

**A FEASIBLE DIABETES MANAGEMENT GUIDELINE FOR PRIMARY HEALTH
CARE PRACTITIONERS IN THE FREE STATE FOR WORKPLACE LEARNING**

by

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DECLARATION

I hereby declare that the compilation of this mini-dissertation is the result of my own independent work. I have acknowledged persons who assisted me in this endeavour. I have tried to use the research sources cited in the text in a responsible way and to give credit to the authors and compilers of the references for the information provided, as necessary. I further declare that this work is submitted for the first time at this institution and faculty for the purpose of obtaining a Magister Degree in Health Professions Education and that it has never been submitted at any other institution for the purpose of obtaining a qualification. I also declare that all information provided by study respondents will be treated with the necessary confidentiality.

Dr M M Rossouw

Date

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DEDICATION

In memory of my two grandmothers:

Dr Maria Magdalena (Marie) Van Niekerk Rossouw [1918 – 2007]

Doctor, social worker at heart, always a lady.

and

Susan (Sannie) Roux Harbor [1922 – 2020]

Caring nurse, missionary, eternal optimist.

You are still loved and missed.

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LIST OF ACRONYMS

ACE-I	Angiotensin converting enzyme inhibitor
ADA	American Diabetes Association
AGREE	Appraisal of Guidelines for Research and Evaluation
APC	Adult Primary Care
ARB	Angiotensin receptor blocker
CPGAE-V1.0	Clinical practice guideline applicability evaluation
CPGs	Clinical practice guidelines
DKA	Diabetic Keto-acidosis
DM	Diabetes mellitus
DNEs	Diabetic nurse educators
DOH	Department of Health
EDL	Essential drugs list
eGFR	Estimated glomerular filtration rate
HbA1C	Glycated haemoglobin
HIV	Human immunodeficiency virus
HSREC	Health Sciences Research Ethics Committee
I.C.PAT	Integrated Care Pathways Appraisal
iCAHE	International Centre for Allied Health Evidence
IDF	International Diabetes Federation
IFG	Impaired fasting glucose
IGT	Impaired glucose tolerance
NCDs	Non-communicable diseases
OGTT	Oral glucose tolerance test
PC101	Primary care 101
PDF	Portable document format
PHC	Primary health care
RSA	Republic of South Africa
SANC	South African Nursing Council
SEMDSA	Society for Endocrinology, Metabolism and Diabetes of South Africa
U&E and Kr	Urea, electrolytes and creatinine
UFS	University of the Free State
WHA	World Health Assembly
WHO	World Health Organization

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SELECTED TERMS AND DEFINITIONS

Adult: According to the Children's Act of 2005, an adult in the Republic of South Africa (RSA) is any person over the age of 18, unless married or legally emancipated at an earlier age (RSA 2005).

Community service: The Community Service programme is defined by the Department of Health of South Africa as the mandatory year of service that all health care professionals must complete before registration with their respective boards as independent practitioners can occur (RSA 2006).

Diabetes mellitus: Diabetes mellitus (DM) or diabetes is defined by the World Health Organization as "a serious, chronic disease that occurs either when the pancreas does not produce enough insulin (a hormone that regulates blood sugar, or glucose), or when the body cannot effectively use the insulin it produces" (WHO 2016:6).

District hospitals/Primary level hospitals: According to the National Department of Health (DOH) (RSA DOH 2002), a District Hospital renders services at primary health care level, thus "provides level 1 (generalist) services to in-patients and out-patients (ideally on referral from a community health centre or clinic). The hospital has between 30 and 200 beds, a 24-hour emergency service and an operating theatre. Generalists from a range of clinical disciplines provide the services. In some circumstances, primary health care services are rendered where there is no alternative source of (*sic*) this care within a reasonable distance". District hospitals also "plays a pivotal role in supporting primary health care on the one hand and being a gateway to more specialist care on the other". For the purpose of this study, the use of the term primary level hospital thus means that this is the first level that primary health care (PHC) clinics refer patients to. Primary level hospitals can then refer patients to secondary or tertiary level hospitals for specialised care if needed.

Endocrinologist: The Cambridge Dictionary (Online) defines an endocrinologist as a doctor specialised in "(t)he branch of physiology and medicine concerned with endocrine glands and hormones". In the South African context of this study, the title of endocrinologist is given to a specialist physician who has subspecialised in the clinical field of endocrinology.

Essential drugs list (EDL): The Department of Health publishes a Standard Treatment Guideline and EDL with updated guidelines every few years. Essential medicines are defined

as being those medications that cater for the health care need priorities of a population, while the EDL then serves at guiding PHC practitioners to which drugs are available for use in the public sector for most common diseases (Sooruth, Sibiyi & Sokhela 2015). The decisions of which medications will appear on the EDL reside with the Pharmacy and Therapeutics Committee.

Evidence based medicine: Evidence based medicine is the “conscientious, explicit, judicious and reasonable use of modern, best evidence in making decisions about the care of individual patients” and “integrates clinical experience and patient values with the best available research information” (Masic, Miokovic & Muhamedagic 2008:219).

Family physician: A specialist in family medicine is known as a family physician, thus meaning a doctor who has “completed postgraduate education in family medicine, such as the MFamMed or MCFP(SA)” (De Villiers 2008:59). In the context of this study, it is important to note that although family physicians are specialists in their own right, they mainly work in primary level care.

Feasible: Something that is “able to be done or achieved” or “practicable, viable or workable”, can be defined as feasible, according to the Cambridge Dictionary (Online). For the purpose of this study, feasibility will have the inherent meaning that – regarding a guideline – feasibility entails compliance with international standards of care while aligned with the available financial and staffing resources in the Free State primary health care, and possible to do practically and conveniently.

Follow-up: Follow-up care in relation to patient care is defined as “maintenance of contact with a patient at one or more designated intervals following diagnosis or treatment especially to examine again or monitor the progress of therapy” (Merriam-Webster:Online). In this study, the term “follow-up” will be used when describing any visits by a patient to PHC practitioners after his or her initial diagnosis for review in regards to the improvement or progress of the specific disease condition.

Management guidelines and clinical practice guidelines: Clinical practice guidelines have been defined as “statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options” (Graham, Mancher, Miller Wolman *et al.* 2011:15). In South Africa, the terminology most often used for these type of guidelines are *clinical management guidelines*, as is the case in the Primary Care 101 guideline (RSA

DOH 2013:i). However, in this study this researcher will preferentially use the term *management guideline*.

Medical officers: In the South African context, this entity is seen as doctors who have not specialised in any field after their initial MBChB degree and who “rely on continuing professional development to extend or refresh their skills” (Howe, Mash & Hugo 2013).

Non-communicable diseases (NCDs): The World Health Organization (WHO) defines NCDs as “chronic diseases (that) are not passed from person to person. They are of long duration and generally slow progression. The four main types of non-communicable diseases are cardiovascular diseases (like heart attacks and stroke), cancers, chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma) and diabetes” (World Health Organization 2014).

Outreach programmes: Merriam-Webster (Online) defines “outreach” as “the extending of services or assistance beyond current or usual limits” and also as “the extent of such services or assistance”. In this study, the context of an outreach programme is that a person or a team of people from a specialist unit visit a primary health care facility to give refresher training to PHC workers regarding specific topics in an effort to improve the knowledge and skills of PHC workers.

Patient: A patient is, according to Merriam-Webster (Online), “an individual awaiting or under medical care and treatment”. For the purpose of this study, a patient will be defined as any adult person who approaches a primary health care facility with the purpose of receiving medical advice or treatment.

Pharmacy and Therapeutics Committee: This committee is a body that exists both at national and provincial level and has as a goal the commitment to “the governance of an effective medicines management system to provide equitable and reliable access to medicines and quality care while making the best use of available resources” (RSA DOH 2015:7 of 10).

Primary health care (PHC) clinics: PHC clinics refer to clinics that are mostly staffed by nursing personnel of whom “at least one member of staff has completed a recognised PHC course” (RSA DOH 2000:9) and where “(d)octors and other specialised professionals are accessible for consultation, support and referral and provide periodic visits” (RSA DOH 2000:9). For this study, the practical definition of PHC clinics will be clinics that are primarily

run by professional nurses and usually have intermittent visits from medical officers (mostly Community Service doctors) who are mainly stationed at primary/district level hospitals in their area. These PHC clinics provide basic care, diagnosis and follow-up for most general medical conditions and refer patients to higher levels for care if the disease condition cannot be managed successfully in the PHC.

Primary health care (PHC) practitioners: Health care practitioners in the PHC setting is the term used to refer to all professional health care providers that work in primary level care, thus encompassing medical officers and family physicians, professional nurses registered with the South African Nursing Council (SANC), pharmacists and pharmacy assistants as well as dieticians, physiotherapists, occupational therapists and radiographers. For the purpose of this study, the term *PHC practitioners* are operationalised to mean doctors and professional nurses working in the PHC setting, as they are the workers who are primarily responsible for diagnosis and management of disease conditions in the PHC setting.

Primary level care: Primary level care is a term that encompasses all services delivered by PHC practitioners at PHC clinics and district hospitals (see definitions of primary health care clinics, primary health care practitioners and district hospitals/primary level hospitals above).

Professional nurse: A professional nurse has a diploma or degree in nursing and has been registered with the South African Nursing Council as a Professional Nurse (South African Nursing Council 2016).

Public sector: The term Public Sector is a widely used but vague term that is officially defined as “the part of the economy which is controlled or owned by the government” according to Merriam-Webster (Online). For the purpose of this study, however, the term will mostly mean the health services delivered by the government in the form of public clinics and hospitals to the general population of the country who do not utilise private medical services.

Regional hospitals/Secondary level hospitals: Mulligan, Fox-Rushby, Adam, Johns and Mills (2003:Box 2) define regional hospitals or secondary level hospitals as facilities that are “highly differentiated by function with five to ten clinical specialities; bed size ranging from 200-800 beds (and are) often referred to as provincial hospital(s)”. In this study, Regional Hospitals will refer to specific facilities in the Free State that are supposed to provide support

to primary level hospitals by way of specialist care (physicians/obstetricians & gynaecologists/surgeons/ paediatricians *etc.*) but no subspecialist care. Regional Hospitals refer to tertiary/academic hospitals for specific services that are not available in the Regional Hospital.

Registrar: In the South African medical community, this term describes doctors who have finished their undergraduate training as well as both their Internship and Community Service mandatory periods, and who have embarked upon specialist training at a university with specialist training programmes and registrar training posts (University of Cape Town: Online).

Subspecialist: According to the Collins English Dictionary (Online), a subspecialist is defined as “a specialist with expertise in a particular area of specialism”. For the purpose of this study, a subspecialist refers to a specialist in a certain field of clinical practice that has obtained a further qualification in a specific sub-division of his or her field. As examples: a Paediatrician can be subspecialised in Neonatology or Paediatric Cardiology and a General Physician can be qualified additionally as a Specialist Nephrologist, Cardiologist or Endocrinologist, to name just a few.

Tertiary hospitals: Mulligan *et al.* (2003:Box 2) define tertiary hospitals as hospitals where “highly specialized staff and technical equipment, e.g. cardiology, ICU and specialized imaging units” are available, and also where “clinical services are highly differentiated by function” and “might have teaching activities”, “often referred to as central, regional or tertiary level hospital(s)”. In this study, the researcher acknowledges that only one such hospital, namely Universitas Central Hospital, exists in the Free State and this facility extends tertiary services not only to the Free State, but also to the Northern Cape, parts of the Eastern Cape and Lesotho.

Workplace learning: “Workplace learning is the way in which skills are upgraded and knowledge is acquired at the place of work” according to Cacciattolo (2015:243). The term was operationalised for this study to mean learning while working, specifically regarding in-depth practical and theoretical knowledge of a subject that was previously only studied superficially.

SUMMARY

There is overwhelming proof that the management that patients with diabetes mellitus (DM) receive in the primary health care (PHC) settings is not adequate, causing poor control of DM and resultant complications. This poor PHC setting management of DM occurs in spite of the existence of multiple guidelines produced both nationally and internationally, and which is specifically aimed at DM management.

The aim of this study was to develop a feasible, primary care DM management guideline for the Free State in order to bridge the knowledge gap of PHC practitioners and consequently improve DM management.

The four objectives of this study were thus defined as doing a comparative study of current national and international DM management guidelines and trends; analysing the *Adult Primary Care 2016/2017 (APC 2016/2017)* guideline's DM management section in terms of its quality; studying the elements of what equates to a feasible PHC setting management guideline; and finally developing a feasible, new DM guideline by synthesizing all of the collected and analysed data.

The study was designed as a desktop study with four distinct phases, each linked to a study objective. Phase I encompassed the comparative analysis of the major, referenced national and international DM management guidelines with the *APC 2016/2017*. Phase II entailed the evaluation of the quality of the *APC 2016/2017* guideline's DM section with the use of two tools as applied by four independent assessors. Phase III consisted of a literature review to contextualise the qualities and characteristics inherent in feasible PHC setting guidelines. In Phase IV of the study, the new management guideline was developed by synthesizing all of the data gathered in the first phases.

The newly developed DM management guideline improved on the content of the *APC 2016/2017* guideline's DM section by aligning its content with frequently referenced international and national DM guidelines. A concerted effort was made to enhance the feasibility of the new guideline by incorporating the features inherent in feasible guidelines, especially in terms of ease of use, incorporation of multi-morbid conditions, and clarity of presentation.

The end-product of this study is a new DM management guideline, aimed at patients in the PHC setting in the Free State, which contains the features that should enhance its feasibility

in this setting. Due to the known application of guidelines as tools for workplace learning, this new guideline was designed to be used as an educational tool during workplace learning and training sessions.

Uptake of the new guideline in the PHC setting by means of a pilot study and implementation will improve the knowledge and confidence of PHC practitioners in the Free State. This improvement in DM knowledge will, in turn, have a positive impact on the management and general health of patients with DM in the Free State PHC setting.

(Key words: Diabetes, management guideline, feasible, primary health care, workplace learning)

A FEASIBLE DIABETES MANAGEMENT GUIDELINE FOR PRIMARY HEALTH CARE PRACTITIONERS IN THE FREE STATE FOR WORKPLACE LEARNING

CHAPTER 1

OVERVIEW AND ORIENTATION TO THE STUDY

1.1 INTRODUCTION

During the course of this study, the researcher developed a feasible diabetes management guideline that can be used as a workplace learning tool in the Free State's primary health care (PHC) clinics with the aim of enhancing the knowledge of PHC practitioners and improving the care patients with diabetes mellitus (DM) receive. For the rest of this study, the target group of patients will be referred to as *patients with DM*, thus meaning patients with a new or previous diagnosis of Type 2 DM, as well as adult patients with Type 1 DM who are already on fixed treatment regimes. The researcher acknowledges that the management of newly diagnosed Type 1 DM, paediatric DM and gestational DM falls outside of the usual scope of practice of PHC practitioners; any newly developed guidelines aimed at the PHC setting should thus not involve these highly specialised conditions.

This study forms part of the larger project, *Health Dialogue Model for patients with Type 2 diabetes: a feasibility study* (from now on to be called *The Health Dialogue Model*), that had been launched by the School of Nursing at the University of the Free State (UFS) and specifically has been incorporated into Phase 3 of Project 2 (cf. Section 1.6; Figure 1.1). The *Health Dialogue Model* has the overall aim to improve DM understanding and care among patients and PHC practitioners alike. With this overarching aim in mind, this research project took the form of a desktop study that was done to develop a feasible guideline for DM management in the Free State PHC setting. This guideline, which also functions as an educational tool, can be used in workplace learning, while simultaneously assisting to improve the general care that patients with DM receive in the Free State PHC setting.

At the start of this research project, the management of adult patients with DM in the Free State PHC clinics was supposed to be guided by the *Adult Primary Care Guide 2016/2017 (APC 2016/2017)* (Republic of South Africa Department of Health (RSA DOH) 2016:77–79) (cf. Appendix A). This guideline takes the form of an algorithm-based approach to symptoms, diagnosis and chronic management of the most common conditions found in

PHC, of which DM is one such condition. The *APC 2016/2017* was succeeded by the *Adult Primary Care 2019/2020* (RSA DOH 2019) early in 2020, after the data collection of this study was already completed. Some commentary about the *APC 2019/2020* can be found in Section 4.6. The study thus focused on the content of the *APC 2016/2017* guideline's DM management section (RSA DOH 2016) and its impact on the care that patients with DM receive in the Free State's PHC setting.

DM management is a very complex task for most practitioners. No amount of classes in undergraduate training can prepare anyone adequately for the reality and complexity of clinical decision-making. Health sciences students have to cover so many topics during their studies that DM can understandably not receive the coverage that endocrinologists envision as being of adequate quality. A large part of training regarding DM is consequently done as workplace learning during internship – in the case of doctors – as well as during community service for doctors and nurses. As community service is, however, mostly done in rural areas with little support or supervision from senior colleagues, PHC practitioners mostly have to rely on available management guidelines to be both a tool for workplace learning and a guide for decision-making.

The *APC 2016/2017* was an attempt to fulfil this role of guidance. Unfortunately, due to all the areas in which the DM section of the *APC 2016/2017* was lacking, it was difficult to see the *APC 2016/2017* as an adequate tool to function as either a true management guideline or a tool for learning. If available local guidelines are seen as inadequate, the expectation then seems to be that practitioners must turn to voluminous international DM guidelines for assistance. Unfortunately, the reality is that the answers found in such international guidelines are often not applicable to the PHC clinics in the Free State and as such may possibly not contribute to better management of patients with DM in this Province.

By developing a feasible guideline, the researcher attempted to address the need of patients with DM in the Free State Province in two ways: firstly, by providing practical options for PHC practitioners in managing their patients: and secondly, as a tool for workplace learning that can assist practitioners in facilitating improved integrated health care of adult patients with DM.

Workplace learning in the PHC setting often takes the form of outreach programmes. These programmes are mostly run by specialists and subspecialists from secondary or tertiary hospitals to PHC areas as a support measure for the practitioners working in such facilities.

During such DM-related outreach programmes, confusion exists regarding whether to use the national guideline, *e.g.* Society for Endocrinology, Metabolism and Diabetes (SEMDSA) guideline (SEMDSA 2017), an international guideline, *e.g.* American Diabetes Association (ADA) guideline (ADA 2019), or the local primary care aimed diabetes guideline, *e.g.* APC 2016/2017 (RSA DOH 2016), as a start-off point for discussion and teaching. It will be useful to have a feasible guideline available in all clinics in the Province that can be used as a general and locally applicable tool for such outreach programmes, as all of the above-mentioned guidelines differ in some elements.

The aim of Chapter 1 is to orientate the reader to the completed study. It commenced with an overview of the research problem of the study and will now be followed by a description of the background to the study as well as with a description of the problem statement and research questions that were investigated during the study. The aim, objectives, overall goal and rationale of the study will then be presented, after which the demarcation of the field and scope of the study will be discussed. A brief synopsis of the research design and methods of investigation will follow. Lastly, a schematic outline of the study will be presented with an accompanying précis of the study, followed by the conclusion to the chapter.

1.2 BACKGROUND TO THE RESEARCH PROBLEM

DM is not only a silent killer, but is also becoming an increasingly notorious mass murderer. The World Health Organization (WHO) and its decision-making body, the World Health Assembly (WHA), have classified diabetes as one of the four main non-communicable diseases (NCDs) that need urgent intervention internationally (The Sixty-sixth WHA 2013). According to the WHO's *Global status report on non-communicable diseases 2014*, NCDs were responsible for 68% of all deaths globally in 2012, of which 4% were directly attributed to DM (WHO 2014). The main cause of death in the group of NCDs was cardiovascular disease (46%) (WHO 2014) and DM is a known major risk factor for coronary artery disease (SEMDSA 2017).

According to the Diabetes Atlas of the International Diabetes Federation (IDF), 9.3% of adults in the age group 20 to 79 has DM, and this number is expected to increase significantly by 2045 (IDF 2019). Globally, 50.1% of patients with DM are not aware of their diagnosis, while in low-income countries, 66.8% of patients with DM remain undiagnosed (IDF 2019).

The IDF estimates South Africa to have had a prevalence of adult patients with diabetes of 12.7% in 2017 (IDF 2019). This estimate is aligned with the Durban Diabetes Study of 2016, which proved a prevalence of 12.9% in an urban South African population (Hird, Pirie, Esterhuizen *et al.* 2016). It is very difficult to find more data that can elucidate the dilemma regarding the current status of DM in South Africa, as the Department of Health (DOH) keep records of only new diagnoses of DM: the incidence of DM in South Africa has subsequently been reported as 2.5 cases per 1 000 people in 2016/17 (Kengne & Sayed 2017). The IDF projects a worrisome international increase of 143% in patients with DM by 2045 (IDF 2019).

In the Free State, difficulty with obtaining reliable DM data has also been experienced. In 2009, a DM prevalence of 7.6% was reported (Groenewald, Van Wyk, Walsh *et al.* 2009), and the only other available numbers available for this Province is from the District Health System database, which merely reports an incidence of 2.5 new cases of DM per 1000 people in 2016/2017 (Massyn 2017).

While the exact scope of the incidence and prevalence of DM in the Free State is currently not known, the presence of DM in patients translate directly to morbidity, mortality, and financial implications (Masharani & German 2018). While the global death rate directly attributable to DM was most recently an estimated 1.6 million deaths per year (WHO 2020), the health expenditure spent on patients with DM are generally 2.3 times higher than the expenditure on patients without DM (ADA 2018). Globally, the IDF estimates that individual countries spend between 8.3% and 19.4% of their total health budgets on DM and its related complications (IDF 2019). In South Africa, the IDF admits to having scanty sources of data, but estimates an expenditure of 3115.5 international dollars per year per patient with diabetes (IDF 2019).

