential Medicines List for Primary Health Care 2014[5] as well as the Adult Hospital Level 2015[6].
- To make policy recommendations to improve the prescribing of aspirin and reduce inappropriate expenditure.

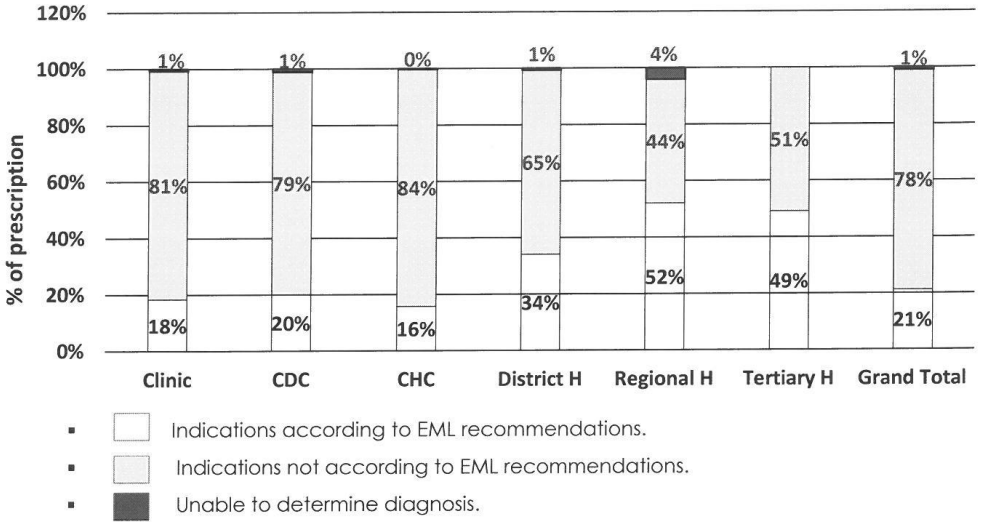
The criteria for evaluation of aspirin were diagnosis-related – see Table 1. As aspirin tablets are prescribed predominantly at district level care, the criteria were based on the recommendations as set out in the Standard Treatment Guidelines and Essential Medicines List for Primary Health Care and Adult Hospital Level (EML)[3, 4]. The MUE study design was a multicentre, retrospective folder review.

Table 1: Indications and dosages for aspirin as per the Standard Treatment Guidelines and Essential Medicines List for Primary Health Care and Adult Hospital Level (EML)[3, 4].

INDICATIONS
1. Atherosclerotic Peripheral Arterial Disease
2. Ischemic Heart Disease (Angina)
3. Myocardial Infarction (Heart Attack)
4. Pre-eclampsia
5. Systemic Lupus Erythematosus (SLE)
6. Cerebrovascular Incident (Stroke)
DOSAGE
75mg (80mg)
150mg

Overall, based on information in patients' medical notes, only around 21% of prescriptions met the criteria for aspirin indications as per the EML[3, 4] (See Graph 1).

Graph 1: Percentage of prescriptions that are according to EML recommendations, not according to EML recommendations and with no diagnosis, 2015.



- Indications according to EML recommendations.
- Indications not according to EML recommendations.
- Unable to determine diagnosis.

Based on the results of the MUE, health professionals were recommended to review aspirin prescriptions for appropriateness. As a follow-up on the above MUE, the usage of aspirin for 2015 was compared with the usage of aspirin in 2016 (see Appendix A). Aspirin usage reduced by 35%; from 2 742 650 packets (14's) to 1 787 700 packets (14's) i.e. a reduction of 954 950 packets (14's). This reduction relates into a savings of R5, 4 million in 12 months.

Staff are encouraged to continue to review all prescriptions for aspirin in terms of appropriate prescribing as per the recommendations in the EMLs.

Thank you to all staff who made this endeavour possible.