Given the international impact of DM on the medical and fiscal health of countries, the WHA passed its resolution to prioritise NCDs (66th WHA 2013). The South African National DOH adopted this resolution in 2013 and published its *Strategic Plan for the Prevention and Control of Non-Communicable Diseases 2013-17* (RSA DOH 2013). In spite of this strategic plan, South Africa continued to score poorly on the IDF's Global Diabetes Scorecard regarding implementation of policies and a framework for monitoring and surveillance of DM amongst others (IDF 2014).

Adequate DM surveillance is an imperative when attempting to improve DM outcomes

(Masharani & German 2018; WHO 2016). The outcome of poorly managed DM is that an increase in complications occur: firstly, in acute complications, but also in chronic microvascular complications; namely, neuropathy, retinopathy, and nephropathy (ADA 2017; Govender, Gathiram & Panajatovic 2017; IDF 2019). Patients with DM are also in general more prone to macrovascular complications - which then present as strokes, myocardial infarcts and peripheral vascular disease (Chawla, Chawla & Jaggi 2016), all with significant effects on health and finances.

The prevention of DM-related complications are largely linked to better DM management and achieving treatment targets (Masharani & German 2018). The international community does not fare well in this regard, with findings of approximately 50% to 70% of patients not reaching the targets set for DM control (Brath, Paldánius, Bader *et al.* 2016; García-Pérez, Álvarez, Dilla *et al.* 2013). The South African numbers are even worse: studies have shown that targets of control are on average only met in 2.7% (Govender *et al.* 2017) to 11.2% (Pillay, Aldous & Mahomed 2015) of patients with DM in the public sector, despite the availability of the *APC 2016/2017* – or its predecessors and/or successors – which is supposed to be distributed to all PHC facilities.

In the PHC milieu, chronic diseases like DM are managed by generalists (Mash, Fairall, Adejayan *et al.* 2012; Steyn, Levitt, Patel *et al.* 2008; Steyn, Lombard, Gwebushe *et al.* 2013), and the first point of contact for most patients for medical management of their chronic diseases are usually with professional nurses: a doctor will then only see the patient if referred for a specific reason (Mash, Fairall, Adejayan *et al.* 2012). The bulk of doctors working in PHC clinics and hospitals in rural areas are either Community Service doctors with limited postgraduate experience or career rural medical officers who also had limited exposure to academic medicine in their postgraduate years (Howe, Mash & Hugo 2013). The limits of the undergraduate curriculum regarding DM management have already been discussed (cf. Section 1.1). This trend of knowledge gaps at the end of formal medical or nursing training is not exclusive to South Africa, for similar issues have been raised in the United Kingdom and the United States of America (Corriere, Minang, Sisson *et al.* 2014).

Workplace learning has been shown to assist in increasing practical knowledge and competencies after graduation (Rowold & Kauffeld 2009). Clinical management guidelines as a form of workplace learning can serve as an educational tool for practitioners, which can increase practitioners' DM knowledge and improve patients' clinical outcomes (Corriere *et al.* 2014). Naidoo, Mahomed, Asmall *et al.* (2014) confirm that a primary care guideline

– in their case the *Primary Care 101: Symptom-based integrated approach to the adult in primary care* (RSA DOH 2011) which was the predecessor of the *APC 2016/2017* – can be used for training purposes. The training that was done with the algorithmic approach based on presenting symptoms improved nurses' knowledge of the management of chronic diseases like hypertension and DM (Naidoo *et al.* 2014).

PHC management guidelines for chronic diseases, *e.g.* *APC 2016/2017*, are widely under-used in the PHC setting: this is a phenomenon that has been experienced personally by the researcher, but has also been noted in other provinces (Govender *et al.* 2017; Igbojiaku, Harbor & Ross 2013; Steyn *et al.* 2013). The reasons for the non-compliance with DOH guidelines are multifactorial, but can be summarised from Steyn *et al.* (2013) to: working conditions, budgetary restraints, shortage of equipment, shortage of staff, shortage of time as well as a poor understanding of PHC conditions by those who draw up national guidelines – even though the guidelines are based on sound clinical practice. While the data used by Steyn and colleagues in their publication was collated between 1999 and 2000, their research article makes a specific note that the research was done at a time of great financial and staff shortages. In the years since the year 2000, the situation has become even more dire, especially in the Free State where the Provincial Department of Health has been under administration since 2014 (Malakoane, Heunis, Chikobvu *et al.* 2020; Malan & Green 2014).

The immense financial pressure in the Free State manifests directly in decreased numbers of staff (Cullinan 2015) and thus decreased services that can be rendered by staff members to patients. Talbot, Reid and Nel (2020) found that nurses in the PHC setting spend a mean time of only six minutes per consultation with patients with DM, and while that study was done in the Northern Cape, no evidence exists that refutes that similar conditions occur in the Free State. Medical officers do not fare much better: anecdotal evidence suggest that they can expect to see up to 50 patients in a 5-6 hour span of time in certain PHC settings in the Free State, which is echoed by findings in the Western Cape (Steyn *et al.* 2008).

As PHC practitioners are expected to see their patients as comprehensively as possible – thus not concentrating solely on *e.g.* the DM aspect of their patients – even 10 minutes per patient might not be adequate time to address all relevant and integrated health issues. Patients with DM frequently presents with systemic manifestations of their DM as well as with other non-DM-related complaints (Masharani & German 2018). PHC practitioners subsequently need a feasible clinical management guideline that can assist them in rapid and correct decision-making that incorporates integrated DM management. PHC

practitioners simply do not have the time to read the voluminous national and international guidelines, *e.g.* ADA guidelines (ADA 2019) or SEMDSA guidelines (SEMDSA 2017) looking for guidance in regards to a patient's DM-related problems. The *APC 2016/2017* (RSA DOH 2016) valiantly tried to address this problem, but on even a superficial scrutiny of the three-page section dedicated to DM (cf. Appendix A), many potential problems could be identified – mostly having to do with loopholes regarding diagnosis; no alternative diagnosis options being given regarding symptoms that mimic DM; management options that do not conform with best practice standards; and unclear advice regarding the approach to problematic patients.

The development of a feasible guideline that is tailor made to the conditions in the Free State, while staying aligned with international DM management aims, and which uses best medical practices and best evidence, was therefore the focus of the researcher in this study.

1.3 PROBLEM STATEMENT

Despite of the increasing incidence of DM in the South African adult population, South Africa does not score well on the IDF's Global Diabetes Scorecard in regards to specific concerns about the "lack of framework for monitoring and surveillance" of DM, inadequate engagement from Government and the reported poor quality of treatment DM patients receive due to lack of financial strength, and maladministration (IDF 2014).

The poor chronic disease control in DM can be attributed in part to the gap in undergraduate training of PHC practitioners as well as to the massive challenges in the Free State – and other provinces' – public PHC sectors. The confusion that can arise when PHC practitioners use different DM management guidelines with differing opinions and approaches can also contribute to the non-compliance of both patients and practitioners with DM management. The DM management guideline supplied by the DOH in the form of the *Adult Primary Care* format guidelines to each PHC facility is supposed to be the most often used instrument regarding decision-making for DM care, but despite the availability of these formats of guidelines since 2011, the management that patients with DM have received from PHC practitioners have not been up to standard (IDF 2014). To address the problem of poor DM management, this study attempted to develop a more feasible DM management guideline to be used as a tool for workplace learning by PHC practitioners within the Province with the aim of improving patient care and competency amongst PHC practitioners in the milieu of the financial constraints of the Free State.

1.4 RESEARCH QUESTIONS

In order to address the problem stated above, the following research questions were posed:

- i. What are the current norms regarding minimum standards in national and international DM management guidelines?
- ii. Does the DM section in the *APC 2016/2017* conform to best practice standards in regards to guideline quality? (See also Section 4.6 regarding the recent publication of the *APC 2019/2020*).
- iii. What are the considerations needed for the development of a feasible clinical management guideline for use in the PHC setting?
- iv. What should a feasible primary care DM management guideline in the Free State consist of?

1.5 THE AIM, OBJECTIVES, OVERALL GOAL AND RATIONALE OF THE STUDY

1.5.1 Aim of the study

The aim of the study was to develop a feasible primary care DM management guideline for the Free State to bridge the knowledge-gap of PHC practitioners by way of a tool for workplace learning, and consequently improve DM management, while at the same time not overburdening the resources of the Province.

1.5.2 Objectives of the study

The following objectives, aligned with the aim of the study, were used to address the aforementioned research questions:

- i. A comparative study of current national and international DM management guidelines and trends (Phase I),
- ii. An analysis of the *APC 2016/2017* guideline's DM section using two instruments to appraise guideline quality (Phase II),
- iii. Studying the elements of what equates to a feasible management guideline in the PHC setting (Phase III), and
- iv. Development of a feasible guideline for the management of patients with DM after synthesizing the above analysed data and tailoring the guideline to be specific to the PHC setting in the Free State (Phase IV).

1.5.3 The overall goal and rationale of the study

The overall goal of this study was to conduct a literature review and an evaluation of existing national and international DM management guidelines in an effort to develop a more feasible guideline for use in the PHC setting in the Free State. In this way, the researcher strove to contribute to the improvement of the overall health of the population of the Free State by assisting practitioners in the PHC setting with a workplace learning tool to bridge the gap in their knowledge and improve their understanding of DM management. The rationale behind this study was that the burden of disease of DM in this province's PHC setting promises to become even more daunting in the near future and that PHC practitioners are in need of more practical and achievable guidelines for management of DM in an effort to decrease the morbidity and mortality of DM.

The researcher has a background in the Free State's PHC setting, as she spent almost ten years in the rural Free State as a PHC medical officer. For the past seven years, she has been the permanent medical officer in the Department of Internal Medicine's Endocrinology subdivision, and consequently has an extensive knowledge of both the challenges that exist in the PHC setting in the Free State as well as the burden of disease of DM as seen in a tertiary institution. Since her appointment in the Division of Endocrinology, she has also been part of outreach projects to local urban PHC facilities and has been exposed once again to the difficulties faced by the practitioners in these PHC facilities in regards to DM care and DM decision-making.

1.6 RESEARCH DESIGN OF THE STUDY AND METHODS OF INVESTIGATION

A short summary of the study design and methodology will be discussed in this section, but will be dealt with comprehensively in Chapter 3. The overarching research model used was a qualitative study in the form of a desktop study. This desktop study had four distinct phases, namely:

Phase I: A comparative analysis of the content of the three major referenced national and international DM management guidelines, namely the guidelines from the IDF (2017), the ADA (2019) and of SEMDSA (2017), as well as comparing these three guidelines to the content found in the *APC 2016/2017* guideline's DM diagnosis and routine care section (RSA DOH 2016).

Phase II: An evaluation of the methodological quality of the current *APC 2016/2017* guideline's DM section using two tools; namely, the *International Centre for Allied Health Evidence (iCAHE) instrument* (Grimmer, Dizon, Milanese *et al.* 2014) and the *Clinical practice guideline applicability evaluation (CPGAE-V1.0) scale* (Li, Xie, Wang *et al.* 2018),

Phase III: A desktop study in the form of a literature review of national and international findings with the aim of conceptualising and contextualising the qualities and characteristics inherent in a feasible and successful clinical management guideline for the PHC setting,

Phase IV: The development of a feasible guideline for the management of patients with Type 2 DM in the PHC setting in the Free State by synthesizing all of the information gathered in Phases 1 to 3 and aligning it with knowledge of resources available in the PHC setting in the Free State.

Ethics Committee approval was requested as a separate study as part of the structured Magister degree, but also to include the study as part of the overarching DM Feasibility study for which the HSREC number approval number is 113/2016. Approval for this study was given by the Health Sciences Research and Ethics Committee with the HSREC number 114/2017 (cf. Section 3.4).

The following schematic overview was designed to assist with an overarching understanding of the study project (cf. Figure 1.1).

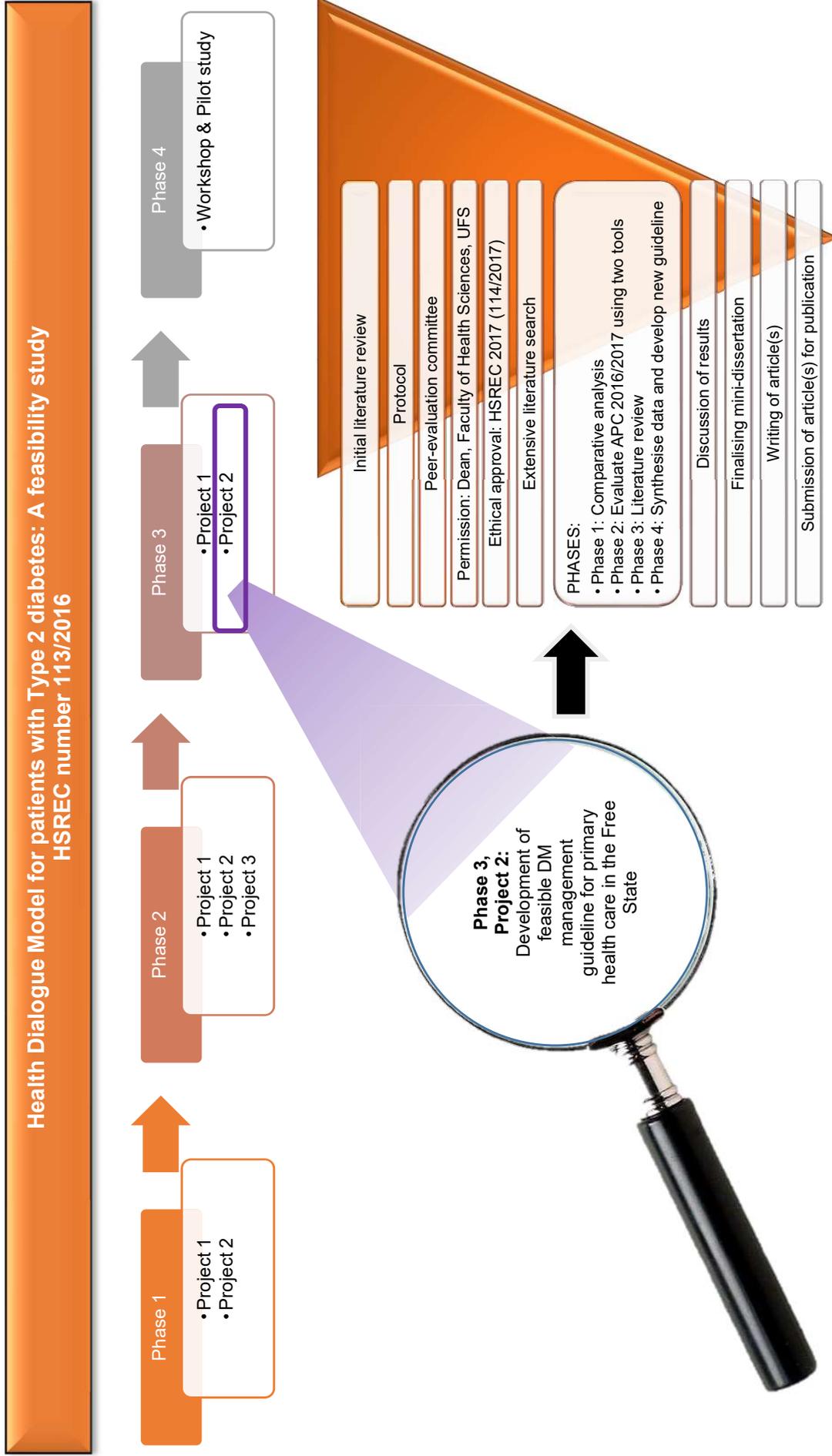


Figure 1.1: Schematic overview of the study (Compiled by the researcher, Rossouw 2020)

As illustrated in Figure 1.1, the study progressed with a phased approach of which the culmination is this mini-dissertation, as well as the projected articles that will be written regarding the findings of the study. Section 1.8 will discuss the implementation of the findings of the study in more detail.

1.7 DEMARCATION OF THE FIELD AND SCOPE OF THE STUDY

This study was conducted in the field of Health Professions Education. The study is interdisciplinary as it formed a bridge between Health Professions Education, the School of Nursing, the Department of Health (DOH) of the Free State as well as the Department of Clinical Medicine (Internal Medicine).

This study concentrated on identifying the elements that have been shown to be essential in a management guideline in order for such a guideline to be implemented successfully, specifically in the PHC setting in resource-strained areas. The knowledge attained from the literature review was applied into developing a new practical guideline, based in international and local expertise regarding the management of new and previously diagnosed patients with DM.

The study was conducted from February 2017 until the end of data collection in October 2019.

1.8 IMPLEMENTATION OF THE FINDINGS OF THE STUDY

The result of this study is the feasible new guideline that was developed for the management of patients with DM in the Free State PHC setting. The guideline itself will be integrated as a pilot study into the *Health Dialogue Model* (cf. Section 1.1), where the goal is to have the guideline used daily in PHC clinics for diagnostic and management purposes and thus to play an integral part in workplace learning and in outreach programmes. The feasibility of the new guideline will be tested formally during the pilot study phase of the *Health Dialogue Model* (cf. Figure 1.1).

Articles containing 1) the literature study that was conducted in preparation for the development of a practical DM management guideline for the rural Free State, and 2) the feasible guideline itself, will be presented for publication.

1.9 ARRANGEMENT OF THE MINI-DISSERTATION

In order to clarify the structure of this mini-dissertation, an overview of the arrangement of the chapters will be discussed below.

CHAPTER 1:	<p>ORIENTATION TO THE STUDY</p> <p>This chapter provided background information as to the rationale, goals, aim and objectives of the study, as well as information regarding the research questions and strategies that were adopted to answer the research question.</p>
CHAPTER 2:	<p>LITERATURE REVIEW</p> <p>Chapter 2 will provide the literature review that was done to investigate the concepts influencing the development of a feasible DM guideline for use in primary health care facilities of the Free State.</p>
CHAPTER 3:	<p>RESEARCH METHODOLOGY</p> <p>In Chapter 3, an in-depth discussion will ensue regarding the different data collection methods, research techniques and sampling used in the different phases of this study. Concepts of reliability, validity, and trustworthiness as applicable to this study, as well as the ethical issues that were encountered and applied to this study, will be detailed.</p>
CHAPTER 4:	<p>RESEARCH RESULTS</p> <p>Chapter 4 will relate the results of the different phases of the study, each with a relevant discussion attached to the results. The final product of the study, namely the newly developed guideline, will also be presented in this chapter.</p>
CHAPTER 5:	<p>CONCLUSIONS AND RECOMMENDATIONS</p> <p>In Chapter 5, a summary of the findings of the study will be found, along with a discussion of the strengths and limitations of the study, the contribution of the study, and the final conclusion and recommendations, based on the findings of the study.</p>

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

In Chapter 2, a general literature review will be done to contextualise the concepts influencing the development of a feasible DM guideline for use in the PHC setting in the Free State. A schematic overview of Chapter 2 is presented in Figure 2.1.

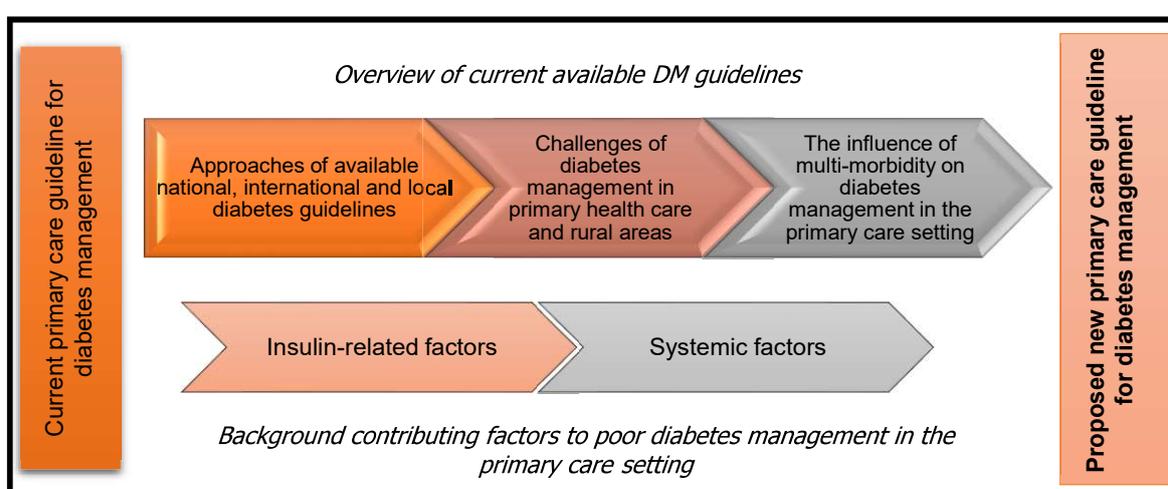


Figure 2.1: Schematic overview of Chapter 2 (compiled by the researcher, Rossouw 2020)

As Figure 2.1 illustrates, the development of the new DM management guideline was influenced not only by the content and layout of the current primary care guideline for DM management, the *APC 2016/2017* (RSA DOH 2016), but also by trends in other currently available DM guidelines, as well as by background contributing factors present in the PHC setting. An overview of the DM management guidelines currently available will therefore be done (cf. Section 2.3), which will encompass the different approaches to DM management guidelines as available in the national and international spheres, the challenges experienced with DM management in the PHC and rural areas, as well as the influence of multi-morbidity on the management of DM. Background factors that contribute to poor DM management in the PHC setting will be discussed in appropriate subsections in terms of insulin-related factors and systemic factors (cf. Section 2.4).

In Chapter 1, introductory comments were made regarding the incidence and impact of type 2 DM in the world. The aim of the literature review of Chapter 2 is not to investigate the phenomenon of the increasing prevalence of DM, but rather to elucidate the current

needs of PHC practitioners and patients with DM in a resource-poor setting such as the Free State.

Before the chapter can continue, a discussion regarding the terminology in regards to guidelines is essential. This discussion will clarify the terminology used in the rest of the study, as well as give reasons for the choices made in regards to the terminology that will be used.