MS K LOWENHERZ

DIRECTOR: PHARMACY SERVICES

DATE: 26/10/17

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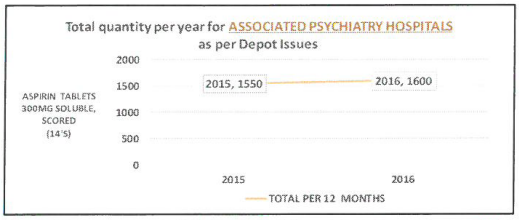
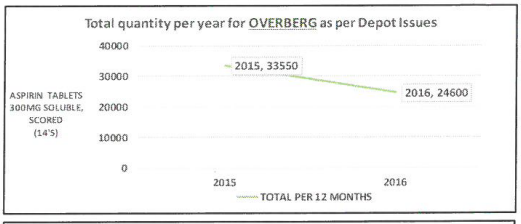
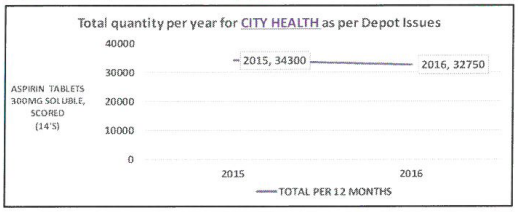
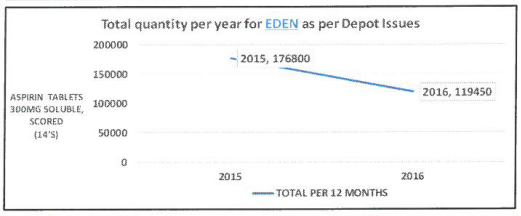
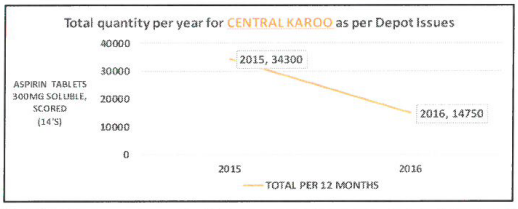
ASPIRIN 300mg Tablet issues from Depots (01 April 2015 to 31 March 2016 vs 01 April 2016 to 31 March 2017)

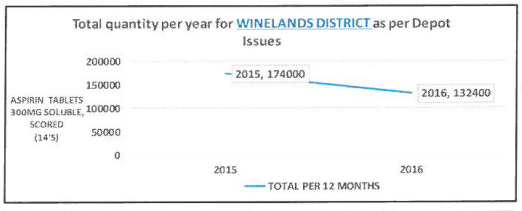


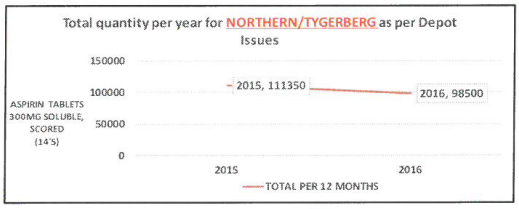


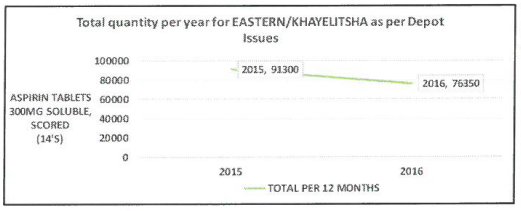


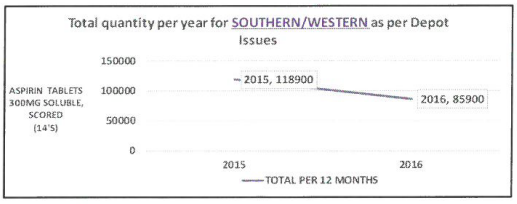


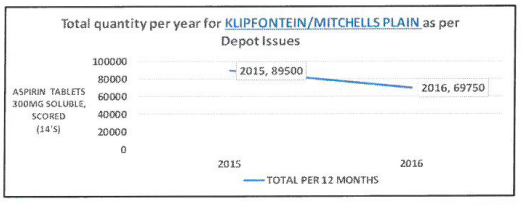


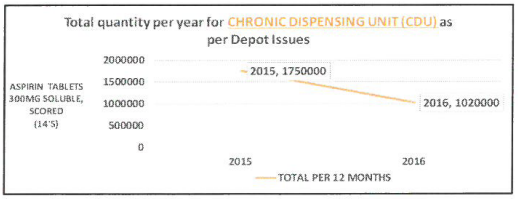


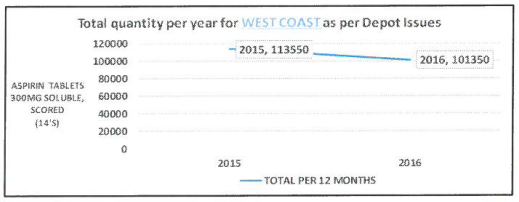


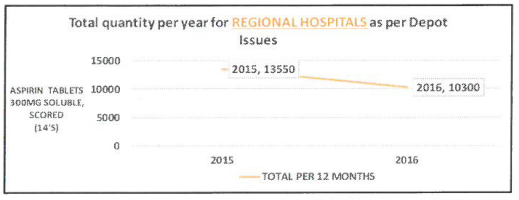


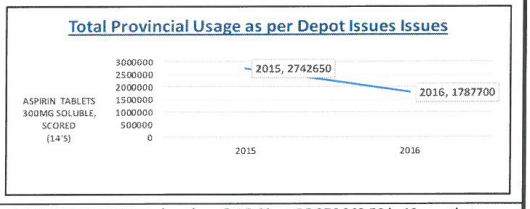












Difference in provincial usage for Aspirin 300mg 14s (2015/16 vs 2016/17): 2 742 650 - 1 787 700 = 954 950 packets less @ R5.63 = ± R5 376 368.50 in 12 months

APPENDIX 2: PHARMACIST MEDICINE THERAPY MANAGEMENT DATA TOOLS

PHARMACIST MEDICINE THERAPY MANAGEMENT DATA FORMS

PHARMACIST'S PATIENT DATA SHEET

Complete below by filling in the required information and making an (X) inside the appropriate box				
Facility name:		**Unique code:**		
Pharmacist name:		**Pharmacist signature:**		
Demographic information	Patient folder number:		Gender: Male❑ Female: ❑	
	Date of Birth/Age:		Allergies:	
Condition	Diabetes Mellitus Type 2 ❑			
Co-morbidities	Hypertension❑	Asthma ❑	Epilepsy ❑	COPD ❑
	Other co-morbidities not listed: specify			

		BASELINE DATA		**POST-PHARMACIST INTERVENTION**		**6-MONTH FOLLOW-UP DATA**	
Date started							
Date completed							
PHYSICAL MEASUREMENT		**DATE**	**RESULT**	**DATE**	**RESULT**	**DATE**	**RESULT**
Weight (kg)							
Height (m)							
Body Mass Index (BMI) kg/m^2							
CLINICAL MEASUREMENT		**DATE**	**RESULT**	**DATE**	**RESULT**	**DATE**	**RESULT**
Blood pressure (mmHg)			At baseline 3 readings				
Fasting Plasma Glucose (mmol/L)			At baseline 3 readings				
Urine test	*Glucose*						
	Ketones						
	Proteins						
LABORATORY TESTS		**DATE**	**RESULT**	**DATE**	**RESULT**	**DATE**	**RESULT**
HbA1c(%)							
Serum Creatinine (µmol/L)							
GFR (ml/minute)							
Total cholesterol (mmol/L)							
PATIENT MEDICINE THERAPY							
Date of prescription							
Name/Dose/Route							
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
Total number of medicines prescribed							

PHARMACIST MEDICINE THERAPY MANAGEMENT DATA FORMS
PHARMACIST ASSESSMENT WORKSHEET

Facility name:
Pharmacist name:
Pharmacist signature:
Date started:
Date completed:
Patent older number:

Complete below by filling in the required information

Date	Medicine therapy problem type	Pharmacist intervention description	Pharmacist recommendation	Outcome: Accepted (A), Partially Accepted (PA), or Rejected (R)	Club Doctor (d) or Clinical Nurse Practitioner (CNP) whom intervention was	Indirect cost per month of medicine therapy

PHARMACIST MEDICINE THERAPY MANAGEMENT DATA FORMS

PHARMACIST ASSESSMENT WORKSHEET

Facility name	**Pharmacist name:**	**Pharmacist signature:**
Date started:	**Date completed:**	**Number of interventions recorded:**
Patient folder number:		

Complete by filling in the required information

Date	Medicine therapy problem category	Medicine therapy problem type	Pharmacist intervention description	Pharmacist recommendation

MEDICINE THERAPY PROBLEM CATEGORIES (A-I) AND TYPES 1-35)

A	**UNNECESSARY MEDICINE THERAPY**		**D**	**DOSAGE TOO LOW**		**F**	**DOAGE TOO HIGH**
1	No medical indication noted		13	Wrong dose		23	Wrong dose
2	Duplicate therapy		14	Medicine frequency inappropriate		24	Frequency inappropriate
3	Non-drug therapy indicated		15	Medicine interation		25	Duration inappropriate
4	Treating avoidable adverse medicine reaction		16	Duration inappropriate		26	Medicine interaction
5	Addictive/recreational					27	Incorrect administration
			E	**ADVERSE MEDICINE REACTION**			
B	**NEEDS ADDITIONAL MEDICINE THERAPY**		17	Undesirable effect		**H**	**NONCOMPLIANCE**
6	Untreated medical condition		18	Unsafe medicine for patient		28	Directions not understood
7	Lack of preventative/prophylactic		19	Medicine interaction		29	Patient refers not to take
8	Synegistic/potentiating effects of medicines		20	Dosage administered or change to rapidly		30	Patient forgets to take
			21	Allergic reaction		31	Medicine product too expensive
C	**NEEDS DIFFERENT MEDICINE PRODUCT**		22	Contra-indications		32	Cannot swallow/administer
9	More effective medicine available					33	Medicine product not available
10	Condition refractory to medicine						
11	Dosage form inappropriate					**I**	**OTHER**
12	Not effective for medical condition					34	Laboratory tests not undertaken
						35	Lack of physical measurements recorded

PHARMACIST MEDICINE THERAPY MANAGEMENT DATA TOOLS

PHARMACIST INTERVENTION LABEL

Date:
Intervention:
Recommendation
Pharmacist:
Sign:

PHARMACIST MEDICINE THERAPY MANAGEMENT DATA TOOLS

COVER PAGE FOR STABLE DIABETIC FOLDER

THURSDAY DIABETIC CLUB
PHARMACIST INTERVENTION LABEL

Date	
Intervention	
Recommendation	
Pharmacist	
Sign	

THURSDAY DIABETIC CLUB
PHARMACIST INTERVENTION LABEL

Date	
Intervention	
Recommendation	
Pharmacist	
Sign	

THURSDAY DIABETIC CLUB
PHARMACIST INTERVENTION LABEL

Date	
Intervention	
Recommendation	
Pharmacist	
Sign	

APPENDIX 3: SEMI-STRUCTURED QUESTIONNAIRE FOR PARTICIPANTS

Medicine therapy management feedback workshop questionnaire

School of Pharmacy
University of the Western Cape
Robert Sobukwe, Bellville,
Cape Town,7535
021-9592190

Date: _____

Medicine therapy management for diabetic club patients at a primary health care clinic: exploring a potential role for pharmacists
Unique code: _____

1. In your opinion, how did the pharmacist contribute to diabetes management at this Community Day Centre?

_____
_____
_____

2. In what way has your management of the diabetic patient changed following the involvement of a pharmacist?

_____
_____
_____

3. From your experience, should a pharmacist be a part of the team in diabetes management at facilities?

_____
_____
_____

4. Would you recommend a pharmacist in the diabetes management team at other community day care centres?

_____
_____

APPENDIX 4: FACILITY STAFF INFORMATION LEAFLET

Facility staff information leaflet

Researcher: Farhaana Sonday
Student Number: 2316144
School of Pharmacy
University of the Western Cape,
Robert Sobukwe, Bellville,
Cape Town, 7535

Medicine therapy management for diabetic club patients at a primary health care clinic: exploring a potential role for pharmacists

Study information sheet

Introduction
I am a Postgraduate student of the School of Pharmacy at the University of the Western Cape. You are invited to volunteer to participate in my research project. The study is called: **Medicine therapy management for diabetic club patients at a primary health care clinic: exploring a potential role for pharmacists**

This sheet gives information to help you to decide if you want to take part in this study. Before you decide whether to participate or not in this study, you should fully understand what is involved. If you do not understand the information or have any questions, do not hesitate to ask me. If you agree to participate, you will be asked to sign a consent form. You will also be given a copy of this information sheet to keep for your own records. You should not agree to take part in the study unless you are completely happy about what we expect of you. Please note that your participation is voluntary and that you may choose to withdraw from the study at any time.

Purpose of the study
The overall purpose of the research study is to explore the potential role of a pharmacist in a multidisciplinary diabetes team by optimizing medicine therapy management. It will also evaluate the impact of a multidisciplinary team approach in diabetes management at a primary health care clinic. Through this study we will be able to evaluate prescriber uptake of pharmacist-led MTM intervention at the primary level of care.

Procedure
The researcher, a pharmacist, will collect data using three pharmacist data collection sheets, a pharmacist label and a semi-structured questionnaire. The data will be

collected over a period of 90 days. The researcher will review the stable diabetic club patient folders with regard to the clinical data and currently prescribed therapy.. Pharmacist interventions will entail medicine therapy adjustments in accordance with the recommended guidelines. Pharmacist interventions will be recorded and recommended to the prescribers in the diabetic club. The recommendation will be provided on the pharmacist label for the prescriber to consider during the consultation. The researcher will also have meetings every two weeks with staff participants to discuss the interventions documented by the researcher. The researcher will assess the stable diabetic club patient folders to determine prescriber uptake of recommendations.

The purpose of the semi-structured questionnaire is to allow us to gain some insight into the participant's experiences, attitudes and perceptions of the potential benefit and role of the pharmacist in diabetes management. The semi-structured questionnaire will be given at the end of the data collection process for staff participants to complete. A pharmacist, an independent assessor, will be available to help you when filling in the semi-structured questionnaire. It will take about ten minutes to fill in and complete.

Risks
We do not think there will be any risks for you in participating in this study.

Benefits
There will be no direct benefit for you from participating in this study. Participation is voluntary and you will not be paid for your time.

Confidentiality
All the information you provide us with will be kept confidential. You will not need to write your name on the questionnaire, the information you give us is anonymous. Your identity will not be revealed when the study is reported or published. Study materials will be kept in a safe place to ensure confidentiality.

Voluntary participation
Your participation in this study is voluntary. You can choose to not take part of the study. You can withdraw from the study at any time. If you wish to take part in the study you will have to sign the consent form.

Contact information
If you have any questions about the study, you can ask them now, or if you agree to participate in the study and have more questions at a later time, you can contact me Farhaana Sonday.