2.2 CLARIFICATION OF GENERAL TERMINOLOGY USED IN REGARDS TO GUIDELINES

The term *guideline* is not universally used when describing the tools used for decision-making at a clinical level. Different organisations have different nomenclatures, which can also change with time, and these differences and changes can cause confusion in an academic setting. The South African National Department of Health (DOH) is one of the organisations that have changed their terminology over the years.

The National DOH has been publishing different versions of guidelines for use by primary care health care workers since 1998. The guidelines were initially known as the *Standard Treatment Guideline and Essential Drugs List* (EDL) (RSA DOH 1998) and was colloquially known as the *EDL* or the *Green Book* (King 2003). The EDL was published in book form with separate chapters per condition, but with text only and minimal flow charts (RSA DOH 1998). The EDL was changed to the *Primary care 101: Symptom-based integrated approach to the adult in primary care* – also known as the *PC101* – in 2011 (RSA DOH 2011), with a second version published in 2013 (RSA DOH 2013). The format of the *PC101* was that of a user-friendly care pathway or organogram published in an A4-sized book, which was designed to be simple to follow. The *PC101* then underwent a name change, and was subsequently styled as the *Adult Primary Care: Symptom-based integrated approach to the adult in primary care (APC)* (Fairall, Mahomed & Bateman 2017; RSA DOH 2016), although the content of the DM sections remained unchanged.

In the foreword of the *PC101*, the description “*clinical management guideline using an algorithmic approach*” is used with reference to its content (RSA DOH 2013). A subtle difference can be detected in the *APC*'s foreword: the developers use the description “*clinical management tool using a series of algorithms and checklists*” (RSA DOH 2016). While the difference between *clinical management guideline* and *clinical management tool*

seems small, a theoretical perspective is vital in evaluating the importance of this nomenclature difference.

A comprehensive research study by Machingaidze, Grimmer, Louw and colleagues (2018) had the core purpose of developing a model to underpin clinical practice guidelines in the context of milieus with strained financial resources. In their publication, the authors suggest that a three-tiered model should be followed when local guidelines are developed, but that care should be taken in differentiating between true *clinical practice guidelines* (CPGs), *evidence based summary recommendations*, and *decision support tools*. The authors also recommend that standard nomenclature should be implemented, for which they suggest *patient management tool* as the preferred name for a decision support tool. The *APC 2017/2017* is thus more a *patient management tool* than a *clinical practice guideline*, according to the definitions given by Machingaidze *et al.* (2018), even though it is commonly known as a guide or a guideline by practitioners working in the PHC setting.

The term *patient management tool* has some drawbacks, though. Search engines do not show widespread use of this nomenclature for the purpose of describing decision support tools. The only *patient management tools* that are found are that of financial planning methods for patients with medical aids, which is not the use that Machingaidze *et al.* (2018) had in mind when proposing the term. The alternative term used mostly in Europe to indicate tools that assist clinicians in practical ways with their daily decisions, is *clinical pathways*.

The term *clinical pathways* have been defined as a method to implement a selected guideline, through "sequences of standardised multi-disciplinary processes or critical interventions that must occur for a specific population towards the desired outcomes within a defined time period" (Vlayen, Aertgeerts, Hannes *et al.* 2005:235). The original purpose of clinical pathways was to be local initiatives to provide assistance in decision making in order to reduce "variation in practice" (Vlayen *et al.* 2005:235), by integrating important factors from various CPGs. The shared goal of both clinical pathways and CPGs are thus to standardise treatment and decrease the variation in care that patients receive for specific conditions. Variety in practice has been touted as a problematic area due to the causation of variations in patient outcomes (Cook, Pencille, Dupras *et al.* 2018; Corallo, Croxford, Goodman *et al.* 2014; Wennberg 2002). A reduction in variation in practice has thus been targeted by CPG creators in an effort to improve the quality of care given to individual patients, which can be measured by improved patient outcomes and a reduction in

unnecessary expenditure (Cook *et al.* 2018).

As the reader can see, many different ways have been used to describe the tools used to assist in medical decision-making. Due to the possible confusion regarding appropriate terminology, the researcher will use the term *management guideline* in the rest of this study to describe the product developed, although it is acknowledged that the definition fits with that of a *clinical pathway* and also with that of a *patient management tool*.

Now that terminology has been clarified, the discussion can progress to the further discussion of the literature overview that shaped the course of this research study.

2.3 OVERVIEW OF CURRENTLY AVAILABLE DIABETES MANAGEMENT GUIDELINES IN TERMS OF APPROACHES, PRIMARY HEALTH CARE CHALLENGES AND MULTI-MORBIDITY

The literature review of this chapter focuses on specific, available management guidelines, not only those made available by the National DOH, but also on those of the Society for Endocrine, Metabolism and Diabetes of South Africa (SEMDSA) and international, leading DM-related organisations, namely the American Diabetes Association (ADA) and the International Diabetes Federation (IDF). The latest versions of their guidelines were used later during this study (cf. Chapter 3 & Chapter 4) for comparative analysis of current trends in DM care. For now, merely some background perspectives in regards to these four mentioned guidelines and their influences on the development of the newly proposed management guideline will be discussed.

2.3.1 Different approaches of international, national and local diabetes management guidelines

International guidelines regarding the integrated management of DM exist in various forms and are updated on a regular basis. The ADA publishes a new clinical practice guideline every year with the most recent one used during this study being published in early 2019. SEMDSA, however, produce a new guideline every 5 years, most recently in 2017. While these guidelines have been produced in full accord with the AGREE II instrument (Brouwers, Kho, Browman *et al.* 2010) regarding the use of evidence and evaluating its recommendations (ADA 2019; SEMDSA 2017), the practical application for use in a primary care setting in South Africa is at times limited, as will be discussed further on in this subsection.

The IDF is another influential organisation with a published DM management guideline. The latest format of their document is aimed at the PHC setting and is called *Clinical Practice Recommendations for managing Type 2 Diabetes in Primary Care* (IDF 2017). In its current format, the IDF's management guideline differs at many levels from the guidelines of the ADA and SEMDSA, due to its specific aim towards *primary care* management of DM.

The first substantial difference between the different guidelines can be found in the number of pages contained in each published DM management guideline. The relative bulk of the ADA, IDF and SEMDSA DM management guidelines are noteworthy when compared to the number of pages devoted to the management of DM in the *APC 2016/2017* (RSA DOH 2016). The number of pages of each of these publications can be found in Table 2.1.

Table 2.1: Allocated numbers of pages in pertinent DM management guidelines from various publishing organisations

Publishing organisation	Year published	Number of pages in guideline
ADA	2019	183
IDF	2017	38
SEMDSA	2017	182
APC 2016/2017	2016	3

The question can rightfully be asked whether the voluminous guidelines of the ADA, IDF and SEMDSA (cf. Table 2.1) can be practically applied in the PHC setting in financially strained provinces like the Free State, as financial strain often leads directly to time constraints of PHC practitioners (cf. Section 1.2). The reverse can, however, also be debated: Is it possible for the *APC 2016/2017* to contain adequate information regarding DM management in its abbreviated format, as it clearly cannot encompass all the information contained in the other three management guidelines mentioned in Table 2.1?

In response to the above question, certain dynamics need to be considered. Firstly, the first three guidelines noted in Table 2.1, that of the ADA, the IDF and SEMDSA, embody the best practices available for DM management. As an example, the guidelines of especially the ADA (2019) and SEMDSA (2017) expound on the usage of the latest and most modern classes of DM medication. These modern classes of DM medications are not necessarily readily available in South Africa, and most definitely not in the Free State PHC setting. Secondly, as the management guidelines from the ADA (2019), SEMDSA (2017) and the IDF (2017) evolved over time from its earlier formats, certain changes have fortunately been made towards suggestions which *are* applicable to the PHC setting in the Free State. Examples of these applicable and implementable changes include a less rigid approach to

HbA1C targets in certain patient groups (ADA 2019 S63 & S140); updated information regarding contra-indications and complications of the use of Metformin (SEMDSA 2017 S39 & S57); as well as possible alternative drugs if certain classes of medication cause complications (IDF 2017:23).

As discussed, some of the changes seen in the latest editions of the ADA and SEMDSA guidelines are eminently translatable to the management of DM in PHC services of even the most cash-strapped provinces. While the argument may be that advocacy for a more intricate management guideline can strain the financial resources of a province, the practice of evidence based medicine should not be ignored in favour of saving money — not even in developing countries — but should be adapted to be appropriate and feasible to the setting (Chinnock, Siegfried & Clarke 2005). The adaption should also be made in a transparent fashion and communicated to the relevant stakeholders (Widyahening, Wangge, Van der Graaf *et al.* 2016).

The challenge is thus to incorporate important evidence based medicine in an adapted manner into a management guideline that is still feasible for use in PHC services, keeping in mind the complexity of DM and its co-existence with other conditions found in the PHC setting.

2.3.2 Challenges of diabetes management in primary health care and rural areas

PHC practitioners in both urban and rural areas are supposed to be the first contact and main source of support for patients who have been diagnosed with DM, as with any other chronic non-communicable disease (Steyn *et al.* 2013; Webb, Rheeder & Van Zyl 2015). DM is a complex disease with many influencing aspects: medication, life style, preventative medicine, social support, and special investigations all play important roles in the management of the disease and its complications (SEMDSA 2017).

The complications that occur due to the presence of DM vary greatly, with micro- and macrovascular complications being the most often quoted complication clusters referenced in the literature (Chawla *et al.* 2016; Masharani & German 2018; Papatheodorou, Banach, Bekiari *et al.* 2018). The development and severity of micro-vascular complications, namely diabetic retinopathy, diabetic nephropathy and peripheral neuropathy in its various forms have been definitively linked to poor control of DM (Chawla *et al.* 2016). Unfortunately, the majority of patients in rural areas, and even from the urban PHC setting, are not timeously

referred to higher levels of care for evaluation and only present to secondary or tertiary levels with severe and non-reversible complications (Brand, Woodiwiss, Michel *et al.* 2013; Rotchford & Rotchford 2002).

The plight of patients in rural areas of South Africa can consequently be harrowing. While data have been gathered in some instances regarding measurable parameters in terms of glucose control, an anthropology study conducted in the Eastern Cape (Oloyede 2013) yielded valuable information emphasising the struggle of rural patients who are reliant on the public health care systems for their DM care. The vast majority of patients interviewed by Oloyede (2013) had no DM education after diagnosis; had no scheduled follow-up dates after diagnosis; had stopped all medication issued for treatment of DM; and had complete misconceptions regarding the life style changes needed to maintain a healthy life with DM. The reality of long-distance travel to the closest clinics; poor DM education as given by PHC practitioners; and poor general availability of support structures are themes that recur in rural areas across all provinces due to the pervasive nature of poverty and inadequately trained PHC practitioners (Oloyede 2013; Pinchevsky, Raal, Butkow *et al.* 2018; Rotchford & Rotchford 2002).

Studies in South Africa regarding the poor control and incidence of DM-related complications in specifically the rural areas of the country have yielded persistently worrisome results across provinces and years. A 2002 study in Kwa-Zulu Natal by Rotchford and Rotchford (2002) yielded similar results of poor control as those of a 2008 study conducted in the Western Cape (Steyn *et al.* 2008) and a Free State study of 2009 (Groenewald *et al.* 2009) in terms of control and the presence of the complications of DM. The picture is equally grim in settings that traditionally have more access to resources than the rural areas: Pillay *et al.* (2015) report poor general care and control of diabetic patients even in a regional hospital in KwaZulu-Natal, while Brand *et al.* (2013) comment on the prevalence of complications and poor control in Gauteng in both primary and tertiary care settings. A forbidding picture is even painted of the control of patients with DM in the South African private health care sector. It was found that only 30% of patients with DM in the private sector achieve targets of control as set out by SEMDSA guidelines (Amod, Riback & Schoeman 2012), and the rate and outcomes of complications in patients with DM are similarly poor between private and public facilities (Pichevsky *et al.* 2018).

In summary, poor disease control of DM is a particular problem in South Africa, and factors specific to the PHC setting often have a profound influence on the management of patients

with DM. The disease is inherently complex, and becomes even more complex once combined with the development of complications. Control of DM is difficult to achieve, and it seems to be an even more daunting achievement in rural areas than in urban areas. Patients therefore present with severe complications but are at risk of not being referred in time to appropriate levels of care, if they are referred at all. These factors seem to be present in most PHC facilities in South Africa. To make matters worse, once a patient has more than one chronic illness, the complexity of disease management increases even more, a subject that will be discussed in the next sub-section.

2.3.3 The influence of multi-morbidity on diabetes management in the primary health care setting

As discussed in Section 2.2, management guidelines have been developed in part to reduce inter-patient care variation. Unfortunately, non-adherence to guidelines are still present in all tiers of medical management, and very much so in regards to DM (Barth, Misra, Moberg Aakre *et al.* 2016; Cook *et al.* 2018; Haque, Navsa, Hayden Emerson *et al.* 2005; Hashmi & Khan 2016). One of the reasons found for non-adherence to management guidelines has been that most guidelines have, as part of their definition, the caveat of being aimed at a “well defined group” of patients (De Bleser, Depreitere, De Waele *et al.* 2006:562). This is understandably not always a realistic expectation in any group of patients, especially not in patients with DM in whom an almost infinite variety of problems, complications and responses can be found (Masharani & German 2018). Patients with DM present with these diverse health problems to their primary care givers, which in the Free State is frequently in the public PHC setting.

According to the *White Paper for the transformation of health systems* (RSA DOH 1997), one of the aims of PHC services is to deliver an integrated service to the patients of the community. This means that all of a patient’s health needs must be evaluated and managed comprehensively, and at primary care level, as far as possible. As an example, a patient seen at a PHC clinic on any given day may have the combined background problems of DM, hypertension and human immunodeficiency virus (HIV) infection, while simultaneously suffering from a lower respiratory infection and a severe headache. PHC practitioners therefore has to evaluate all of these conditions concurrently, but with knowledge of how the different illnesses and medications may interact with one another. Separate guidelines exist for the management of almost all these separate ailments, but integrating the guidelines with one another is a very difficult task. The incorporation of evidence based DM

care with the management offered for other acute and chronic conditions in a patient with DM is therefore a critical element of integrated services.

The issue at hand is thus the presence and management of multi-morbidity, *i.e.* patients “with two or more chronic morbidities” (Barnett, Mercer, Norbury *et al.* 2012), in patients in the PHC setting. When investigating non-communicable diseases in Scotland, Barnett *et al.* (2012) report significant multi-morbidity in all age groups, but with a significant percentage in the elderly as well as in patients living in poor socio-economic circumstances. Folb, Timmerman and Levitt *et al.* (2015) found similar results in South Africa: they comment specifically on the need to improve integration of disease management in NCDs, and warn of possible interactions and co-existence of different NCDs and their medications. Lalkhen and Mash (2015) evaluated more than one province in South Africa and make specific mention of the difficulty that PHC practitioners have in combining the recommendation of guidelines tailored to individual NCDs when confronted with the large proportion of patients with co-morbid and multi-morbid conditions. The above studies only evaluated the presence of multiple NCDs in single patients, without the confounding influences of communicable diseases and other health promotion entities.

In addition to NCDs, communicable diseases also have a significant impact on patients with DM. The presence of both DM and HIV in the same patient is a common finding in South Africa (SEMDSA 2017). When one adds the presence of communicable diseases like HIV in patients with DM, the possible complications, control problems and drug interactions multiply (Pillay, Aldous & Mahomed 2016). Co-infection of HIV with DM is not discussed in the *APC 2016/17* guideline’s DM section at all, and the necessity to screen patients who are known to have HIV for the presence of DM is also not mentioned in its HIV section (RSA DOH 2016). This is in direct contrast to the SEMDSA guideline that presented a whole chapter regarding the interactions between DM and HIV in their most recent published guideline (SEMDSA 2017). The non-cohesion of separate guidelines is not only found in regards to communicable and non-communicable diseases, but also in regards to other screening programme guidelines.

Depression, pregnancy, cardiovascular risk, cancer and vaccination needs can all be present in a patient with DM, influencing treatment options profoundly, and screening as part of health promotion is thus advised (ADA 2019; SEMDSA 2017). Although the *APC 2016/17* guideline’s DM section attempts some integration with cardiovascular risk screening, pregnancy screening, and depression screening (cf. Appendix A), it is done in a cumbersome

and non-user-friendly manner, inhibiting the integration of different conditions into a cohesive treatment programme.

Other conditions that frequently co-occur with DM are hypothyroidism, dyslipidaemia and Vitamin B12 deficiency (ADA 2019; Masharani & German 2018; SEMDSA 2017). Separate national guidelines exist for some of these conditions, but are often not aligned: while the *Consensus Statement regarding dyslipidaemia* (Klug, Raal, Marais *et al.* 2018) mentions the effect that DM and hypothyroidism can have on dyslipidaemia, the same information is not found in the SEMDSA guideline (SEMDSA 2017). The SEMDSA guideline makes a fleeting reference to possible thyroid function testing in patients with DM, while the subject gets much more attention in the *SEMDSA/ACE-SA Guideline for the Management of Hypothyroidism in Adults* (Dave, Klisiewicz, Bayat *et al.* 2015). All of these guidelines' recommendations also differ substantially from the guidance offered in the *APC 2016/17* guideline's DM section. The same can be said about the discussion around Vitamin B12 deficiency: it is described in both the SEMDSA 2017 and the ADA 2019 management guidelines as a possible and frequent side-effect of Metformin use, but is not mentioned at all in the *APC 2016/2017*. As Metformin is the drug that is used most often in type 2 DM, it is difficult to understand why no mention of this deficiency is made in the *APC 2016/17* guideline's DM section.

None of the above conditions, *e.g.* HIV, depression, hypothyroidism, or Vitamin B12 deficiency, can be seen as non-PHC level conditions when evaluated individually. Unfortunately, scant allowance is made for managing the presence of this type of multi-morbidity in the *APC 2016/2017* management guideline. Recommended integrated care options for management once multi-morbidity becomes present, are even rarer. As integrative care is the aim of the PHC setting, this oversight is extremely important to correct if any guideline that has holistic care for patients with DM in the PHC setting as its aim. As Chiang, Jani, Mair and colleagues (2018) describe so aptly, it seems inappropriate to continue with the current focus on single disease management in regards to patients with DM. In summary, the aim of any feasible management guideline should be to incorporate enough management options that will give practitioners leeway to respond to an individual patient's needs, based on the presence of multi-morbid conditions.

2.4 BACKGROUND CONTRIBUTING FACTORS CONTRIBUTING TO POOR DIABETES MANAGEMENT IN THE PRIMARY HEALTH CARE SETTING IN TERMS OF INSULIN-RELATED FACTORS AND SYSTEMIC FACTORS

The poor management that patients with DM receive on average in the PHC has been illuminated in Section 2.3.2. Contributors to DM-specific sub-optimal management has been examined by numerous researchers, and an overview of these findings will be presented in the following two sub-sections. These causes and factors were divided into *insulin-related factors*, and the *systemic factors* specific to DM management in the PHC of the Free State.

2.4.1 Insulin-related factors contributing to poor diabetes management in primary health care settings

While good quality DM care is a holistic endeavour, with many different aspects of patient care being important, the main focus of most guidelines are – and should continue to be – adequate glycaemic control (Masharani & German 2018). The literature supports the view that to achieve control, the use of insulin at earlier phases during the natural progression of type 2 DM will have beneficial effects (Mashitisho & Mashitisho 2016; Meneghini 2009; Owens 2013). Unfortunately, this is one of the main areas in which DM management guidelines are not being followed adequately (Amod *et al.* 2012; Haque *et al.* 2005; Monanabela 2015).

The phenomenon of non-adherence to DM management guidelines in regards to the initiation of insulin in patients who need it has been studied intensively as to its prevalence and causes. Monanabela (2015) describes the clinical inertia in PHC facilities in the Western Cape where the treatment of poorly controlled patients with DM was kept unchanged in 60 to 76% of cases, irrespective of the fact that 77% of patients had glycaemic values outside of the target ranges. This finding of clinical inertia is an echo of similar findings by Amod *et al.* (2012) and Haque *et al.* (2005), who found significant hesitancy in regards to the initiation and titration of insulin on primary care level, irrespective of a patient's DM control or lack thereof. Barriers to insulin initiation thus exist and have been explored as to causes for and solutions to this inertia.

Barriers to initiating insulin have been found to be most often due to a combination of doctor factors, patient factors and systemic factors (Furler, Spitzer, Young *et al.* 2011; Hashmi & Khan 2016; Khunti, Khunti & Seidu 2019; Ross 2013):

- Doctor – or PHC practitioner – factors tend to encompass a variety of factors: from distrust in clinical guidelines, poor DM knowledge, discomfort with their own knowledge about insulin, and fear of hypoglycaemia, to discomfort in regards to adding insulin to the treatment of a patient who is already on a complex regime of medications (Ross 2013; Rushforth, McCrorie, Glidewell *et al.* 2016). Inadequate knowledge is especially problematic: a study in PHC clinics in KwaZulu-Natal found that, while the majority of nurses in the studied clinics had inadequate DM-related knowledge and were thus not able to manage their patients with DM sufficiently, the nurses were unaware of their lack of knowledge and consistently scored their perceived knowledge as higher than what their true knowledge was found to be (Moodley 2006). Furthermore, training sessions in the PHC setting often have only a short-term effect, as high staff turnover causes the loss of DM-trained personnel (Naidoo *et al.* 2014).
- Patient factors are usually psychological fear of injections and needles; emotional fear because their disease has now apparently deteriorated; fear of weight gain; and previous bad experiences with insulin in self or a family member (Furler, Blackberry, Walker *et al.* 2014; Nelson, Wallston, Kripalani *et al.* 2018).
- Systemic factors are usually difficulty in accessing diabetic nurse educators or endocrinologists; the financial aspects of consumables associated with insulin use; and logistical issues *e.g.* travelling distances (Furler, Blackberry, Manski-Nankervis *et al.* 2015; Haque *et al.* 2005).

For every barrier that has been named in regards to the timely initiation of insulin in patients with DM, solutions have been postulated in the literature, most of which focus on education. Solutions for both doctor and patient factors lie mostly in improving the training of doctors and nurses and subsequent training of patients (Furler *et al.* 2015; Haque *et al.* 2005). Training can take the form of an appropriate management guideline as there is agreement that a management guideline can function as an educational tool (Hashmi & Khan 2016) and that doctors who use DM guidelines have better overall DM knowledge than non-users (Corriere *et al.* 2014). Moodley (2006:102) reports that “the time period since qualification was inversely related to nurses’ knowledge” of DM: their knowledge thus deteriorate with time. Workplace learning and continuous education programmes consequently play a vital role in PHC settings, and education and re-education of practitioners should have a high priority for policy makers.

2.4.2 Systemic factors contributing to poor diabetes management in primary health care settings

Glycaemic control does not rely on medical management alone. Good glycaemic control also relies on systemic support of both the patient and of the relevant setting in which the patients receive their primary care.

The systemic factors that influence poor DM management and control are more difficult to address and pose a significant problem in the Free State. The lack of support staff, namely podiatrists, ophthalmologists and optometrists, diabetic nurse educators, dieticians, occupational therapists, qualified pharmacists, and social workers in PHC facilities are severe (Morapela 2017; Rispel, Blaauw, Ditlopo *et al.* 2018). In regards to diabetic nurse educators, the whole Free State Province has only one working in the public sector, and her base is in a tertiary hospital complex, not in a PHC setting. This is far from ideal, as numerous studies have found that the presence of diabetic nurse educators in any health facility is immensely helpful to both doctors and patients in regards to DM management (Furler *et al.* 2011; Furler, O'Neal, Speight *et al.* 2017; Manski-Nankervis, Furler, Blackberry *et al.* 2014). These systemic barriers cannot be improved by educational interventions alone, but needs managerial will as well as financial investment from the national and provincial DOH. The heavy burden of patient load in the PHC facilities, especially in view of the DOH's promulgation of integrated care of patients at PHC level (RSA DOH 1997), makes financial support of PHC facilities an even stronger imperative.

Given the above information, factors that contribute to the poor quality of DM care in the PHC setting in South Africa, and by implication in the Free State, can be condensed to the following:

- Inadequate conversion to insulin therapy (Amod *et al.* 2012; Haque *et al.* 2005);
- Inadequate DM knowledge of practitioners (Khunti *et al.* 2019; Naidoo *et al.* 2014);
- Poor recognition of own deficits in DM knowledge by practitioners (Moodley 2006);
- High turnover of DM-qualified staff (Naidoo *et al.* 2014);
- Inadequate numbers of diabetic nurse educators (Furler *et al.* 2017; Manski-Nankervis *et al.* 2014);
- Insufficient support staff (Morapela 2017; Rispel *et al.* 2018; Steyn *et al.* 2013); and
- Significant financial constraints in primary health care and inadequate resources (Haque *et al.* 2005; Steyn *et al.* 2013).

These are all background factors specific to DM management in the PHC setting that had to be kept in mind during the development of a feasible DM management guideline. Future DM training of PHC practitioners can also focus on some of these factors, which will then hopefully ensure better outcomes for patients with DM in the Free State.

2.5 CONCLUSION

The overarching aim of this study is to develop a feasible management guideline for DM for use in the Free State PHC setting. Many international and local factors influence such a developmental process and these factors were discussed in the literature review of this chapter. The educational aspects of a well-developed guideline were mentioned, and some contributors to poor DM management, which can be influenced positively by a new, feasible DM management guideline, were discussed.

While the literature review gave general information regarding this study, it also prepared the reader for understanding the choices that were made during the methodology section, which will be discussed in Chapter 3.

CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

Chapter 3 will encompass a description of the methodologies used in this study, with each research method discussed separately and in depth. This chapter will outline the research design and research methodologies followed during the various phases of this study. The different data collections methods used in these phases will be discussed, and the research sample and sampling will be described. The details regarding the design process involved in final guideline development will also be discussed. The final part of this chapter will outline the concepts of reliability, validity, and trustworthiness as applicable to this study, as well as the ethical principles applied to this study.

3.2 THEORETICAL BACKGROUND TO THE RESEARCH DESIGN

This research was designed as a qualitative study that made use of a comparative document analysis, a critical document evaluation using validated tools, and a desktop study to obtain the necessary data to develop a new DM management guideline. While a qualitative approach usually concentrates on *building understanding of how and why* certain things work (Sullivan & Sargeant 2011), it also requires of the researcher to demonstrate the path by which a certain judgment is reached (Westbrook 2018). In other words, qualitative studies ask questions that rarely have direct *yes/no* answers, but rather try to clarify phenomena (Sullivan & Sargeant 2011). In the case of this research, an important phenomenon to study was the elements of *what* equates to a feasible guideline, and thus the reasons *why* certain guidelines are being adhered to while other guidelines are disregarded during DM management. The answers found can then *build an understanding* of what is required of the newly developed DM management guideline in order to aim to fulfil its hope of being a feasible product for the PHC setting.

The methodologies pursued in each of the phases will now be described in detail. In order to fulfil the objectives of the study, four distinct phases were developed to answer the research questions posed (cf. Sections 1.4 & 1.6). The four phases of the study were the following:

Phase I: A comparative analysis of the *content* of the three major DM management guidelines referenced both nationally and internationally was conducted. These major guidelines were then also compared to the locally promoted PHC setting DM management guideline. The four guidelines that were thus compared to each other were the DM guidelines of the IDF (2017), the ADA (2019) and SEMDSA (2017), as well as the APC 2016/2017 guideline's DM diagnosis and routine care section (RSA DOH 2016).

Phase II: An evaluation of the *methodological quality* of the current APC 2016/2017 guideline's DM diagnosis and routine care section was conducted using the *International Centre for Allied Health Evidence (iCAHE) instrument* (Grimmer *et al.* 2014), and the *Clinical practice guideline applicability evaluation scale (CPGAE-V1.0)* (Li *et al.* 2018) as the standard.

Phase III: A desktop study in the form of a literature review was done with the aim of conceptualising and contextualising the qualities and characteristics inherent in a feasible and successful DM management guideline for the PHC setting.

Phase IV: This phase encompassed the processes involved in the development of a feasible guideline for the management of DM in the PHC setting in the Free State by synthesizing all the information gathered in Phases I to III and aligning it with knowledge of resources available in the PHC setting in the Free State.

Methodologies pursued in these four phases will now be discussed separately in regards to the methodology of research technique(s), population, sampling, and data collection.

3.2.1 Phase I: Comparative analysis of diabetes management guidelines

During Phase I of this study, a document analysis was done of four selected documents. Phase I was concerned with the *content* of the selected documents, not the *methodological quality* of the documents. The content of the documents was compared to each other in a thematic and structured manner, all of which will be discussed in the following four sections.

3.2.1.1 *Research technique: Comparative analysis*

The research technique performed during this phase of the study was a document analysis, in the form of a comparative analysis of four selected documents. A document analysis finds, selects, appraises and synthesises data found in documents (Bowen 2009), but then

also yields data that can be organised into themes (Labuschagne 2003). The documents analysed and the critical analysis of the found data serves as a form of triangulation, which enhances the value of the retrieved data (Bowen 2009). The selection of the documents used in this phase of the study will be discussed in the next section.

3.2.1.2 *Sampling of documents for comparative analysis*

The documents that were purposively sampled for this phase of the study consisted of the DM management guidelines published by each of the following organisations: The American Diabetes Association (ADA), the International Diabetes Federation (IDF), the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA), and the South African National DOH.

The reasons why these guidelines were purposively chosen as the sample to be evaluated regarding their approaches to DM management are as follows:

- i. The ADA is the world's most referenced association in regards to DM management in the Western world (Piller 2019);
- ii. The IDF is the international umbrella organisation that oversees more than 240 different national diabetes associations in seven regions in the world, and has a special focus on the management of DM in the PHC setting (IDF 2018);
- iii. SEMDSA is the leading South African society in regards to DM management, which also brings the South African perspective to the discussion, especially in regards to the prevalent co-morbid conditions found with DM in our country; and
- iv. The *APC 2016/2017* guideline's DM section is the mandated National DOH management guideline in regards to DM management, and is therefore the standard of care that is used in the PHC setting of the Free State.

A comparative analysis was thus done between one national society-directed guideline, one local PHC-setting guideline, and two international DM guidelines. This comparison was done in order to compare their content, namely their management advice and approaches, with each other in a thematic and structured manner.

3.2.1.3 *Data collection*

Guidelines in regards to DM management from 2016 to 2019 were sourced from the websites of the ADA and the IDF, directly from SEMDSA, and from the South African National DOH.

The ADA publishes their DM guideline on an annual basis on their Diabetes Care website. As the 2020 guideline was not yet published at the time of this research, the 2019 guideline was sourced for this study. The ADA's guideline is freely available as a PDF (portable document format) document on their website (www.care.diabetesjournals.org) and was downloaded from there by the researcher.

The IDF published DM guidelines in 2005, 2012 and 2017. The 2017 guideline was sourced from their website (www.idf.org/e-library/guidelines) for this study and downloaded by the researcher.

SEMDSA publishes DM guidelines for South Africa every five years. Their 2017 guideline is thus the latest available guideline from their society, and their next updated guideline is only expected in 2022. The printed version of this guideline was obtained by the researcher, as published in the *Journal of Endocrinology, Metabolism and Diabetes of South Africa* in 2017 (SEMDSA 2017).

The South African National DOH published and disseminated the *APC 2016/2017* (RSA DOH 2016), which was the version of this guideline that had been published at the time of completion of this research study. The *APC 2016/2017* was published by the DOH, but the original document was developed by – and is available from the website of – the Knowledge Translation Unit (www.knowledgetranslation.co.za/pack/south-africa/). The researcher thus downloaded the electronic version of the *APC 2016/2017* from the above website. See also Section 4.6 in regards to the *APC 2019/2020*.

3.2.1.4 Data analysis

Data analysis of this section of Phase I consisted of three separate but linked actions. Firstly, themes were identified with which to organise the comparative analysis. Secondly, guiding questions were linked to the themes identified, and thirdly, a Rubric was developed on which to reflect the answers found by the guiding questions.

Steps to identify and organise themes and questions

A comparative analysis was performed on the four chosen guidelines' content according to specific themes. Three steps were followed to identify and organise the themes; namely, firstly, to do an initial identification of themes; secondly, to expand the themes; and thirdly, to identify the final list of themes.

- Step one, the initial identification of themes, was based on the list of eight topics provided by the IDF in their 2017 DM guideline's methodology description. These eight topics are *screening and diagnosis, targets for glucose, lifestyle changes, overweight/obesity, initial treatment, add-on treatment, cardiovascular risk factors, and other* (IDF 2017). The IDF's topics are each clarified further by a list of aligned questions attached to the topic (IDF 2017).
- In step two, the topics provided by the IDF were then expanded upon by evaluating the *APC 2016/2017* guideline's DM section according to the IDF's topics and aligned questions. Where content existed in the *APC 2016/2017* guideline that were not included in the IDF's topics, the topics were expanded to include these content items in question format. Furthermore, once the ADA and SEMDSA guidelines were read through and further topics were identified that were not discussed in either the IDF or the *APC 2016/2017*, and the topics were relevant to the PHC setting, these topics were also included in the list of expanded questions.
- In step three, the final six broad themes were identified by collating certain themes found in the IDF's topics, and renaming and expanding other themes for the sake of clarity.

Completion of guiding questions aligned to themes

The guiding questions, aligned to the themes above, were then each answered by the researcher, by applying every question to each of the four selected guidelines. The guidelines were individually read through multiple times, and the answers to the questions were written down in detail in a tabulated format.

Reflecting the assessment of the guidelines on a Rubric

To finalise the comparative analysis of the four selected DM guidelines, a Rubric was compiled to reflect the findings of the individual assessment of each guideline's content (cf. Appendix B). This Rubric was compiled from the questions aligned to the themes generated in step one to three of the *Steps to identify and organise themes and questions* section above. The answers found during the completion of the questions were then scored to reflect the different answers or approaches of the individual guidelines.

The scoring of the Rubric was drawn up to reflect the degree of detail with which each question was answered by the respective guidelines. The rubric had four possible scores, namely

- *Not Answered/Discussed At All*, when the question was not addressed by the guideline at all;
- *Discussed with minimal detail*, when the answer was given as a yes/no or single sentence response;
- *Discussed with moderate detail*, when the answer to the question was discussed in at least a paragraph or more, but not in as extensive detail as another guideline; and
- *Discussed with extensive detail*, with all aspects of the question answered, sometimes a whole chapter dedicated to the topic.

The rubric thus enables the reader to evaluate the recommendations given by the selected guidelines in a comparative manner.

Once the comparative analysis of the content of the four guidelines was completed, the study progressed to Phase II; namely, the evaluation of the *methodological quality* of the *APC 2016/2017*.

3.2.2 Phase II: Evaluating the methodological quality of the *Adult Primary Care 2016/2017* guideline's diabetes management section

The second phase of this study had the objective of answering the second research question, namely to determine whether the *APC 2016/2017* guideline's DM section conforms to the best practice standards of DM guideline *quality*. The methodology followed during this evaluation will now be discussed.

3.2.2.1 *Research Technique: Document analysis*

Phase II of this research study was done by way of a document analysis, with the document analysed being the DM management section of the *APC 2016/2017* (RSA DOH 2016). Only this one document was purposively sampled during this phase of the study, as it was the guideline available to the HCPs in the Free State's public PHC sector and thus reflected the standards of care in this sector.

3.2.2.2 *Selection of assessment tools*

In order to appraise the quality of the *APC 2016/2017* guideline's DM section, two separate tools were sourced in the literature: the *International Centre for Allied Health Evidence (iCAHE) instrument* (Grimmer *et al.* 2014) and the *Clinical practice guideline applicability*

evaluation (CPGAE-V1.0) scale (Li *et al.* 2018). Purposive selection of these two tools were done as each has its own distinct focus with resultant strengths and weaknesses, and the two thus complement each other.

The International Centre for Allied Health Evidence instrument

The iCAHE instrument (Grimmer *et al.* 2014) was developed as a shortened version of the *Appraisal of Guideline Research and Evaluation (AGREE II)* tool (Brouwers *et al.* 2010), to evaluate the *quality of the development methodology* of management guidelines. The AGREE II is the internationally acknowledged tool used to assess the quality of guideline development methodology, but it is laborious to use and needs specialised training before it can be applied (Grimmer *et al.* 2014). The iCAHE instrument (Appendix C), on the other hand, is user friendly, short, has been validated for use by busy end-users without specialised training, and results in valid quality assessment (Grimmer, Machingaidze, Dizon *et al.* 2016). The *applicability* or *relevance* of a guideline to the clinical setting is not evaluated with the iCAHE tool (Grimmer *et al.* 2014), and this aspect of a management guideline thus needs a separate method of evaluation.

The iCAHE instrument consists of 14 binary-scored questions, with minimal subjective interpretation required (Grimmer *et al.* 2016) (cf. Appendix C). For each *yes* answer, one (1) mark is allocated, and for each *no* answer, zero (0) marks are allocated. The end-result is a mark out of fourteen (14), which can be converted to a percentage.

The Clinical practice guideline applicability evaluation scale

The CPGAE-V1.0 scale (Li *et al.* 2018) was chosen for this study to fill the applicability gap left by the iCHAE instrument. This CPGAE-V1.0 scale (cf. Appendix D) evaluates four domains, namely the technical level of a management guideline, the coordination of support in the guideline, the structure and content of the guideline, and the role of the guideline. No other tool could be found in the literature to evaluate these specific aspects of management guideline appraisal.

The CPGAE-V1.0 scale consists of nineteen statements in regards to the management guideline being assessed (cf. Appendix D). Each of these statements must be commented on or answered by using a grading scale from one (1) to four (4), in which 1 correlates with "Very poor" and 4 correlates with "Very good". Once the answers have been filled in by assessors, domain scores are calculated as follows:

$$\text{Standardised domain score} = \frac{\text{Observed score} - \text{minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}} \times 100\%$$

The *observed score* is the overall domain score of all the appraisers combined, and higher scores indicate better guideline applicability (Li *et al.* 2018).

3.2.2.3 *Selection of assessors*

The developers of the iCAHE instrument did not make any specific recommendations regarding the number of assessors needed to appraise a guideline using this instrument (Grimmer *et al.* 2014; Grimmer *et al.* 2016). To aid in a decision regarding the number of assessors needed for this study, the AGREE II tool (Brouwers *et al.* 2010) was consulted as it is the tool on which the iCAHE instrument is based (Grimmer *et al.* 2014). The AGREE II tool requires the use of at least three, ideally four, separate assessors for the evaluation of a guideline (Brouwers *et al.* 2010). Based on this requirement, it was decided to use four assessors as well during this phase of this research study.

In a qualitative study, participants can be purposefully selected as to be the best informed regarding the phenomenon that is being studied, and therefore augmenting the conclusions drawn from the study (Sargeant 2012). For this reason, the selection criteria for assessors were defined as:

- medical doctors;
- working in the Free State PHC setting within the last 3 years; and
- having had at least 5 years of cumulative experience since graduation.

The reason for these selection criteria was that the perspectives of doctors who are frequent end-users of the *APC 2016/2017* guideline were required, not just the perspectives of guideline developers and guideline researchers. As the doctors who work in the PHC setting in the Free State are mostly medical officers, family medicine registrars, or family medicine specialists, the assessors were consequently chosen from this specific pool of doctors. Specialist endocrinologists do not visit the PHC setting in the Free State as a rule, and as the *APC 2016/2017* is also not aimed at sub-speciality users, endocrinologists were excluded from the pool of assessors.

3.2.2.4 *Data collection*

The Department of Family Medicine is aware of who most of the doctors are who are

working in the PHC setting in the Free State. For this reason, a family medicine specialist working in the Department of Family Medicine was contacted to assist in compiling a shortlist of possible assessors who would meet the inclusion criteria for this phase of the study and who were assumed to be available and willing to assist in this endeavour. Five names were initially sourced in this manner, and five more names were added as a snowballing effect after contacting two of the names on the initial list. The list of ten names was then shortened, based on convenience, to a shortlist of eight names. The convenience factor was namely that these eight doctors lived or worked in the Mangaung Metropolitan Municipality area, making them easily reachable in person by the researcher. The first four names on the list were then contacted in person by the researcher and all four indicated willingness to participate in the project. Individual meetings with each assessor were then scheduled where possible.

During these scheduled meetings, the researcher met three of the doctors individually at their places of work, where the goal of the research project and the reason for their requested participation was explained to them. The three assessors who were met personally were each given paper copies of the iCAHE-tool and the CPGAE-V1.0 scale, as well as a copy of the *APC 2016/2017* guideline's first five pages and the three pages of its DM section. The assessment forms were marked with the initials of the assessors. The fourth assessor was only available by telephone, but the same explanation process was followed as per the personal meetings. In this case, copies of documents were e-mailed to the assessor. A *Participant Consent Form and Information Leaflet* (cf. Appendix E) was also given to each assessor before commencement of the assessment.

During the meeting with the assessors, whether by telephone or in person, they were asked whether they had immediate access to the *APC 2016/2017* guideline, and as none did, they were then provided with a copy. The assessors were then shown the three pages concerning the management of DM, and a suggestion was made to acquaint themselves with the guideline once again before attempting to fill in the iCAHE-tool or CPGAE-V1.0 scale. Each of the four assessors was required to apply both the iCAHE instrument (Grimmer *et al.* 2016) and the CPGAE-V1.0 scale (Li *et al.* 2018) to the three pages of the DM section of the *APC 2016/2017* guideline.

Reminder messages were sent to the participating assessors after four weeks and then monthly until the assessment forms were received back. If an assessor failed to complete the assessment forms after two reminders, another assessor was chosen from the shortlist, and the same procedures followed to acquaint the new assessor with the study. Only one

of the original assessors was replaced in this manner. The completed assessment forms were returned to the researcher in person by each participating assessor.

As the iCAHE-tool (Grimmer *et al.* 2014) has binary answers, reconciliation of discrepant answers was not needed. Reconciliation of discrepant answers when using the CPGAE-V1.0 scale (Li *et al.* 2018) was also not necessary, as the scoring system has been developed for multiple assessors of the same guideline, irrespective of discrepant answers. No follow-up meetings with assessors were consequently necessary.

Once the evaluation of the *APC 2016/2017* guideline's DM section was completed, the study progressed to the literature study phase. The methodology followed during the literature study will now be discussed.

3.2.3 Phase III: A desktop study to conceptualise and contextualise the qualities and characteristics needed to develop a feasible diabetes management guideline for the primary health care setting

This third phase of the study addresses the third research question, namely to study the considerations needed in order to develop a feasible DM clinical management guideline for use in the PHC setting. The desktop study took the form of a literature review in which these elements or considerations that would have an influence on the feasibility of such a DM management guideline were explored.

3.2.3.1 *Research technique: literature review*

According to Onwuegbuzie and Frels (2016:xiv) a comprehensive literature review can be used as a separate study and must comply with ethical research standards, namely "integrity, scholarly responsibility, social responsibility and (by respecting) rights, dignity and diversity".

The seven steps suggested by Onwuegbuzie and Frels (2016) for a comprehensive literature review are:

- (1) Explore beliefs and topics;
- (2) Initiate search;
- (3) Store and organise information;
- (4) Select/de-select information

- (5) Expand the search;
- (6) Analyse and synthesize; and
- (7) Present the comprehensive literature review report.