Contact details:
Farhaana Sonday
School of Pharmacy Postgraduate Student
021 904-4416
Email: 2316144@myuwc.ac.za

APPENDIX 5: INFORMED CONSENT FORM

Informed consent form

School of Pharmacy
University of the Western Cape,
Robert Sobukwe, Bellville,
Cape Town, 7535
021-9592190

Study title: Medicine therapy management for diabetic club patients at a primary health care clinic: exploring a potential role for pharmacists

Date: _____ Unique code: _____

Name of Participant: _____

1. The purpose of the study has been explained to me and I understand the objectives.
2. I am provided with the opportunity to ask questions and given adequate time to rethink the issue.
3. I have been provided with an information sheet on this study.
4. I understand that that participation in this study is voluntary and that I may withdraw my participation at any time.
5. I understand that I will not be identified in any report from this study.
6. I understand that any information I provide for the study will be kept secure by the researcher.
7. I agree to this, provided my privacy is guaranteed.
8. I hereby give consent to participate in this study.

.....	.....	.....
Signature of participant	Date	Place
.....	.....	.....
Signature of Witness	Date	Place

Statement by the Researcher

I provided written information regarding this study. I agree to answer any future questions concerning the study as best as I am able.

.....	.....	.....	.....
Farhaana Sonday	Signature	Date	Place

APPENDIX 6: CODES USED FOR ORGANIZING DATA FOR ANALYSIS

CODING DATA

MEDICINES PRESCRIBED IN STABLE TYPE 2 DIABETIC PATIENTS								
Biguanide-Metformin	**Sulphonylureas-Glimepiride**	**Insulin**	**Thiazide diuretic Hydrochlorothiazide**	Angiotensin-converting enzyme inhibitors **Enalapril**	**Angiotensin receptor blockers-Losartan**	**Calcium Channel Blockers-Amlodipine**	**Beta blockers - Atenolol**	**High ceiling diuretic-Furosemide**
None=0 Yes=1	None=0 Yes=1	None=0 Yes=1	None=0 Yes=1	None=0 Yes=1	None=0 Yes=1	None=0 Yes=1	None=0 Yes=1	None=0 Yes=1
Aspirin	**Simvastin**							
None=0 Yes=1	None=0 Yes=1							

OTHERS
Prescribers Doctor=0 Clinical Nurse Practitioner=1 **Data collection period** Baseline=BL Post-Pharmacist Recommendation =PPR 6-month follow-up=6-MFU

Co-morbidities
Yes=1 No=0 Diabetes Mellitus II=1 Hypertension=1 **Abbreviations** Asthma=Ast Epilepsy=E Chronic Obstructive Pulmonary Disease=COPD Dislipidaemia=D Osteo-arthritis=OA GORD=G Peripheral Neuropathy=PN Chronic Kidney Disease=CKD Congestive Cardiac Failure=CCF Allergic Rhinitis=AR Ischaemic Heart Disease=IHD Arthalgia=A

Medicine Therapy Problems (MTPs) commonly encountered	**Number of interventions for each class**	**Medicine Therapy (MT) outcome**
1.No medical indication noted=1 6.Untreated medical condition=2 7.Lack of preventative/prophylactic=3 8.Synergistic/potentiating effects of medicines=4 13. Wrong dose(dose is too low)=5 19. Medicine interaction=6 22. Contra-indications=7 23. Wrong dose (dose is too high)=8 24. Medicine frequency inappropriate=9 34.Laboratory tests not undertaken=10 35.Lack of physical measurements recorded=11	None=0 1=1 2=2 3=3	Accepted=0 Partially accepted=1 Rejected=2 None=3 Accepted and Partial=4 Accepted and Rejected=5

Aspirin MT	**Furosemide MT**	**Simvastatin MT**
None=0 Yes=1	None=0 Yes=1	None=0 Yes=1
Aspirin Outcome	**Furosemide Outcome**	**Simvastatin Outcome**
Accepted =0 Partially Accepted=1 Rejected=2 None=3	Accepted =0 Partially Accepted=1 Rejected=2 None=3	Accepted =0 Partially Accepted=1 Rejected=2 None=3

APPENDIX 7: ETHICAL APPROVAL:
BIOMEDICAL ETHICS COMMITTEE OF THE UNIVERSITY OF THE WESTERN CAPE

UNIVERSITY of the WESTERN CAPE

OFFICE OF THE DIRECTOR: RESEARCH
RESEARCH AND INNOVATION DIVISION

Private Bag X17, Bellville 7535
South Africa
T: +27 21 959 2988/2948
F: +27 21 959 3170
E: research-ethics@uwc.ac.za
www.uwc.ac.za

21 October 2016

Prof A Bheekie, Ms F Sonday and Dr M Van Huyssteen
School of Pharmacy
Faculty of Sciences

Ethics Reference Number: BM/16/4/11

Project Title: Medicine Therapy Management for diabetic club patients at a primary health care clinic: exploring a potential role for pharmacists.

Approval Period: 28 September 2016 to 28 September 2017

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval. Please remember to submit a progress report in good time for annual renewal.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

PROVISIONAL REC NUMBER -130416-050

APPENDIX 8: ETHICAL APPROVAL: WESTERN CAPE DEPARTMENT OF HEALTH

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
Health.Research@westerncape.gov.za
tel: +27 21 483 6857: fax: +27 21 483 9895
5th Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: WC_2016RP43_75
ENQUIRIES: Ms Charlene Roderick

University Of The Western Cape

Robert Sobukwe Road

Bellville

Cape Town

7535

For attention: Ms Farhaana Sonday

Re: Medicine therapy management for diabetic club patients at a primary health care clinic: exploring a potential role for pharmacists.