In this research study, the literature review (which forms part of the third objective of this study) was only done according to steps 2 to 7 as given above (Onwuegbuzie & Frels 2016), as step 1 would constitute a repetition of the information gathered in Chapter 2 of this study. By using steps 2 to 7, it was ensured that the information regarding the feasibility of management guidelines as used in the PHC setting could be collected, synthesized and summarised thematically (Onwuegbuzie and Frels 2016).

3.2.3.2 Data bases searched

The following data bases were searched as part of the primary search of this literature review: MEDLINE with Full Text, Academic Search Ultimate, CINAHL with Full Text, Health Source: Nursing/Academic Edition, PsycINFO, Africa-Wide Information, SPORTDiscus with Full Text. These data bases were selected by a librarian skilled in literature searches, in accordance with the aim of the literature review. Search words in the primary search included *clinical guideline*, *clinical pathway* and *primary health*, *primary care*, *medical care*, as well as *good*, *successful*, *feasible*, *practical*, and *ease* or *easy*. Other search terms included *non-adherence*, *non-compliance*, *elements of*, *pre-requisites*, *components*, *characteristics* and *considerations*. The primary search also included articles found during the protocol development of the study.

A secondary search was done when the references for the studies found during the primary search were evaluated. Studies were identified based on their titles and date of publication. Those specific articles were then sourced from the ResearchGate data base as well as the Google and Google Scholar search engines.

3.2.3.3 Sampling of documents found in search

To fulfil the *select* aspect of Step 4 of the literature review (Onwuegbuzie & Frels 2016), articles were evaluated according to *inclusion criteria*. As an inclusion criterion, studies had to be published from 2006-2019. The reason for the cut-off point of 2006 is that one of the leading publications regarding the definition of clinical pathways were published in 2006 (De Bleser et al. 2006), and the findings of the De Bleser study affected almost all the research done on pathways after that year.

Furthermore, at least two of the following criteria had to be present in the findings of the article in order to be included in the study:

- One or more guideline, not limited to DM management, but specifically aimed at the PHC setting, had to be evaluated in the article, *and either*
- An exploration of the reasons for a successful or unsuccessful PHC specific guideline had to be part of the article, *or*
- Advice or suggestions as given by end-users of PHC guidelines for improved future guidelines had to be present in the article.

All the articles found during the literature search were also evaluated according to a set of *exclusion criteria*. For some articles, the presence of exclusion criteria was already evident in the title, while in other articles, the exclusion criteria manifested only in the abstract or in the full text article. The exclusion criteria were as follows:

- Could not be linked to completed studies.
- Could not be accessed in full text format. This exclusion was only done after exhaustive attempts via inter-library services and even contacting the authors of specific articles via ResearchGate yielded no results.
- The article's conclusions focused on aspects of PHC guidelines not applicable to this study.

These inclusion and exclusion criteria ensured that only articles containing information aligned to the aim and objectives of the study were included in the literature review. Figure 3.1 details the processes followed during this sampling of documents for the literature review.

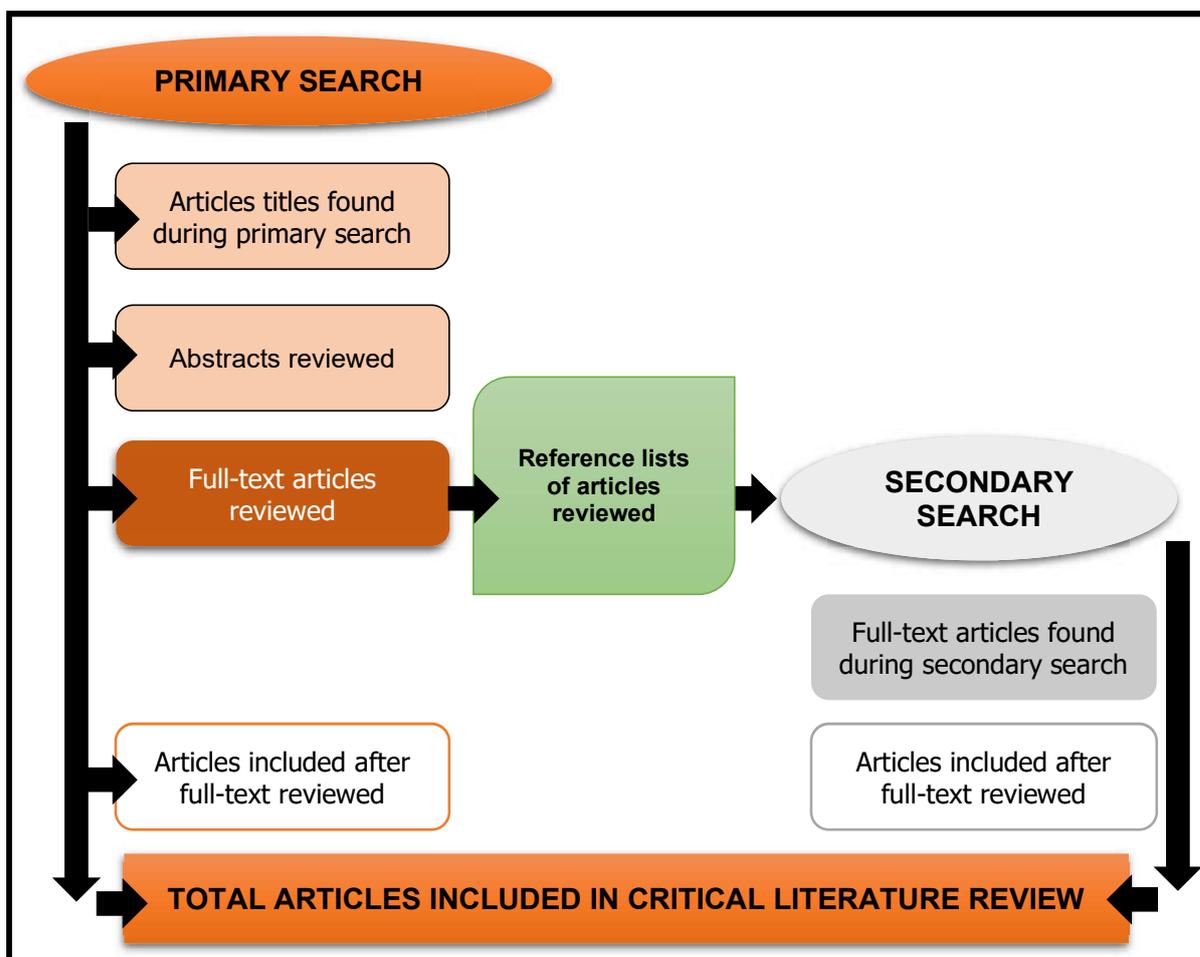


Figure 3.1: Schematic overview of process of critical literature review article sampling

Figure 3.1 thus details the method that was followed to select the final list of articles that were included in the literature review part of this study. This final pool of selected articles was then evaluated and analysed according to the objectives of the study, which will be described in Section 3.2.3.4.

Onwuegbuzie and Frels (2016) describe the fifth step of the literature review process as being an *expansion of the search*. The authors detail an extensive process of using two or more innovative modes to “increase the rigor and integrity of the literature review process” (Onwuegbuzie & Frels 2016:177). The different possible sources that can be used for such an expansion of the search are exemplified in Table 3.1.

Table 3.1: Examples of other sources of information to expand the literature search [Collated from Onwuegbuzie & Frels (2016)]

Task	Sources of information
Media	Audio tool, e.g. Audio books Videos Photographs, drawings, paintings
Observations	On-site observations Mapping observations

Task	Sources of information
	Geographic observation systems Ground truthing
Documents	Dissertations, theses, monographs Encyclopaedias Government documents Trade catalogues Legal and public records and information Grey literature e.g. unpublished works Conference papers Blogs
Experts(s)	Interviews with experts e.g. in-person, via computer mediated communication or via e-mail Delphi-based interviews
Secondary data	Already analysed secondary data e.g. data-bases Raw secondary data

In this study, expansion of the literature search as described in Table 3.1 were not done specifically, for the following reasons:

- Media sources of information was not applicable to the objectives of this study.
- Observational sources of information were not applicable to the desk-top nature of the study.
- Applicable documents, e.g. relevant government documents, were already assimilated into the primary search of this study.
- Expert interviews are not applicable to the desk-top nature of this study
- Sources of secondary data were already used during the primary search.

Furthermore, the data collected during the primary and secondary searches delivered material of adequate quantity and quality in order to produce the desired product. The decision not to expand the search further was corroborated when the findings of the literature review showed a point of saturation regarding the data gathered.

3.2.3.4 Analysis of data

The sixth step of the literature review process is that of analysis and synthesis (Onwuegbuzie & Frels 2016). The process of analysis and synthesis in this phase was aligned to the objective of this part of the study, namely to study the elements that would influence the feasibility of a new DM clinical management guideline. The evaluation of the feasibility focused on *practical* and *non-generic advisory content* that can be incorporated into a newly proposed management guideline. The literature review was thus designed to evaluate the barriers and facilitators to feasible PHC setting guidelines, but also to incorporate general comments made by end-users of guidelines which could offer

information regarding feasibility features of guidelines. Findings were grouped into themes, as will be discussed in Chapter 4 as part of the seventh step of the literature review process, namely that of *presenting the literature review report* (Onwuegbuzie & Frels 2016).

The literature review was thus completed. The findings gathered during the literature review were used to guide and enhance the final phase of the study.

3.2.4 Phase IV: Development of a feasible management guideline for patients with diabetes mellitus in the primary health care setting in the Free State

During the fourth and final phase of this study, the objective was to develop a management guideline for patients with DM, which would be feasible for use in specifically the PHC setting in the Free State. This phase of the study was done via a synthesis of all of the findings from sections 3.2.1 to 3.2.3., with the final product being the proposed, new DM management guideline. The methodology of how the synthesis and development of the new guideline took place will now be discussed.

3.2.4.1 *Research technique: Step-wise building process*

The development of a management guideline can be a complex, time consuming and potentially costly process (Machingaidze *et al.* 2018). To simplify the procedure, the researcher adapted the first six steps suggested by Panella, Marchisio and Di Stanislao (2003), who developed an eight-step process to build clinical management guidelines. The full eight steps that Panella *et al.* (2003) suggest, are:

- (1) Selecting the practice area;
- (2) Building a multi-disciplinary work-team;
- (3) Defining the diagnosis;
- (4) Defining the patients to be treated with this guideline;
- (5) Reviewing of current practice and literature;
- (6) Developing the clinical path;
- (7) Piloting and implementing the clinical guideline; and
- (8) Ongoing evaluation of the guideline.

The final two steps will not be part of this study, but will rather be developed for follow-up studies.

3.2.4.2 Sampling

The documents used to develop the new management guideline were the data generated during Phases I to III (cf. Sections 3.2.1 - 3.2.3) of this study.

3.2.4.3 Data collection

This collected data were synthesised by following steps 1 to 6 as suggested by Panella *et al.* (2003), (cf. Section 3.2.4.1.). In this research study, step 1 was pre-defined by the study's aim and objectives as described in Chapter 1. Step 2 describes the building of a multi-disciplinary team: this management guideline was developed as part of Master's dissertation and the researcher together with her supervisors formed the multi-disciplinary team to develop the proposed, new management guideline. A multi-disciplinary *approach* was also used by the researcher to offer patients a holistic and integrated service by way of the new management guideline: dietetic services, mental health services, foot care and general nursing care were all incorporated into this proposed guideline.

Steps 3 and 4, namely *defining the diagnosis* and *defining the target patients*, were already defined during the planning phases of this study; namely, adult patients with DM who are not pregnant. The target patients were further refined by the study's goal, which states that the management guideline is aimed at patients with DM who utilise the services offered by the PHC setting in the Free State.

Step 5, reviewing the current literature, was encompassed during Phase I and Phase III (cf. Sections 3.2.1 - 3.2.3) of this study. The data gathered during these phases of the study formed the base from which the new management guideline could be designed.

3.2.4.4 Data synthesis

The 6th step of management guideline development is the development of the actual guideline (Panella *et al.* 2003). The data collected in Step 5, *i.e.* during phase I and phase III as well as information gathered while reviewing literature for Chapter 2 of this study were synthesised into the developed, feasible management guideline. The feasible management guideline consist of two sections, namely a *Diabetes Follow-up* section, and a *Newly diagnosed diabetes and /or Acutely ill patient with diabetes* section.

In an effort to assist the reader with understanding the design and synthesis process,

schematic diagrams were drawn to illustrate the development process. Figure 3.2 illustrates the *Diabetes Follow-up* section of the management guideline.

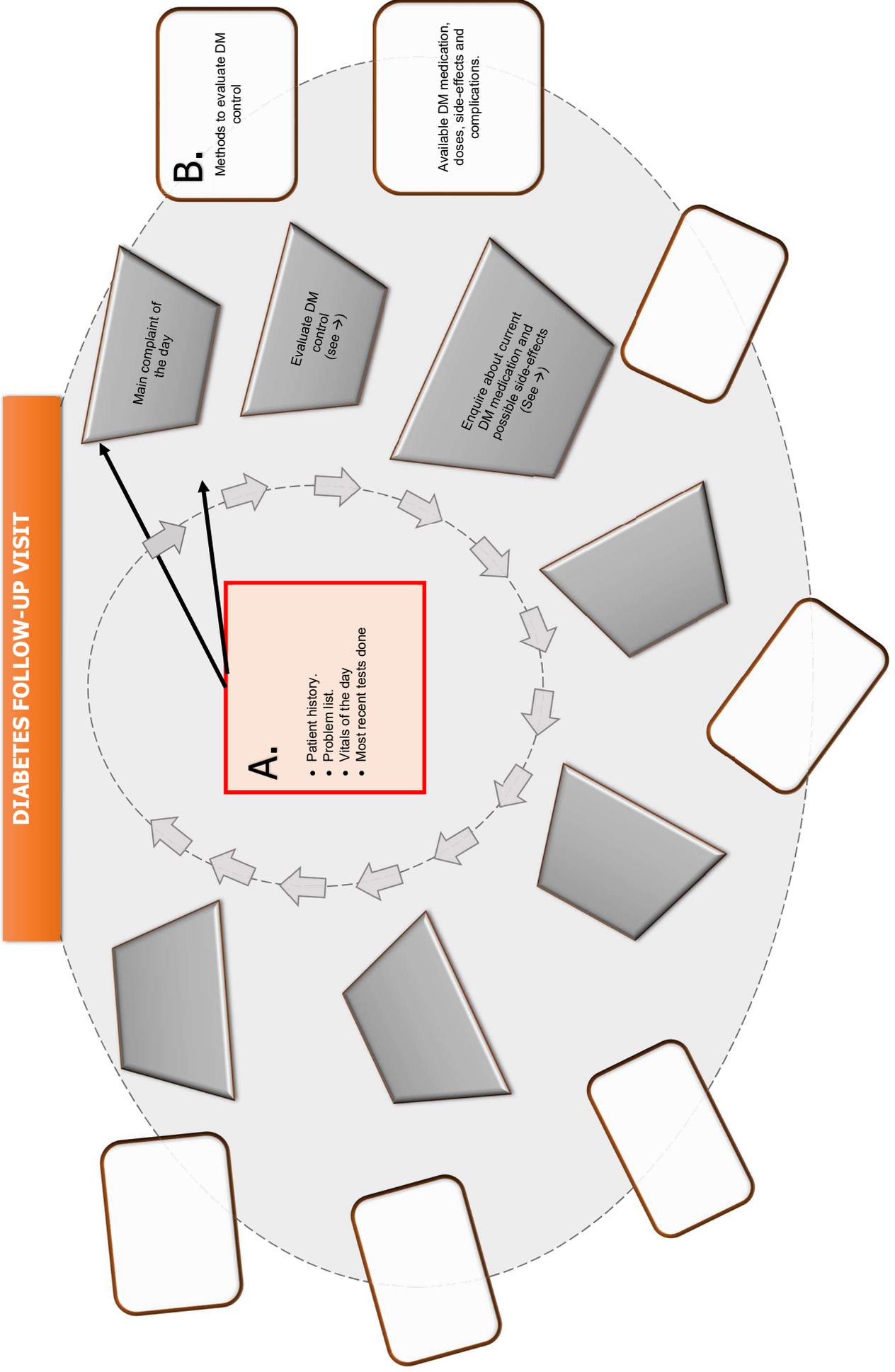


Figure 3.2: Diagrammatic framework and excerpt of the diabetes follow-up section of the new management guideline

As Figure 3.2 illustrates, the diabetes follow-up section of the guideline comprises of the information needed by PHC practitioners during a standard PHC setting follow-up visit of a patient with DM. The general design of the circular flow in the centre, marked **A** in Figure 3.2, was influenced by the flow suggested in the ADA's *Decision cycle for patient-centered glycemetic management in type 2 diabetes* (ADA 2019:S35) (cf. Appendix F). The section marked **B** on the figure represent the additional information needed for PHC practitioners to make decisions during the clinical consultation. Information found in section **B** is cross-referenced with **A** for ease of use. The information chosen for use on the management guideline, whether in **A** or **B**, was aligned to the best practices espoused by the clinical DM guidelines as condensed during Phase I of the study. The information and sources in the management guideline, used to make decision suggestions, were all referenced.

The text on the newly developed management guideline was typed mostly in black for ease of reading. The *APC 2016/2017* (RSA DOH 2016) influenced the design of this guideline in regards to the colour coding of the levels of medicine prescriptions. The same colour codes were used as in the latest version of the *APC guideline*, to denote which medicines can be prescribed by registered nurses, and which by clinic-level doctors.

The second part of the management guideline encompasses the *Newly diagnosed diabetes and /or Acutely ill patient with diabetes* section (cf. Figure 3.3). The design of this section of the new guideline followed mostly the same basic principles as with the *Diabetes Follow-up* guideline, but with some important differences.

Newly diagnosed diabetes and/or acutely ill patient with diabetes

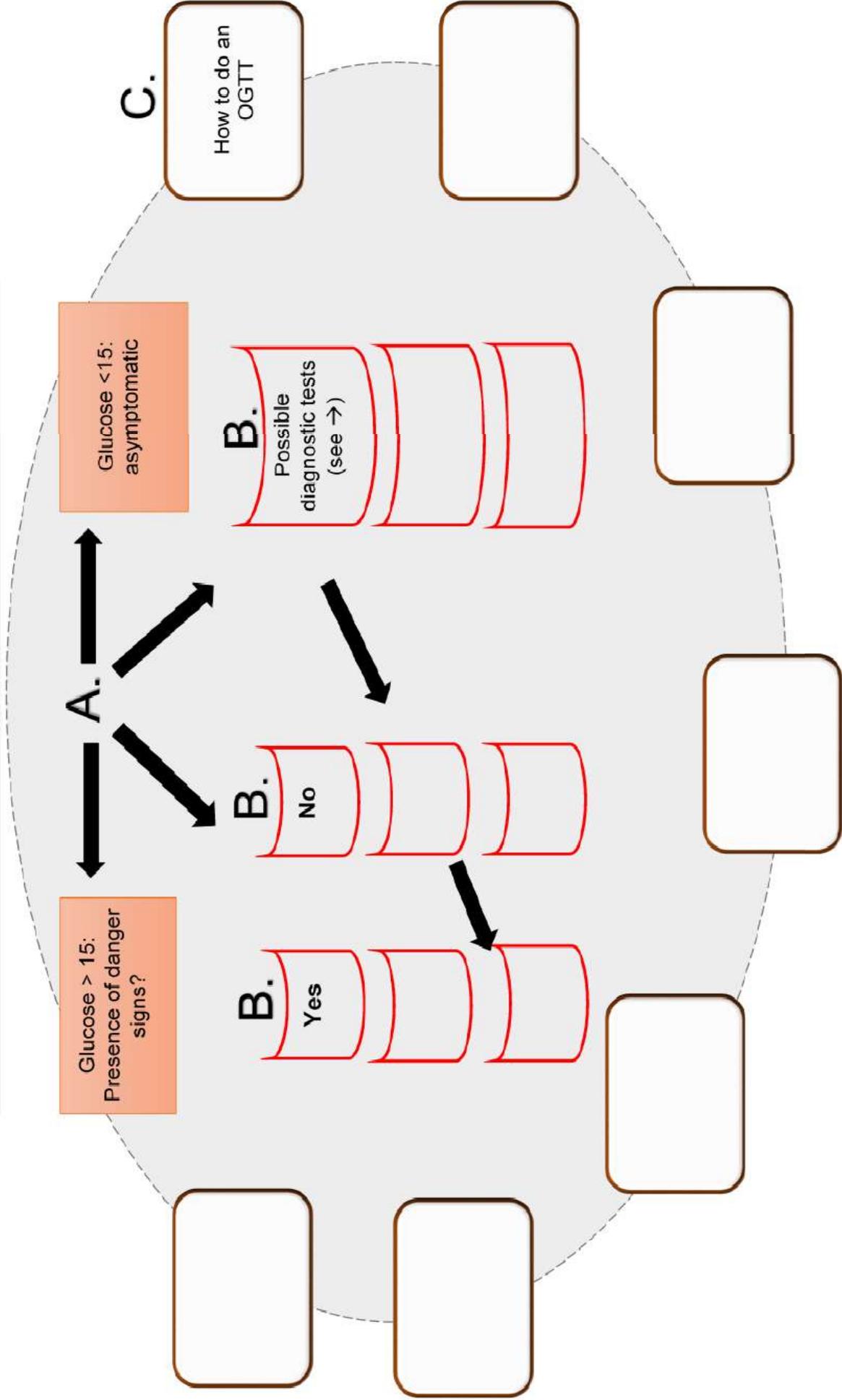


Figure 3.3: Diagrammatic framework and excerpt of the section for newly diagnosed diabetes and acutely ill patients with diabetes of the new management guideline

The design of the flow-diagram used in this management guideline (Figure 3.3), specifically the central flow-diagram **A**, was influenced by the format of the diabetes diagnosis section of the *APC 2016/2017 guideline* (RSA DOH 2016). The information in the standardised diagnosis of DM, as seen in **A** and **B**, was obtained from Phase I of the study and aligned with the known resources of the PHC sector of the Free State.