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact following people to assist you with any further enquiries in accessing the following sites:

Kleinvlei CDC	**Sr Volente Jonkers**	**021 904 4416**

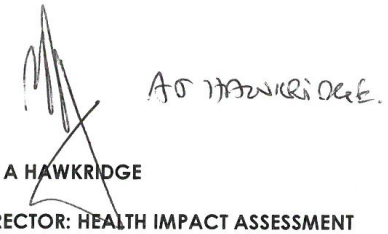
Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).

3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).

4. The reference number above should be quoted in all future correspondence.

Yours sincerely



DR A HAWKRIDGE

DIRECTOR: HEALTH IMPACT ASSESSMENT

DATE: 2/11/2016.

CC **M PHILLIPS** **DIRECTOR: KESS**

APPENDIX 9: LETTER OF INTENT TO FACILITY MANAGER

School of Pharmacy
University of the Western Cape,
Robert Sobukwe, Bellville,
Cape Town, 7535
Tel: 021-9592190
abheekie@uwc.ac.za

7 November 2016
Sr. V. Jonkers
Facility Manager: Kleinvlei CDC
C\o Albert Philander &Melkbos Roads,
Kleinvlei, 7100, Cape Town
violente.jonkers@westerncape.gov.za

Dear Sr. V. Jonkers

RE: Letter of intent to conduct research study at Kleinveli Community Day Centre

We hereby request permission for Ms.FarhaanaSonday to conduct her research study at Kleinvlei community Day Centre. Ms.Sonday is enrolled for the M.Pharm programme at the School of Pharmacy University of the Western Cape.

The study design is an evaluation one consistingof quantitative and qualitative methods whereby prospective and retrospective data will be collected from patient files.

Attached please find the following supporting documents:

- The proposal for the research study titled: Medicine therapy management (MTM) for diabetic club patients at a primary health care clinic: exploring a potential role for pharmacists.
- Ethical approval obtained from the Biomedical Science Research Ethics Committee of the University of the Western Cape.
- Research study approval obtained from the Department of Health Western Cape.

The aim of the study is to determine the pharmacist's role in optimising MTM of stable chronic diabetic club patients at a primary care clinic.

The objectives are:
(i) Orientate facility staff to a pharmacist's medicine therapy management (MTM)framework for stable chronic diabetic patients attending Kleinvlei CDC diabetes club.
(ii) Conduct a pilot study on MTM for chronic stable diabetic patients
(iii) To obtain and evaluate current primary clinical data (HbA1c), secondary clinical data (fasting plasma glucose, postprandial glucose and urine dipstix test) and medication therapy profile of stable chronic diabetic patientsusing pharmacist'sdata collection sheets (current prescriber practice).
(iv) Offer pharmacist's MTM recommendations in accordance with the STG's and EML (RSA, 2014) (pharmacist-led intervention).
(v) To determine prescriber uptake of pharmacist-led interventions diabetic club patients during the data collection period (prescriber uptake).
(vi) To explore staff experiences regarding pharmacist MTM recommendations in diabetes management.

During the course of the study period, medicine therapy recommendations will be provided and directed to the prescribing staff. For this study, there will be no direct patient interaction. The study will be conducted in a manner that will not disrupt the facility's services.

Sincerely
AngeniBheekie*PhD*
Principal supervisor

APPENDIX 10: STATISTICAL ANALYSIS OF CLINICAL PARAMETERS SYSTOLIC BLOOD PRESSURE, DIASTOLIC BLOOD PRESSURE, FASTING PLASMA GLUCOSE AND URINE DIPSTICK ANAYSIS

1) Below is an example of a medicine therapy problem and the outcome statistically analysed by applying the paired sample t-test.

Example:
Medicine Therapy Problem 8: *Synergistic/potentiating effects of medicines*
Outcome: *Accepted*

Table 1: Statistical testing systolic blood pressure

Estimates

Measure: systolic Estimates

blood_pressure	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
1	144.900	6.910	129.269	160.531
2	148.900	8.477	129.724	168.076
3	140.200	5.591	127.552	152.848

Pairwise Comparisons

Measure: systolic

(I) blood_pressure	(J) blood_pressure	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	2	-4.000	8.439	.647	-23.091	15.091
	3	4.700	7.789	.561	-12.920	22.320
2	1	4.000	8.439	.647	-15.091	23.091
	3	8.700	7.635	.284	-8.571	25.971
3	1	-4.700	7.789	.561	-22.320	12.920
	2	-8.700	7.635	.284	-25.971	8.571

Based on estimated marginal means

a. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).