Similarly to the design of Figure 3.2, **C** on the figure represents the additional information needed for PHC practitioners to make decisions during the clinical consultation, which was also sourced from Phase I of the study. Information found in the **C** section is also cross-referenced with **A** and **B** for ease of use, and the same colour coding and referencing methods were used as in Figure 3.2.

During the development of both these management guidelines, care was taken to adhere as much as possible to the guiding factors that were obtained from Phase III of the study. These factors were incorporated into decisions made regarding the format and layout of the new guideline, but not formally represented on the new guidelines' diagrammatic frameworks.

The new management guideline was thus developed in the format of two large posters, which can be attached to the walls of consultation rooms in the PHC setting. These poster-format guidelines were then synchronised with a PowerPoint® presentation of the same two designs. The PowerPoint® format was seen as an important part of the educational aspect of the management guideline, as this format can be used effectively to train PHC practitioners in the facilities where the new guideline will be piloted or implemented, ideally during workplace learning and outreach sessions.

In order to develop a user-friendly format for the new, proposed management guideline, a qualified graphic design company was approached to assist with the design process. The graphic designer was responsible for the colour co-ordination, flow of the poster and presentation, readable font sizes, and any other general design features. The researcher remained responsible for the data on the posters, the references used, as well as for the spell check of all information on both the poster and presentation.

This concludes the methodology section of the proposed, new DM management guideline's development. Rigour and ethical considerations will be discussed in the next section.

3.3 TRUSTWORTHINESS

In qualitative studies, trustworthiness is frequently seen as the collective quality criteria of

credibility, transferability, dependability, and confirmability (Korstjens & Moser 2018). The evaluation of the quality of a qualitative research study should not happen on completion of the study only, but should be built into each step of the research process (Morse 2018). Sullivan and Sargeant (2011) are of the opinion that the term *trustworthiness* is used to describe and establish the credibility of a finding, making the term *trustworthiness* an all-encompassing term for a credible and valid study.

Credibility is defined as the confidence that can be placed in the veracity of the research findings, and whether plausible information is drawn from the research data (Korstjens & Moser 2018). It should thus be easy to prove that the conclusions drawn from the data are not falsifications, and that the evidence presented are not be refutable by others (Silverman 2005).

Transferability is concerned with the applicability of a research study and its findings to a different setting: detailed descriptions in the study methodology are thus required so that readers can establish the transferability of the data to their own settings (Korstjens & Moser 2018).

Dependability is the way in which the findings remain stable over time, and whether it is repeatable if another researcher did the same study in the same context (Forero, Nahidi, De Costa *et al.* 2018; Korstjens & Moser 2018).

Confirmability is closely linked to reliability, and refers to how neutral, objective and accurate the gathered data are (Houghton, Casey, Shaw *et al.* 2013). For confirmability to be proven, it must be shown that the findings of the study are undoubtedly derived from the collected data (Korstjens & Moser 2018).

Each phase of the research done during this study will therefore now be discussed regarding its overall trustworthiness.

3.3.1 Phase I: The comparative analysis

The *dependability* of the comparative analysis of the ADA (2019) guideline, the IDF (2017) guideline, the SEMDSA (2017) guideline, and the APC 2016/2017 guideline's DM section lie in the stability of the data collected from these different guidelines. The data were not open for interpretation, but rigorous evaluation of each whole guideline was needed due to the different aspects of each subject that were evaluated in different chapters or sections of each guideline.

The *credibility* of the gathered data is also simple to prove, as the information presented in each of the above management guidelines is stable and easily obtainable. The value that this researcher has added in regards to this section was only in organising the data into a simple, comparative format, with referencing of the page number(s) on which the specific answers were found.

The *confirmability* of this section lies in the neutrality of the gathered data, and can be verified on an audit trail due to meticulous record-keeping.

Transferability was enhanced by the detailed methodology that accompanied this section. The gathered data are also aimed at a specific setting, and therefore the conclusions drawn by the reader should be applicable to the same type of setting only.

3.3.2 Phase II: the document analysis of the *Adult Primary Care 2016/2017* guideline's diabetes management section

Credibility was achieved in this phase of the study in the following ways, by:

- Choosing the pool of assessors carefully according to the inclusion criteria stipulated, in order to ensure that their findings were valid for the PHC setting in the Free State;
- Selecting the assessment tools to align with the aim and objective of this phase of the study, and by using these tools appropriately and with an adequate number of users;
- Using assessment tools with a numerical answer system - which was not open for interpretation by the researcher (Appendices C & D); and
- Storing the assessment forms securely so that answers can be verified upon request.

The *transferability* of this phase of the study is of adequate quality due to the detailed methodology section aligned with it. If the same study methods are used in different PHC settings in regards to the *APC 2016/2017* guideline's DM section, similar results should be found.

The proof of the *dependability* of Phase II of the study lies mostly in the stability of the analysed document (Bowen 2009), namely the *APC 2016/2017* guideline's DM section. The document did not change while being evaluated, and could thus be reviewed repeatedly by different assessors. The inclusion and exclusion criteria for the choosing of assessors also improved the dependability of this phase of the study.

Confirmability during this phase of the study can be proved by storage of the assessment forms, but is enhanced by using an adequate number of assessors. These multiple responses served as a type of triangulation of the qualitative data (Bowen 2009), as different assessors – working in slightly different genres in the PHC setting – often came to roughly the same conclusions regarding the *APC 2016/2017* guideline's DM section. Interpretive bias consequently did not influence the answers given by assessors and reflects positively on the neutrality of the data (Houghton *et al.* 2013).

3.3.3 Phase III: The literature review

The *credibility* of this phase of the study is sound, as reasons for including and excluding studies are valid and based on transparent inclusion and exclusion criteria. The findings are credible, as the articles are easily verified and the content applicable to this study taken verbatim from the articles.

The methodology of this phase of the study is *transferable*, as long as the same inclusion - and exclusion criteria for articles are followed. The applicability of this phase of the study to the feasibility of management guidelines for the Free State PHC setting and the alignment with the aim and objective of the overall study are thus key to its transferability.

The *dependability* of this phase of the study is shown by the research steps followed during the literature review, which are transparent and repeatable. The themes with which the literature review was organised were aligned with the study's aim and objectives and were based on a valid source.

Confirmability of the literature study may be more difficult to prove, as unintentional bias from the researcher may have influenced the decision of which elements in articles found were deemed more or less important. However, this was overcome by objectively synthesising information from the selected articles. In addition, the steps taken during the literature study were transparent and are repeatable, were aligned with the objective of the study; and copies of the articles used during this phase of the study were all kept. Together, all these measures enhance the confirmability of the literature review phase of this study.

3.3.4 Phase IV: The development of the new management guideline

During the development phase of the new management guideline, the researcher relied on the suggestions of Dixon-Woods, Cavers, Agarwal and colleagues (2006) that an

interpretive synthesis must integrate the induction and interpretation of findings to formulate a product. The product of the synthesis is thus theory founded in the studies that have been included in the literature review (Dixon-Woods *et al.* 2006). This interpretive slant may throw the trustworthiness of the new guideline into question, but the following clarifications regarding its trustworthiness should verify this aspect of the research project. The new management guideline can be evaluated for trustworthiness regarding aspects of its *content*, the *built-in factors to enhance feasibility*, and its *applicability to the PHC setting in the Free State*.

The *credibility* of the content used in the new management guideline is enhanced by the source documents used: the guidelines of the ADA (2019), the IDF (2017) and SEMDSA (2017), as well as the *APC 2016/2017* (RSA DOH 2016) are easily accessible and its combined content thus verifiable. The application of the checklist provided by the *Integrated Care Pathways Appraisal Tool* (I.C.PAT) (Whittle 2009; Whittle, McDonald, Dunn *et al.* 2004) (cf. Appendix G) to the newly developed management guideline during and after the development process also enhances the credibility of the new management guideline. This I.C.PAT checklist proves that a valid guideline development process was followed.

Features needed to *enhance the feasibility* of the guideline were built into the new management guideline, and these features were based on the results of the literature review; that is, Phase III of the study. As the literature review was based on principles of credibility, transferability, dependability and confirmability, the results can be seen as being of adequate quality to be applied to the development of the new management guideline.

A critical, but less easily definable element of this development phase, is the knowledge and experience of the *PHC setting in the Free State* as brought by the researcher: by being aware of the resources available in the PHC setting, the design of the new management guideline had this knowledge inherently built into its features to improve its feasibility. The credibility of this knowledge can thus be contested, but can be tested in the pilot studies that will follow this research study.

The *transferability* of this phase of the study lies mostly in the detailed methodology describing the processes followed to develop the new management guideline. The focus on feasibility, DM and the PHC setting allows for transferability of the findings of this phase of the study to similar PHC settings. The educational material that has been developed simultaneously with the poster-format of the guideline further enhances the transferability of the management guideline: the presentations regarding DM management at PHC

settings during the pilot of this new management guideline will be aligned with each other and re-enforce the educational content.

The *dependability* of the new management guideline can be tested by the referencing that was done throughout it, and by using the same source documents and methodology as used by this researcher. The source documents are also neutral and stable, and thus dependable.

Phase IV of this study has proven its *confirmability* by clearly referencing each suggestion on the proposed new management guideline and its veracity can easily be checked.

3.4 ETHICAL CONSIDERATIONS

Ethical clearance for this study was received from the Health Sciences Research and Ethics Committee (HSREC) of the University of the Free State, with approval number 114/2017 given (cf. Appendix H). Furthermore, ethical considerations were part of every phase of this research project in accordance with *The Singapore Statement on Research Integrity* (Resnik & Shamoo 2011). Each phase will now be evaluated individually regarding these ethical aspects.

3.4.1 Phase I: The comparative analysis

Ethical considerations during the comparative analysis were to maintain the integrity of the source documents and to cite any material used, according to the *Singapore Statement's* responsibilities of data integrity and respect for authorship (Resnik & Shamoo 2011). This was achieved by meticulous recording of relative page numbers, and referencing of the source documents. No patients, case studies or vulnerable population groups were involved in the comparative analysis of the evaluated guidelines.

3.4.2 Phase II: The document analysis of the *Adult Primary Care 2016/2017* guideline's diabetes management section

No patients or case studies were part of this phase of the study. Ethical considerations were, however, applied during this phase of the study in the following manner to address the responsibilities of *data sharing, record keeping, conflict of interest* and *social responsibility* (Resnik & Shamoo 2011).

- Conflict of interest: The assessors who were approached to analyse the *APC 2016/2017* guideline's DM section were not coerced into taking part in the study, and received no financial, monetary or other gains from their participation.
- Data sharing: Assessors' personal details were not relevant to the study, as long as they fitted the profile as selected for inclusion criteria of assessors. No identification of the assessors was thus made anywhere in the study.
- Social responsibility: Information leaflets and consent forms to participate in this study (cf. Appendix E) were issued to and signed by each participant.
- Record keeping: The completed and signed consent forms are kept in a place of safety, as are all the completed tools that were handed in to the researcher by the assessors. These hard copies will all be kept in a locked cabinet in the home office of the researcher for a period of five years on completion of this study, after which it will be destroyed by shredding and incineration.

3.4.3 Phase III: The literature review

The ethical integrity of the literature review was kept intact by following the principles of honesty and accountability from the *Singapore Statement*: specifically, the responsibility of *data integrity* was enhanced (Resnik & Shamoo 2011) by utilising an experienced librarian during the primary search of the literature review, and by aligning the inclusion and exclusion criteria related to the literature review with the aim, objectives and purpose of the study. Secondly, all literature used during the study were properly cited and referenced, thus maintaining honesty in regards to *authorship* (Resnik & Shamoo 2011). Thirdly, all literature used during the final literature study was evaluated in full text format, and copies of the full text were kept as PDF files by the researcher to maintain *stewardship* and *record keeping* responsibilities.

3.4.4 Phase IV: The development of the new management guideline

This phase of the study also did not involve patients or case studies. During this phase of the study, the *Singapore Statement's* principles and responsibilities were referred to by the following means:

- *Honesty and accountability* (Resnik & Shamoo 2011): Proper referencing and citations were done for all material taken from source documents.
- The responsibilities of *education* and *social responsibilities* (Resnik & Shamoo 2011): The newly developed management guideline was aligned with the aim and objectives

of the study; namely, to be applicable and feasible to PHC practitioners in the Free State, and to be functional as a tool for workplace learning.

The piloting and implementation of the proposed, new management guideline will need its own set of ethical considerations and approvals from the HSREC and the Free State Department of Health.

3.5 CONCLUSION

Chapter 3 dealt in the detail with the various methodological processes followed during this research process. The reasons why these methodologies and subsequent products can be viewed as trustworthy, and therefore worthy of a trial of implementation, were also discussed. Ethical considerations, which strengthen the integrity of the study product, were evaluated in depth.

Chapter 4 will now follow, with a description of the results of each phase of the research study.

CHAPTER 4

RESULTS AND DISCUSSIONS

4.1 INTRODUCTION

This research study consisted of four distinct phases. Each of the first three phases produced its own separate results, which were then synthesised into the final product of this study. During the chapter that will now follow, the findings of each phase of the study will be presented and discussed separately.

4.2 PHASE I: THE COMPARATIVE ANALYSIS OF DIABETES MANAGEMENT GUIDELINES

During Phase I, a comparison was made between the content and recommendations found in the following DM management guidelines:

- American Diabetes Association's 2019 guideline: *Standards for Medical Care in Diabetes – 2019* (ADA 2019);
- International Diabetes Federation's 2017 guideline: *Recommendations for Managing Type 2 Diabetes in Primary Care* (IDF 2017); the
- *The Society for Endocrinology, Metabolism and Diabetes of South Africa Guideline for the Management of Type 2 diabetes mellitus 2017* (SEMDSA 2017); and
- *Adult Primary Care 2016/2017 guideline's* DM management section (RSA DOH 2016).

As discussed in Chapter 3, the data analysis of the comparative analysis was done after themes were identified - with which the information collated from the different guidelines could be organised. While these themes were initially based on the eight topics identified in the IDF's guideline (IDF 2017), the following changes were made to suit the purpose of this study:

- Three topics of the IDF were collated to form a single theme, namely *targets of glucose control and lifestyle changes*;
- All glucose lowering treatments were discussed in a single topic;
- An additional theme of *complications of DM* was added;
- *Cardiovascular risk factors* were expanded into *related special investigations* to include more co-morbid conditions than only cardiovascular disease; and

- The theme of *other* was renamed to *miscellaneous* to include topics not discussed in any of the five previous themes.

The six broad themes which were thus identified according to the above process, are:

- I. Diagnosis and Screening for DM;
- II. Targets for glucose control and lifestyle changes;
- III. Discussion on glucose-lowering treatment;
- IV. Discussion on the complications of DM;
- V. Related special investigations; and
- VI. Miscellaneous topics.

The guiding questions that were then aligned to the six themes can be seen in Table 4.1. For ease of future reference in this chapter, the questions were numbered.

Table 4.1: Six themes and their aligned guiding questions, used to evaluate the diabetes management guidelines

Theme I	
Diagnosis and screening for DM	<ol style="list-style-type: none"> 1. Which patient population is described as "at risk"; thus, needs diabetes screening? 2. Is doing an oral glucose tolerance test (OGTT) advised in certain circumstances? 3. Is method of doing OGTT correctly discussed? 4. What are the diagnostic values of the OGTT? 5. How should pre-diabetes be managed? 6. How should pre-diabetes/high risk individuals be followed up/reviewed?
Theme II	
Targets for glucose control and lifestyle changes	<ol style="list-style-type: none"> 7. Which target HbA1C is advised? 8. How often is repetition of an HbA1C advised for a patient on treatment? 9. Are factors influencing the interpretation of HbA1C discussed? 10. What is the targeted fasting blood glucose (if HbA1C target is <7%) for patients on treatment? 11. What is targeted 2hr post-prandial / random blood glucose for a patient on treatment? 12. Is special populations discussed in terms of control targets/special considerations? 13. How frequently is testing of blood glucose at home advised? 14. Is hypoglycaemia explored?
Theme III	
Discussion on glucose-lowering treatment	<ol style="list-style-type: none"> 15. Metformin: Are contra-indications and/or complications discussed? 16. Sulphonylureas: Are contra-indications and/or complications discussed?
Theme IV	
Discussion on the complications of DM	<ol style="list-style-type: none"> 17. Is micro-albumin testing advised? 18. How frequently is micro-albumin testing advised? 19. What steps/treatments are advised when micro-albuminuria is present? 20. Are side-effects/complications/contra-indications for use of an angiotensin converting enzyme inhibitor (ACE-I) discussed? 21. Is an alternative option to ACE-I explained or offered? 22. Foot exam: How often advised? What to look for? 23. Eye exam: How often advised? By whom should it be performed? 24. Screening for depression / mental health recommended? 25. Is autonomic neuropathy discussed?
Theme V	
Related special investigations	<ol style="list-style-type: none"> 26. How frequently is urea, electrolytes and creatinine (U&E+Kr) testing advised? 27. Is K (potassium) testing advised, and how frequently? 28. Is Vitamin B12 testing advised or discussed? 29. How often is Lipid testing advised?

	<p>30. Which element of the lipogram is targeted for treatment? [Total cholesterol/Low density lipoprotein(LDL)/ High density lipoprotein (HDL) /Triglycerides]</p> <p>31. Which cholesterol-lowering treatment is advised?</p> <p>32. What is the advised lipid treatment target?</p> <p>33. Is HIV testing advised in DM patients or vice versa?</p> <p>34. Is thyroid function testing ever advised? (Under which circumstances?)</p>
<p>Theme VI</p> <p>Miscellaneous topics</p>	<p>35. What is the target Body Mass Index (BMI) for patients with DM?</p> <p>36. Is cancer screening discussed?</p> <p>37. Are vaccinations recommended?</p> <p>38. Is smoking discussed?</p> <p>39. Point of care testing of HbA1C discussed?</p> <p>40. Injection site inspection for lipohypertrophy discussed?</p> <p>41. What is the recommended route for insulin in an emergency?</p>

The above six themes and their aligned 41 guiding questions of Table 4.1 were then used to formulate a Rubric (cf. Appendix B; Section 3.2.1.4). The Rubric was completed by initially answering each question directly on the Rubric, and by adding the page numbers from where the answers were sourced. Once the Rubric was completed in this manner, the interpretation of the answers was simplified by using a scale to score each answer. The scale, as described in Section 3.1.2.4, scored each answer as either *Not answered/Discussed at all (-)*, *Discussed with minimal detail (+)*, *Discussed with moderate detail (++)*, or *Discussed with extensive detail (+++)*. The rubric that was completed in this fashion is attached as Appendix I.

The results of the comparative analysis will now be given, with a comparison between the guidelines of the ADA (2019), the IDF (2017) and SEMDSA (2017) given first, after which the DM management section of the *APC 2016/2017* guideline will be compared to the first three guidelines.

4.2.1 Comparison of the content of the guidelines published by the American Diabetes Association, the International Diabetes Federation, and the Society of Endocrinology, Metabolism, and Diabetes of South Africa with each other

The comparative analysis of the DM management guidelines of the ADA, the IDF and SEMDSA highlighted areas where the guidelines agree, areas where they disagree, as well as gaps that exist and require guidance. To assist in this regard, Table 4.2 was compiled to showcase the results. It was found that greater alignment existed between the DM management guidelines of the ADA and SEMDSA than between these two guidelines and the IDF (cf. Table 4.2).

Table 4.2: Results of comparative analysis of the DM management guidelines of the ADA (2019), IDF (2017) and SEMDSA (2017)

Themes in which comparisons of alignment were done	ADA vs SEMDSA	ADA and SEMDSA vs IDF	ADA vs SEMDSA	IDF vs ADA and SEMDSA	Not answered by IDF at all
	Question number(s) aligned		Question number(s) not aligned		Question number(s)
<i>Theme I:</i> Diagnosis and screening for DM	1-6	4,5,6	-	1,2,3,	-
<i>Theme II:</i> Targets for glucose control and lifestyle changes	7-14	11	-	7,10,12,13, 14	8,9
<i>Theme III:</i> Discussion on glucose-lowering treatment	15-16	15-16	-	-	-
<i>Theme IV:</i> Discussion on the complications of DM	17-24	17,18,21, 23,24	25	19,22	20,25

Themes in which comparisons of alignment were done	ADA vs SEMDSA	ADA and SEMDSA vs IDF	ADA vs SEMDSA	IDF vs ADA and SEMDSA	Not answered by IDF at all
	Question number(s) aligned		Question number(s) not aligned		Question number(s)
<i>Theme V: Related special investigations</i>	26-33	26,30,31,32	34	29	27,28,33,34
<i>Theme VI: Miscellaneous topics</i>	37-41	38	35,36.	39	35,36,37,40,41
Total number of responses per alignment category	37	16		12	13
Percentage per alignment category	90.2%	39.0%	9.8%	29.3%	31.7%

(- : not applicable to theme)

When comparing the DM management guidelines of the ADA (2019) and SEMDSA (2017), responses to the different questions were answered in comparative detail, thus by giving *moderate* or *extensive detail* in 90.2% of the questions (cf. Table 4.2). The exceptions to these, where markedly different responses were given, were the answers to questions 25, 34, 35 and 36. These four questions were concerned with autonomic neuropathy, thyroid function testing, weight and body mass index (BMI), and cancer screening. In all four these instances, the topics were discussed in significantly more detail in the ADA's than in the SEMDSA guideline (cf. Appendix I).

The IDF's guideline showed more variation in its answer to the 41 questions (cf. Table 4.2). Only 39.0% of questions were answered with almost the same attention to detail and with answers aligned to those of the ADA and SEMDSA. In 12 cases, the answers given by the IDF guideline were significantly less detailed than those found in the other two guidelines. A total of 13 out of 41 questions (31.7%) in the IDF guideline were not discussed at all. Theme II had the responses where the IDF did not align with the ADA and/or SEMDSA, while Themes V and VI had the biggest number of questions that the IDF did not answer at all.

Of specific note is the responses to Questions 4, 7, 10, 11, 12 and 13 (cf. Appendix I). These six questions relate to frequent diagnostic and therapeutic dilemmas faced by PHC practitioners working with patients with DM, namely diagnostic values of an oral glucose tolerance test (OGTT), target values of blood glucose, and target values of HbA1Cs. In all three of these guidelines, the questions were answered with moderate to extensive detail, but the answers differ substantially from each other. For example, SEMDSA's suggested OGTT diagnostic values (cf. Question 4) were answered in detail by the SEMDSA guideline, earning an *extensive detail* score on the rubric, but were of a different standard than the other two guidelines.

While the DM management guidelines of the ADA, SEMDSA and the IDF were found to be relatively aligned as far as its approaches to DM management aspects, the *APC 2016/2017* guideline's DM section still had to be evaluated. The findings of that aspect of the comparative analysis will follow in the next section.

4.2.2 Comparing the content of the *Adult Primary Care 2016/2017* diabetes guideline with the set standard

The same 41 guiding questions were posed to the *APC 2016/2017* (RSA DOH 2016), and the responses differed significantly from the guidance offered by the ADA, SEMDSA and the IDF's DM management guidelines. A summary of the answers and its comparison to the other three guidelines can be viewed in Table 4.3.

Table 4.3: Results of direct comparison of APC 2016/2017 guideline's DM management section (RSA DOH 2016) to guidelines of the ADA (2019), IDF (2017) and SEMDSA (2017)

Themes	Number of questions in the theme	Number of questions <u>not answered at all</u> by the APC	Number of questions answered <u>poorly</u> or <u>substantially different</u> by the APC in comparison to the ADA and SEMDSA	Number of questions where the answers in the APC correlates well to the ADA and SEMDSA	Number of questions where APC correlates <u>poorly</u> with IDF	Number of questions where APC <u>correlates well</u> with or <u>better than</u> the IDF
I	6	4	1	1	1	1
II	8	2	4	2	3	3
III	2	0	2	0	2	0
IV	9	2	3	4	2	6
V	9	5	4	0	3	1
VI	7	5	1	1	0	2
TOTAL	41 (100%)	18 (43.9%)	15 (36.6%)	8 (19.5%)	10 (24.4%)	13 (31.7%)

The answers given on the Rubric (Appendix I) was tabulated to indicate when the answers of the *APC 2016/2017* compared well to those found in the ADA, IDF and SEMDSA guidelines, meaning the same amount of detail was used in the answer, or roughly the same *yes* or *no* answer was given to a question. As Table 4.3 reveals, only eight of the 41 questions gave the same quality of information as the guidelines of the ADA and SEMDSA. A full 43.9% of the total number of evaluating questions were not answered at all by the *APC 2016/2017*. No guidance was thus given by the *APC 2016/2017* in regards to those topics in the management of patients with DM. A list of these non-answered 18 questions has been attached as Appendix J.

Fifteen questions were deemed to be *answered poorly or substantially different* when compared to the ADA and SEMDSA: those were the instances in which the *APC 2016/2017* scored only *minimal detail* while the other guidelines scored at either *moderate* or *extensive detail*, or where the answers given by the *APC 2016/2017* to a clinical problem responded in a completely different manner from the other guidelines. When the same comparison is made even to the IDF, ten questions were answered poorly by the *APC 2016/2017* (cf. Table 4.3).

In regards to the questions where the *APC 2016/2017* compared equally or favourably to the other guidelines, eight questions were answered to an equal standard as the ADA and SEMDSA. Moreover, 13 answers given by the *APC 2016/2017* were of an equal or better standard than that of the IDF's guideline (cf. Table 4.3).

Of note, some of the answers that were completely different from those found in the guidelines evaluated in Section 4.2.1 are related to frequently seen conditions and complications in the Free State. These questions were related to the follow-up regime of patients with a high risk to develop DM; the frequency with which blood glucose should be measured at home; the steps to be followed if micro-albuminuria is present; the method(s) of doing an eye examination; the approach to lipid testing; HIV testing in patients with DM, and the route of insulin injection during an emergency. In some of these cases, the details offered by the *APC 2016/2017* were just substantially less than the other guidelines; for example, the target HbA1C of patients with DM. In other cases, such as the frequency of glucose checks at home in patients on insulin, the information offered differed significantly: from *6-10 times per day* (ADA 2019), to the *APC 2016/2017*'s suggestion of *once a week on waking*.

4.2.3 Discussion of the comparative analysis

During this comparative analysis, a wide variety in approaches towards the management of DM was found. The reasons for these variations in the approaches are implicit to the specific aims and purposes of each of these different guidelines. Both the ADA and SEMDSA produce voluminous and comprehensive guidelines, aimed at all levels of DM management: chapters for primary care, in-hospital care, specialised conditions and comprehensive follow-up are presented in both these guidelines (ADA 2019; SEMDSA 2017). The IDF's guideline, on the other hand, is a short, 34-page version aimed at primary care specifically, and thus much less comprehensive in its approach. The *APC 2016/2017* guideline's DM management section is even shorter: it consists of three pages only and its usage is also

aimed specifically at the PHC setting (RSA DOH 2016).

Because of these diverse approaches and target audiences, it would not be completely rational to compare the content of the *APC 2016/2017* to that of the content offered by the DM guidelines of the ADA (2019) or SEMDSA (2017). An equal comparison with the IDF's guideline (2017), on the other hand, should be possible, as it is also aimed at the PHC setting. The disparities that were found in the *APC 2016/2017* are therefore even more glaring when it is noted that its guidance are not even favourably comparable to that of the IDF: only 31.7% of answers offered by the *APC 2016/2017* were of the same or better quality than those of the IDF. Of the 18 questions that were not answered at all by the *APC 2016/2017*, nine were also not answered by the IDF, but seven were answered with substantially more information by the IDF.

This side-by-side comparison made it simple to find glaring differences in opinion, and also where absolute consensus was found on certain topics. Expert consensus can be used as the more appropriate evidence for a certain condition, especially in the developing world, and specifically where little direct evidence for a certain population group exists (Minas & Jorm 2010). Specific areas of the separate themes in which the guidelines agreed or differed from each other will now be accentuated further.

4.2.3.1 *Theme I: Diagnosis and screening for diabetes*

The *APC 2016/2017* lags far behind in the diagnosis of and screening for DM. The discrepancy in the frequency of screening for at-risk patients, namely every five years where other guidelines suggest every three years (cf. Appendix I), is particularly worrisome. The complete lack of OGTT guidance to address borderline cases or cases of impaired glucose tolerance (IGT) and impaired fasting glucose (IFG) is a severe oversight. The IDF deems an OGTT to be eminently do-able in the PHC setting, as it is included in their guideline aimed at the PHC setting (IDF 2017).

4.2.3.2 *Theme II: Targets for glucose control and lifestyle changes*

In this theme, the *APC 2016/2017* had a few aspects in need of attention. The rigid HbA1C target was one facet that was completely misaligned with the approach of flexibility in regards to co-morbidity now followed by the other three guidelines. The frequency of glucose checks that should be done by a patient using insulin is also a glaring discrepancy: this misalignment is assumed to be in response to the perceived high cost of glucose

monitoring equipment. However, the consensus, as evidenced by the guidance given by the ADA (2019) and SEMDSA (2017), indicates that much more frequent glucose monitoring is urgently needed by patients using insulin, regardless of the possible cost.

4.2.3.3 *Theme III: Discussion on glucose-lowering treatment*

While the discussion of the contra-indications and side-effects of Metformin and sulphonylureas by the *APC 2016/2017* seem to be adequately detailed on the surface, the information supplied by this guideline differs completely from that of the other guidelines (cf. Appendix I). Contra-indications not mentioned at all by any other guideline are mentioned, while complications are not discussed at all. This creates the impression that the authors of the *APC 2016/2017* were using an outdated pharmacological source when compiling the guideline, and this does not inspire confidence.

4.2.3.4 *Theme IV: Discussion on the complications of diabetes*

In this theme, the *APC 2016/2017* seemed to have the best correlation with the other three guidelines, as four out of nine questions correlated well with the answers given by the other three guidelines (cf. Table 4.3). These questions related specifically to the suggested frequency of certain tests that need to be done to evaluate for complications of DM.

On the other hand, there is Question 23, relating to the frequency of retinal screening. In this regard, the *APC 2016/2017* was not aligned to the other three guidelines at all. Understandably, issues like retinal pictures for eye examinations are contentious in the Free State PHC setting, as there are very few retinal cameras and trained personnel in this setting (De Wet & Ackermann 2000; Cairncross, Steinberg & Labuschagne 2017). The availability of these type of services will not magically improve in the near future, as retinal cameras are extremely costly instruments. That clear guidance, aligned to international standards and practice, cannot be given in the regard of retinal pictures, is thus evident.

4.2.3.5 *Theme V: Related special investigations*

The *APC 2016/2017* once again fared disappointingly poorly in this theme. No alignment of the *APC 2016/2017* with the other guidelines seems to exist, as five questions were not answered at all, and the other four were answered poorly in comparison to the recommendations made by the ADA and SEMDSA (cf. Table 4.3). The only consolation is that that the IDF also did not give any recommendations in four of the questions: this seems

to indicate that the two guidelines that target the PHC setting specifically are hesitant to recommend relatively costly special investigations.

The two questions in this theme where the *APC 2016/2017* had completely discrepant answers in relation to the other three guidelines, were related to the lipogram and lipid treatment (cf. Questions 30 & 31; Appendix I). Guidance offered by the *APC 2016/2017* in regards to management of lipid abnormalities are completely opposed to national and international guidance documents (ADA 2019; IDF 2017; Klug *et al.* 2018; SEMDSA 2017), with the only possible reason for this disparity being the cost implication of correct treatment (Klug *et al.* 2018). It stands to reason that the cost of investigations and treatment is most likely the driving force behind this inconsistency.

What is less clear, is why the presence of HIV as a co-morbid condition to DM is given so little attention in the *APC 2016/2017*, despite its prevalence in South Africa (Pillay *et al.* 2016). Question 33 dealt with this aspect of DM management guidelines, and the fact that the inter-relationship between HIV and DM was not discussed at all in the *APC 2016/2017* is an oversight that needs to be corrected.

4.2.3.6 Theme VI: Miscellaneous topics

The *APC 2016/2017* once again had a dismal performance in this last theme of the comparative analysis. Five questions were not answered at all; one had a completely discrepant answer; and only one question compared favourably to the guidance given by the ADA (cf. Table 4.3; Appendix I). The problem with the fact that these topics are not discussed, is that these topics are important aspects of integrated care and multi-morbidity in patients with DM (cf. Section 2.3.3). Weight loss encouragement, cessation of smoking, frequent vaccinations and appropriate cancer screening are integral to primary care and preventative medicine, especially for patients with DM, and should be integrated into their chronic management.

The recommendations of using point of care HbA1C meters for follow-up of DM control is a new feature seen in the national and international sphere, and shows great promise to improve timeous treatment changes (Motta, Shephard, Brink *et al.* 2017; Spaeth, Shephard & Schatz 2014). Introducing this type of meters in the Free State PHC setting will potentially have a meaningful impact on the lives of patients with DM, as HbA1C results are available within minutes and another visit to the clinic for the purpose of getting blood results becomes unnecessary.

4.2.4 Summary of results of Phase I

While mild to moderate differences in the approach of various guidelines are acceptable and understandable, significant deficiencies of the *APC 2016/2017* guideline's DM section was exposed by this comparative analysis. Not only were discrepant answers found, but aspects of DM management that were completely neglected in the *APC 2016/2017*, in comparison with the guidelines from the ADA, IDF and SEMDSA.

A further topic that is worth mentioning, is the effort it took for the researcher to find the answers to seemingly innocuous questions by fine-combing the different guidelines. The answers that were sourced from especially the ADA guideline (2019) and the SEMDSA guideline (2017) were at times extremely complex to understand or difficult to find, as the answers were spread over more than one chapter, or more than one table or figure. This difficulty once again emphasised the problem that PHC practitioners have to find guidance to a clinical problem while seeing patients in busy facilities.

4.3 PHASE II: THE QUALITY EVALUATION OF THE *ADULT PRIMARY CARE 2016/2017* GUIDELINE'S DIABETES MANAGEMENT SECTION

The *APC 2016/2017* guideline has previously been evaluated in regards to its quality, albeit when it was still known as the PC101 (cf. Section 2.3.1.2) (Grimmer *et al.* 2016). Grimmer and colleagues evaluated the whole document and not the DM management section as a separate entity. The evaluation of the PC101 by Grimmer *et al.* (2016) focused more on the quality of the development processes and the transparency of these processes, and less on the quality and feasibility of the guideline's clinical content.

To reach a conclusion regarding the feasibility of the *APC 2016/2017* guideline's DM section, two aspects of this guideline had to be assessed, namely:

- The rigour and completeness of development; as well as
- The applicability of the guideline to the PHC setting in the Free State.

The assessment tools used for this purpose were the *International Centre for Allied Health Evidence* (iCAHE) instrument (Grimmer *et al.* 2014) for *rigour and completeness* (cf. Appendix C), and the *Clinical practice guideline applicability evaluation* (CPGAE-V1.0) scale (Li *et al.* 2018) for the *applicability* aspect (cf. Appendix D). Four independent assessors applied both of these assessment tools to the *APC 2016/2017* guideline's DM section, reflecting their experience as end-users of the PHC guideline.

The different cadres of the four assessors who participated in this study reflected the demography of medical doctors working in the PHC setting in the Free State. One of the participants is a Family Medicine specialist, two are career medical officers, and one is a medical officer who had already completed community service and was at the time considering an application to a registrar position while continuing to work in the PHC setting.

The findings of these two assessment tools will now be presented separately. A discussion of the findings will follow afterwards.

4.3.1 Assessment of the Adult Primary Care 2016/2017 using the International Centre for Allied Health Evidence instrument

The *iCAHE*-instrument (cf. Appendix C) consists of 14 simple questions; each question is answered either *yes* (1) or *no* (0).

Table 4.4: iCAHE Instrument quality checklist (Grimmer et al. 2014) applied by four assessors to the DM management section of the APC 2016/2017

Checklist items and score	Assessor 1	Assessor 2	Assessor 3	Assessor 4
Availability				
Is the guideline readily available in full text?	0	0	0	0
Does the guideline provide a complete reference list?	0	0	0	0
Does the guideline provide a summary of its recommendations?	0	0	0	0
Score (/3)	0/3	0/3	0/3	0/3
Dates				
Is there a date of completion available?	1	1	1	1
Does the guideline provide an anticipated review date?	0	0	0	0
Does the guideline provide dates for when literature was included?	0	0	0	0
Score (/3)	1/3	1/3	1/3	1/3
Underlying evidence				
Does the guideline provide an outline of the strategy used to find underlying evidence?	0	1	0	0
Does the guideline use a hierarchy to rank the quality of the underlying evidence?	0	0	0	0
Does the guideline appraise the quality of the evidence which underpins its recommendations?	0	0	0	0
Does the guideline link the hierarchy and quality of underlying evidence to each recommendation?	0	0	0	0
Score (/4)	0/4	1/4	0/4	0/4
Guideline developers				
Are the developers of the guideline clearly stated?	0	1	0	1
Does the qualifications and expertise of the guideline developer(s) link with the purpose of the guideline and its end users?	0	0	0	0
Score (/2)	0/2	1/2	0/2	1/2
Guideline purpose and users				
Are the purpose and target users of the guideline stated?	1	1	1	1
Score (/1)	1/1	1/1	1/1	1/1
Ease of use				
Is the guideline readable and easy to navigate?	1	1	1	1
Score (/1)	1/1	1/1	1/1	1/1
SCORE (/14)	3/14	5/14	3/14	4/14

No = 0; Yes = 1

As Table 4.4 demonstrates, there was mostly agreement between the assessors regarding the quality of the DM management section of the *APC 2016/2017*. Discrepancy was only found in two questions; namely, in whether the developers of the guideline were clearly stated: two assessors marked the answer as *no*, then qualified the answer by making a footnote stating “*only states DOH*”. The two other assessors gave the answer as *yes*, citing the same reason, namely that the National DOH is the developer. Only one assessor gave a discrepant answer in the question related to the strategy used to find the best evidence: no reason was required by the instrument or offered by the assessor as to the reason for this judgement decision.

The three questions that received resounding *yes* answers, were the following:

- Is there a date of completion available?
- Are the purpose and target users of the guideline stated?
- Is the guideline readable and easy to navigate?

Once the assessors' scores were combined, the average score out of a possible 14 marks was calculated to be 3.75 out of 14, giving an average percentage of 26.8%. The *APC 2016/2017* guideline's DM management section thus only received a 26.8% score in regards to *rigour and completeness* according to the *iCAHE* instrument (Grimmer *et al.* 2014).

4.3.2 Assessment of the Adult Primary Care 2016/2017 using the Clinical practice guideline applicability evaluation scale

The *CPGAE-V1.0* scale (Li *et al.* 2018) differs in format from the *iCAHE* instrument in the following ways: a grading scale for answers are offered; domain scores and a total score for the scale can be calculated; space for individual comments by assessors exists; and a page with explanations or clarifications of the questions are attached at the end of the document (cf. Appendix D). The responses to this scale by the assessors will be discussed in two phases: first the numeric answers, and then the individual comments made by assessors.

4.3.2.1 Numeric responses by assessors

In their assessment of the *APC 2016/2017* guideline's DM management section with the *CPGAE-V1.0* scale (Li *et al.* 2018), the four assessors showed wider variation in their

responses when compared to responses given when the *iCAHE* instrument was used. This variation between assessors are expected, and the creators of the scale thus developed a formula to calculate domain scores and the final scores as a combination of the scores given by different assessors.

The *CPGAE-V1.0* scale evaluates the applicability of the guideline to its environment, and uses four domains to do so (Li *et al.* 2018). Nineteen statements are made in the scale, and assessors score their assessment of the veracity of the statement as either 4 (Very good), 3 (Good), 2 (Poor), or 1 (Very poor) (Li *et al.* 2018). In this research project, three statements from the scale were excluded from use in the final tally of the score. These statements were eliminated due to the following reasons:

- Statement three: “*Compared to the unit health care level*”. This researcher already asked assessors when handing out the material not to answer this question, as, for the purpose of this study, the *APC 2016/17* guideline’s DM management section is seen as the unit health care level, and thus cannot be compared to itself.
- Statement nine: “*The physico-chemical examination is reasonable*”. Three out of four assessors wrote in the comments section that the question did not make sense to them or that they felt unable to answer it.
- Statement nineteen: “*The role of improving medical technology level*”. Three out of four assessors did not answer the question and commented that the question did not make sense or that they were not sure what the aim of the question is.

These three statements were consequently removed from the scale, and the domain scoring adjusted to reflect the removal of these three items from the total score. Table 4.5 reflects the individual scores given by each assessor to the different statements of the scale, once applied to the DM management section of the *APC 2016/2017*.

Table 4.5: The CPGAE-V1.0 scale (Li *et al.* 2018) as applied by four assessors to the DM management section of the APC 2016/2017

Domains	Assessor 1 (A1)	Assessor 2 (A2)	Assessor 3 (A3)	Assessor 4 (A4)
Domain 1: Technical level				
1. Compared to the country health level (SEMDSA guideline)	3	2	3	2
2. Compared to the local health care level (Hospital level EDL)	4	3	2	3
3. Compared to the unit health care level:	Question Excluded			
4. Compared to other related clinical and diagnosis programs:	3	2	2	2
Domain 2: Coordination of support				
5. Coordinate with the contents of relevant standards or guidelines	3	3	2	2
6. Coordinate with multidisciplinary.	1	1	1	3

Domains	Assessor 1 (A1)	Assessor 2 (A2)	Assessor 3 (A3)	Assessor 4 (A4)
Domain 3: Structure and content				
7. The scope of the application is clear	1	3	3	3
8. The diagnostic point is accurate	2	3	2	2
9. The physico-chemical examination is reasonable.	Question Excluded			
10. The structure is complete and reasonable.	4	3	2	2
11. The content is complete and reasonable.	3	3	3	2
12. The content is clear.	4	3	3	3
13. The technical contents support each other.	4	3	3	3
14. There is no contradiction between the contents.	2	3	3	3
15. The extensibility of the guideline.	2	3	2	3
Domain 4: The role of the guideline				
16. The convenience of the clinical application.	4	4	2	3
17. Rational use of medical resources.	4	3	3	3
18. The role of regulating medical management and guaranteeing medical service quality.	3	3	3	2
19. The role of improving medical technology level.	Question Excluded			

[Score: 4 (Very good), 3 (Good), 2 (Poor), 1 (Very poor)]

The first two statements of the scale (cf. Table 4.5) were clarified by adding the specific guideline with which the assessors had to compare the applicability of the *APC 2016/2017* guideline's DM section. In the case of the *country health level*, the guidance offered by the SEMDSA guideline (SEMDSA 2017) was used as the baseline. In the case of the *local health care level*, the guideline that is used in hospitals, namely the *Standard Treatment Guidelines and Essential Medicines List for South Africa: Hospital Level Adults* (RSA DOH 2015) was used as a reference point for the comparison. The statement that received the lowest scoring from the highest number of assessors, was statement six: *co-ordinate with multidisciplinary (sic)*. Three of the four assessors scored this statement as having a very poor application in the DM management section of the *APC 2016/2017*. No other statement's scores were as pronouncedly poor, and no statement stood out as being scored much higher than the other statements.

Only one assessor scored the *APC 2016/2017* guideline's DM management section with recurrent values of four, indicating that the application of many aspects of this guideline was experienced to be *very good* (A1). This evaluation contrasts with the scores given by the other three assessors (A2, A3 & A4).