Table 2: Statistical testing diastolic blood pressure

Estimates

Measure: diastolic

blood_pressure	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
1	81.700	1.407	78.518	84.882
2	85.900	3.089	78.912	92.888
3	81.700	3.763	73.189	90.211

Pairwise Comparisons

Measure: diastolic

(I) blood_pressure	(J) blood_pressure	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	2	-4.200	3.101	.209	-11.216	2.816
	3	.000	3.235	1.000	-7.319	7.319
2	1	4.200	3.101	.209	-2.816	11.216
	3	4.200	4.767	.401	-6.585	14.985
3	1	.000	3.235	1.000	-7.319	7.319
	2	-4.200	4.767	.401	-14.985	6.585

Based on estimated marginal means

a. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).

Table 3: Statistical testing fasting plasma glucose

Estimates

Measure: Fasting glucose

blood_glucose	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
1	7.210	.723	5.573	8.847
2	9.600	1.513	6.177	13.023
3	10.120	1.288	7.207	13.033

Pairwise Comparisons

Measure: Fasting glucose

(I) blood_glucose	(J) blood_glucose	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
1	2	-2.390	1.068	.052	-4.805	.025
	3	-2.910*	1.027	.020	-5.233	-.587
2	1	2.390	1.068	.052	-.025	4.805
	3	-.520	1.066	.637	-2.931	1.891
3	1	2.910*	1.027	.020	.587	5.233
	2	.520	1.066	.637	-1.891	2.931

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).

Table 4: Statistical testing urine dipstick analysis

a) Urine glucose

Estimates

Measure: Urine_glucose

Glucose	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
1	.667	.333	-.102	1.435
2	.556	.338	-.224	1.335
3	.889	.512	-.292	2.070

Pairwise Comparisons

Measure: Urine_glucose

(I) Glucose	(J) Glucose	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	2	.111	.309	.729	-.602	.824
	3	-.222	.547	.695	-1.484	1.040
2	1	-.111	.309	.729	-.824	.602
	3	-.333	.553	.563	-1.608	.941
3	1	.222	.547	.695	-1.040	1.484
	2	.333	.553	.563	-.941	1.608

Based on estimated marginal means

a. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).

b) Ketone

Estimates

Measure: ketone

ketones	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
1	.000	.000	.000	.000
2	.000	.000	.000	.000
3	.000	.000	.000	.000

c) Protein

Estimates

Measure: protein

proteins	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
1	.500	.269	-.108	1.108
2	.100	.100	-.126	.326
3	.200	.200	-.252	.652

Pairwise Comparisons

Measure: protein

(I) proteins	(J) proteins	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	2	.400	.306	.223	-.291	1.091
	3	.300	.213	.193	-.183	.783
2	1	-.400	.306	.223	-1.091	.291
	3	-.100	.233	.678	-.628	.428
3	1	-.300	.213	.193	-.783	.183
	2	.100	.233	.678	-.428	.628

Based on estimated marginal means

a. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).

2) The following tables below reflect the data which was statistically analysed and found to be statistically significant with p<0.05.

Table 5: Statistically significant P-value for systolic blood pressure

Medicine Therapy Problems	**Significant P-value for systolic blood pressure**			
	Outcomes	***Baseline***	***Post-Pharmacist intervention***	***6-month follow-up***
1.No medical indication noted	A	X	X	X
	R	0.026*	0.04*+0.026*	0.04*
6.Untreated medical condition	A	X	X	X
	R	0.05*	0.05*	X
7.Lack of preventative/prophylactic	A	0.018*	0.018*	X
	R	X	X	X
8.Synergistic/potentiating effects of medicines	A	X	X	X
	PA	--	--	--
	R	0.002*	0.02*+0.024*	0.024*
13. Wrong dose(dose is too low)	A	0.020*	X	0.020*
	PA	0.028*	X	0.028*
	R	0.036*	0.036	X
19. Medicine interaction	A	--	--	--
	R	--	--	--
22. Contra-indications	A	--	--	--
	PA	--	--	--
	R	--	--	--
23. Wrong dose (dose is too high	A	X	X	X
	PA	X	X	X
	R	X	X	X
24.Medicine frequency inappropriate	R	--	--	--
34.Laboratory tests not undertaken	A	0.019*+0.047*	0.019*	0.047*
	R	X	X	X
35.Lack of physical measurements recorded	A	0.011*	0.011*	X
	PA	--	--	--
	R	X	X	X

Outcomes A= Accepted PA= Partially accepted R= Rejected; Statically significant *p<0.05;
-- Not detected; Not statically significant X

Table 6: Statistically significant P-value for diastolic blood pressure

Medicine Therapy Problems	Significant P-value for diastolic blood pressure			
	Outcomes	*Baseline*	*Post-Pharmacist intervention*	*6-month follow-up*
1.No medical indication noted	A	X	X	X
	R	X	X	X
6.Untreated medical condition	A	X	X	X
	R	X	X	X
7.Lack of preventative/prophylactic	A	X	X	X
	R	X	X	X
8.Synergistic/potentiating effects of medicines	A	X	X	X
	PA	--	--	--
	R	X	X	X
13. Wrong dose(dose is too low)	A	0.011*	X	0.011*
	PA	X	0.035*	0.035*
	R	X	X	X
19. Medicine interaction	A	--	--	--
	R	--	--	--
22. Contra-indications	A	--	--	--
	PA	--	--	--
	R	--	--	--
23. Wrong dose (dose is too high	A	X	X	X
	PA	X	X	X
	R	X	x	X
24.Medicine frequency inappropriate	R	--	--	--
34.Laboratory tests not undertaken	A	0.008*	X	0.008*
	R	X	X	X
35.Lack of physical measurements recorded	A	0.005*	X	0.005*
	A	--	--	--
	R	X	X	X

Outcomes A= Accepted PA= Partially accepted R= Rejected; Statically significant *p<0.05;
-- Not detected; Not statically significant X

Table 7: Statistically significant P-value for fasting plasma glucose

Medicine Therapy Problems	Significant P-value for fasting glucose			
	Outcomes	*Baseline*	*Post-Pharmacist intervention*	*6-month follow-up*
1.No medical indication noted	A	X	X	X
	R	X	X	X
6.Untreated medical condition	A	X	X	X
	R	0.040*	X	0.040*
7.Lack of preventative/prophylactic	A	X	X	X
	R	X	X	X
8.Synergistic/potentiating effects of medicines	A	0.020*	X	0.020*
	PA	--	--	--
	R	0.007*+0.008*	0.007*	0.008*
13. Wrong dose(dose is too low)	A	0.032*	x	0.032*
	PA	0.019*	0.019*	X
	R	X	X	X
19. Medicine interaction	A	--	--	--
	R	--	--	--
22. Contra-indications	A	--	--	--
	PA	--	--	--
	R	--	--	--
23. Wrong dose (dose is too high	A	X	X	X
	PA	X	X	X
	R	X	X	X
24.Medicine frequency inappropriate	R	--	--	--
34.Laboratory tests not undertaken	A	X	X	X
	R	0.027*+0.030*	0.027*	0.030*
35.Lack of physical measurements recorded	A	X	X	X
	PA	--	--	--
	R	0.019*+0.009*	0.019*	0.009*

Outcomes A= Accepted PA= Partially accepted R= Rejected; Statically significant *p<0.05;
-- Not detected; Not statically significant X

Table 8: Statistically significant P-value for urine dipstick analysis

Medicine Therapy Problems	Significant P-value for urine dipstick urine analysis									
	Outcomes	*Glucose*			*Ketones*			*Proteins*		
		Baseline	*Post-Pharmacist intervention*	*6-month follow-up*	*Baseline*	*Post-Pharmacist intervention*	*6-month follow-up*	*Baseline*	*Post-Pharmacist intervention*	*6-month follow-up*
1.No medical indication noted	A	X	X	X	X	X	X	0.049	X	0.049
	R	X	X	X	--	--	--	X	X	X
6.Untreated medical condition	A	X	X	X	X	X	X	X	X	X
	R	X	X	X	X	X	X	X	X	X
7.Lack of preventative/prophylactic	A	X	X	X	--	--	--	X	X	X
	R	X	X	X	--	--	--	--	--	--
8.Synergistic/potentiating effects of medicines	A	X	X	X	--	--	--	X	X	X
	PA	--	--	--	--	--	--	--	--	--
	R	X	X	X	--	--	--	X	X	X
13. Wrong dose(dose is too low)	A	X	X	X	--	--	--	X	X	X
	PA	0.020*	0.015*	0.020*+0.015*	--	--	--	X	X	X
	R	X	X	X	--	--	--	X	X	X
19. Medicine interaction	A	--	--	--	--	--	--	--	--	--
	R	--	--	--	--	--	--	--	--	--
22. Contra-indications	A	--	--	--	--	--	--	--	--	--
	PA	--	--	--	--	--	--	--	--	--
	R	--	--	--	--	--	--	--	--	--
23. Wrong dose (dose is too high	A	X	X	X	--	--	--	X	X	X
	PA	X	X	X	--	--	--	X	X	X
	R	X	X	X	X	X	X	X	X	X
24.Medicine frequency inappropriate	R	--	--	--	--	--	--	--	--	--
34.Laboratory tests not undertaken	A	X	X	X	--	--	--	X	X	X
	R	X	X	X	X	X	X	X	X	X
35.Lack of physical measurements recorded	A	X	X	X	--	--	--	X	X	X
	PA	--	--	--	--	--	--	--	--	--
	R	X	X	X	X	X	X	X	0.045*	0.045*

Outcomes A= Accepted PA= Partially accepted R= Rejected; Statically significant *p<0.05; -- Not detected; Not statically significant X