The numerical scoring of a guideline is only the first aspect of the *CPGAE-V1.0* scale, as the comments made by assessors in response to their scoring of specific statements can also offer valuable insight. These comments will be discussed separately.

4.3.2.2 *Individual comments by assessors*

While Assessors 2 and 4 did not offer any additional comments after scoring each statement, the other two participants made various comments. Not all the comments made were equally clear or understandable, but should be read in conjunction with the score given by each assessor in Table 4.5. Even so, the comments made by the two different assessors highlight that each PHC practitioner has a unique perspective in regards to the management of DM (cf. quotes #1 & #2):

#1 *"Very clear on medication use and applicability of special investigations. Could limit burden of uncontrolled disease" [A1]*
 #2 *"Some of the treatment recommended is unavailable in the PHC setting" [A3].*

Assessor 3 made comments regarding the inconvenience of having a booklet-format guideline that necessitates paging two and fro (cf. quotes #3), and also seemed to be more aware of the other chronic health programmes that can impact the management of DM (cf. quotes #4 & #5):

#3 *"Entails a lot of paging to and fro. This may be time consuming in a very busy facility."*
 #4 *"Monitoring not as structured as in other programmes, e.g. HIV"*
 #5 *"Poor: certain conditions e.g. HIV and drug interactions of Alluvia with diabetes".*

In addition, Assessor 3 also commented on the usefulness of a practical flowchart format to simplify management (cf. quotes #6 & #7):

#6 *"One large chart would however be more efficient to avoid paging to different sections. Flow chart simplify the ability to manage"*
 #7 *"One chart would be more convenient".*

Assessor 1's approach leaned more towards risk management and resource availability. In regards to a multi-disciplinary approach in the PHC setting, Assessor 1 clearly stated that this type of team is not available in the PHC setting, which is reflected by the score of very poor given to this question by three out of the four assessors (cf. quote #8; Table 4.5):

#8 *"The multidisc. [sic] team not available in PHC clinics!"*

Both of these two assessors (A1 & A3) made similar comments about the impeded resources at the PHC level, even though these similar comments were not made in response to the same questions (cf. quotes #9 & #10):

#9 "Taking into consideration resources available on PHC level" [A1]
 #10 "Gap in availability of resources in facilities" [A3].

Assessors 1 and 3 also made similar comments regarding the vagueness of certain aspects of the guideline, with specific reference to the diagnosis of DM and pre-diabetes, the HbA1C recommendation, and the management of an acutely high blood glucose in a patient (cf. quotes #11, #12 & #13):

#11 "Pre-Diabetes diagnostic is vague" [A1]
 #12 "Random glucose levels considered for action is high. Action is delayed with elevated glucose e.g. >20: use of actrapid not included early enough?" [A3]
 #13 "HbA1C recommendation and guideline @ gluc 4-11,1 [sic] might be confusing" [A1].

While the fact that no clear referencing was present was noted by Assessor 1, it seems that this absence was not troublesome to Assessor 3, as no similar comments were made anywhere in the responses (cf. quote #14):

#14 "Not clear references [sic]" [A1].

Another opposing view that was shown, was that one assessor viewed the format of the APC 2016/2017 as being helpful in a busy PHC clinic [A1], while the other assessor viewed the format and the need to page to and fro, as a hindrance in the same setting [A3] (cf. quote #15 & again quote #3).

#15 "Could be valuable in PHC clinic setting where patient numbers are high" [A1]
 #3 "This may be time consuming in a very busy facility" [A3]

These individual responses helped solidify the numeric responses as given by the different assessors.

4.3.2.3 Domain score calculations of Adult Primary Care 2016/2017 guideline's diabetes management section according to the Clinical practice guideline applicability evaluation scale

After the three non-evaluated statements were excluded, the domain scores and total scores of the evaluation of the APC 2016/2017 guideline's DM management section were calculated according to the formula described in Section 3.2.2.2 (cf. Table 4.6).

Table 4.6: Domain score calculations APC 2016/2017 guideline's DM management section according to the CPGAE-V1.0 scale (Li et al. 2018)

Domain and score calculations	Standardised domain score formula	Total Domain score
Domain I A1: 3+4+3+10; A2: 2+3+2= 7; A3: 3+2+2+7; A4: 2+3+2+7 Total 31 Minimum possible score: 1x3x4=12 Maximum possible score: 4x3x3=48	$\frac{(31 - 12)}{(48 - 12)} \times 100\%$	Domain I: 52.7%
Domain II A1: 3+1=4; A2: 3+1=4; A3: 2+1=3; A4: 2+3=5 Total 16 Min possible score: 1x2x4=8 Maximum possible score: 4x2x4=32	$\frac{(16 - 8)}{(32 - 8)} \times 100\%$	Domain II: 33.33%
Domain III A1: 1+2+4+3+4+4+2+2=22; A2: 3+3+3+3+3+3+3+3=24; A3: 3+2+2+3+3+3+3+2=21; A4: 3+2+2+2+3+3+3+3=21 Total:88 Minimum possible score: 1x8x4=32 Maximum possible score: 4x8x3=128	$\frac{(88 - 32)}{(128 - 32)} \times 100\%$	Domain III: 58.3%
Domain IV A1: 4+4+3=11; A2: 4+3+3=10; A3: 2+3+3=8; A4: 3+3+2=8 Total: 37 Minimum possible score: 1x3x4=12 Maximum possible score: 4x3x4=48	$\frac{(37 - 12)}{(48 - 12)} \times 100\%$	Domain IV: 69.4%

(A1 = Assessor 1; A2 = Assessor 2; A3 = Assessor 3; A4 = Assessor 4)

Table 4.6 clarifies the combined assessors' findings, in that certain domains scored significantly better than others: Domain IV, *the role of the guideline*, received a very high score, while Domain II, *co-ordination of support*, was scored lowest. The two domains concerned with the *technical level* and *structure and content* scored between 52% and 59%.

The Total Domain score for the APC 2016/2017 guideline's DM management section according to the CPGAE-V1.0 scale (Li et al. 2018) was then calculated according to the same formula:

Total score over all 4 domains:

$$\frac{(31 + 16 + 88 + 37) - (12 + 8 + 32 + 12)}{(48 + 21 + 128 + 48) - (12 + 8 + 32 + 12)} \times 100 = 56.3\%$$

The APC 2016/2017 guideline's DM management section was thus scored by its end-

users, as having only a 56.3% applicability to the PHC setting in the Free State.

4.3.3 Discussion of results of the quality evaluation

The research question pertaining to this phase of the study, was: does the DM management section in the *APC 2016/2017* conform to best practice standards in regards to guideline development? The objective was thus to analyse the *APC 2016/2017* guideline's DM section using these two instruments to appraise guideline quality – which, in the context of this study, was further clarified as being the quality of both development and applicability to the PHC setting in the Free State. The data collected during this phase of study do not necessarily need finely nuanced interpretation: the results clearly show the inadequacies of the DM management section of the *APC 2016/2017* guideline. The inadequacies are especially significant in the rigour of development as well as the applicability of the content of this specific guideline to the needs of the Free State's PHC setting.

The two instruments used to assess the quality of the *APC 2016/2017* guideline's DM management section (RSA DOH 2016) both evaluated the guideline unfavourably. Where the iCAHE instrument (Grimmer *et al.* 2014) gave only a 26.8% score in regards to *rigour and completeness*, the CPGAE-V1.0 scale (Li *et al.* 2018) scored it at 56.3% for *applicability*. This suggests that the DM management section of the *APC 2016/2017* guideline was poorly formulated, which could be responsible for it scoring an average applicability in the PHC setting. This finding is of great relevance as it reflects end-user's perspective on the guideline.

When using multiple assessors, tools and instruments to evaluate a guideline, one has to accept that interpretation of questions and concepts will differ, and personal viewpoints and experiences of assessors will have an impact on their interpretation and judgement. However, Westbrook (2018:764) succinctly states that "(a)ccepting the facts of an imperfect evaluation is a starting point for evaluation", but adds that qualitative research should be committed "to portray what a program, policy, or project means to those it is intended to serve". To that purpose, the evaluation given by each assessor is valuable in its own right, especially because assessors in this study were chosen from a group of end-users of the *APC 2016/2017* guideline. There should be no reason why these end-users should have less of a voice than professional guideline developers with skills in regards to statistics and methodology, but no experience in the field targeted by the guideline.

The findings of this evaluation thus stand in direct contrast to those of Machingaidze *et al.*

(2018) who scored the *PC101* (RSA DOH 2013) in its totality with a much higher score: they scored the *PC101*, whose DM management section was an exact copy of the *APC 2016/2017* guideline in regards to content, with a score of 58% according to the AGREE II tool. Grimmer *et al.* (2016), used the iCAHE instrument on the *PC101* (RSA DOH 2013) as well, and gave it a total score of 43%. While both these studies evaluated the guideline as a whole and did not assess the DM management section separately, the contrast in the opinion of professional guideline appraisers to the opinion of guideline end-users is quite stark.

While the inadequacies in the *APC 2016/2017* guideline's DM management section have now been clearly presented, the focus can now move to areas in the guideline that consequently need to be addressed by future guidelines. Following from the findings of the two instruments, both the numeric answers and the individual comments made, it is clear that the following aspects need improvement in any future guidelines to enhance applicability in the PHC setting:

- Referencing of suggestions and/or guidance;
- Clarity concerning who designed and/or developed the guideline;
- Clarity regarding when the guideline should be reviewed and/or renewed;
- Drugs recommended should be applicable and/or available in the Free State;
- No confusion in recommendations should be present;
- An attempt should be made to integrate multi-disciplinary care;
- An attempt should be made to integrate DM with multi-morbid conditions;
- A guideline should be easy to navigate and readable;
- The content should be clear and non-contradictory; and
- The guideline should possibly be on a single page, to decrease to-and-fro paging.

While the iCAHE instrument (Grimmer *et al.* 2016) has four questions pertaining to evidence, the levels of evidence, and the linkage of recommendations to evidence, the CPGAE-V1.0 scale (Li *et al.* 2018) is more concerned with whether a guideline compares well to the country and local health levels. This seems to take into consideration that the levels of evidence and the hierarchy of evidence is not as important as having a guideline that is supported by the available resources.

The researcher thus took all of these findings into account while developing the new proposed guideline for DM management in the PHC setting in the Free State, in an effort to improve the feasibility and thus usage of such a new guideline.

4.4 PHASE III: THE LITERATURE REVIEW

The literature review that formed the third phase of this research study was conducted to explore the elements and considerations that will influence the development of a feasible DM management guideline that can be used in a PHC setting. The aim of this review was therefore to evaluate the elements that ensure the feasibility of the said guidelines, and also to identify the elements present in existing PHC guidelines that may cause guidelines to have poor uptake by its end-users. This completes the final aspect of the literature review as suggested by Onwuegbuzie and Frels (2016), namely the *presentation of the literature review report* (cf. Section 3.2.3.1). The results of the review will now be presented in a step-wise manner.

4.4.1 Results of literature search

The results and the pathways for both the primary and secondary literature searches are presented in Figure 4.1. A total number of 139 articles were sourced during the primary and secondary searches, which was then whittled down to a final number of 30 articles for final inclusion into the literature review. Inherent inclusion and exclusion criteria for the articles were based on the objective of this phase of the study, namely to investigate elements that would make a new DM guideline more feasible, specifically for the PHC setting.

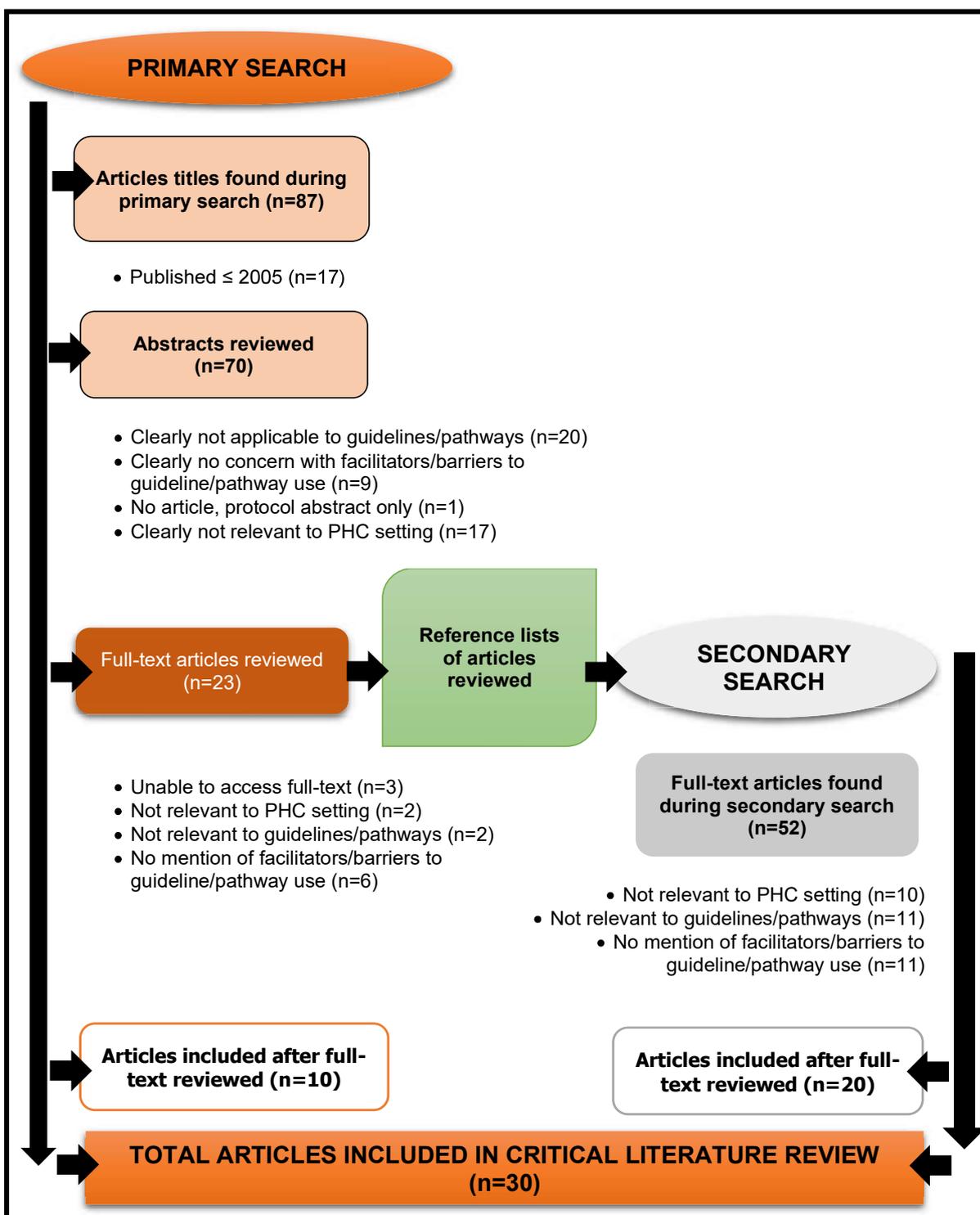


Figure 4.1: Schematic overview of results of critical literature review article sampling

As Figure 4.1 demonstrates, articles were excluded at various times during the search and selection process according to the pre-determined inclusion and exclusion criteria (cf. Section 3.2.3.3).

Articles that were excluded as not being relevant to the PHC setting, were usually aimed at tertiary level processes, for instance guidelines for in-hospital post-operative care after

invasive surgeries. Those articles that evaluated the effects of an implemented guideline in a PHC clinic, but did not evaluate the reasons for adherence or non-adherence to the guideline, were also not applicable to this literature review and thus excluded during the search process.

The articles selected to be reviewed were then analysed according to the aim and objective of the phase of this study.

4.4.2 Thematic analysis of reviewed literature

A simple grid format was used to present the findings of the literature review, with the directly quoted words in the article used when needed. Generic and specific factors relevant to feasibility factors were identified and divided into *barriers* and *facilitators or enablers*. Separate attention was given to general comments made by end-users of guidelines, especially when practical advice was contained in those comments.

Examples of *generic factors* are those instances when an article described feasibility factors as *doctor factors* or *patient factors*. Emphasis was placed on *specific factors*; for instance, suggestions that a feasible guideline “*must not increase the paperwork*” or “*must have adequate space to write notes on*”, during the analysis of the selected literature.

The completed literature study is attached as Appendix K, and consists of ten pages. All the included articles were evaluated individually and given equal time and attention in order to find the specific information needed. A discussion of the findings will follow in the next section.

4.4.2.1 *Intrinsic barriers and facilitators to guideline uptake in the primary health care setting*

During the review and analysis of selected literature (cf. Appendix K), many similarities and common factors were found as to the reasons why guidelines may have poor adherence in the PHC sector. While the lack of time, money and resources were almost universally decried as reasons for guideline non-usage in the PHC setting, more specific complaints regarding guidelines were also raised.

While *barriers* were discussed frankly and in detail in most of the articles found during the literature search, practical elements that can enable the uptake of a guideline into primary

care were less easy to identify. The *facilitators* or *enablers* to a good guideline were mostly described in broad and non-specific entities, but some specifics were found on deeper analysis. Nevertheless, four themes emerged regarding both *barriers* and *facilitators*.

The researcher made the conscious choice to use the simplest possible language in describing the themes, to avoid falling back into the generic descriptions of *patient factors* and *doctor factors*. The four themes that will be described, are the following:

- Autonomy of PHC practitioners;
- Educational issues;
- The need for simplification; and
- Trust issues.

Autonomy of primary health care practitioners

A *barrier* to guideline uptake in the PHC, is, firstly, in the form of inherent threats to the autonomy of PHC practitioners, either by the guideline being too prescriptive or by disregarding complexities of different patients: these types of guidelines are less likely to be followed (Carlsen, Glenton & Pope 2007; Deutsch, Benyo, Xie *et al.* 2018; Evans-Lacko, Jarrett, McCrone *et al.* 2010; Harrison, Légaré, Graham *et al.* 2010; Jabbour, Newton, Johnson *et al.* 2018; Kenefick, Lee & Fleishman 2008). Contextual factors, for instance patient preferences, can be present in certain patients - which tend to stop some PHC practitioners from following a guideline rigidly (Austad, Hetlevik, Mjølstad *et al.* 2015; Harrison *et al.* 2010; Mercuri, Sherbino, Sedran *et al.* 2015; Vander Schaaf, Seashore & Randolph 2015). This is linked to the fact that most guidelines are not integrated with one another and do not factor in the intricacy of holistic patient care, as well as the presence of multi-morbidity in patients (Austad *et al.* 2015; Grimsmo, Løhre, Røsstad *et al.* 2018; Hashmi & Khan 2016; Khunti *et al.* 2019; Rankin, Butow, Thein *et al.* 2015; Steyn *et al.* 2013). Multimorbidity and the burdens of the poly-pharmacy associated with it, is consequently a major concern that needs to be addressed in some way in a guideline (Grimsmo *et al.* 2018), as well as to elucidate when it may be necessary to deviate from a guideline in a specific patient (Mazrou 2013; Papanikitas & Lunan 2018).

The opportunity in a guideline for choices and for tailor-making these choices to the patient's needs (Evans-Lacko *et al.* 2010; Grimsmo *et al.* 2018), is seen as an important *facilitator* that can increase adherence to a guideline.

Educational issues

A major *barrier* to guideline adherence, raised in multiple articles, was the need for staff to be informed and educated on guidelines (Deutsch *et al.* 2018; Hashmi & Khan 2016; Khalifa & Alswailem 2015; Khunti *et al.* 2019; Lugtenberg, Zegers-van Schaick, Westert *et al.* 2009; Solà, Carrasco, Díaz del Campo *et al.* 2014; Zwolsman, Te Pas, Hooft *et al.* 2012). This is partly due to an overload of available guidelines in the wide field of general practice, with little time for PHC practitioners to familiarise themselves with such a range (Abdelhamid, Howe, Stokes *et al.* 2014; Austad *et al.* 2015; Basedow, Runciman, Lipworth *et al.* 2015; Carlsen *et al.* 2007). Furthermore, the high turnover of staff, thus causing the loss of previously trained staff, was lamented in more than one study (Almatar, Peterson, Thompson *et al.* 2016; Evans-Lacko *et al.* 2010; Jabbour *et al.* 2018; Khalifa & Alswailem 2015; Reilly, Newton & Dowling 2007).

The educational aspect of PHC guidelines in regards to the training of practitioners was also mentioned as a possible *facilitator* to guideline uptake: it was suggested that new guidelines must be easily available and that PHC practitioners should be made aware of its existence (Jabbour *et al.* 2018; Taba, Rosenthal, Habicht *et al.* 2012). Furthermore, multiple comments were made regarding the need for – and potential positive effect of – training of PHC practitioners in the usage of any new guideline (Evans-Lacko *et al.* 2010; Jabbour *et al.* 2018; Rankin *et al.* 2015; Reilly *et al.* 2007; Taba *et al.* 2012).

An educational aspect of guidelines that is more targeted at patients, is the suggestion that information leaflets be linked to guidelines: these leaflets can then be handed out to patients, as it assists in empowering patients with knowledge (Carlsen *et al.* 2007; Donald, McBrien, Jackson *et al.* 2016).

The need for simplification

A *barrier* that was frequently identified during the literature review, is that of the complexity of certain guidelines, with some guidelines even requiring complex calculation scores to be performed (Almatar *et al.* 2016). This is juxtaposed to a subset of PHC practitioners complaining that certain guidelines are too simple or not complex enough (Almatar *et al.* 2016; Lugtenberg *et al.* 2009; Palmer, Brown, Evans *et al.* 2018; Taba *et al.* 2012; Vander Schaaf *et al.* 2015).

Confusing guidelines, with recommendations that are unclear or difficult to understand, or

even different professional groups that recommend dissimilar treatment in the same patient (Evans-Lacko *et al.* 2010; Khunti *et al.* 2019; Lugtenberg *et al.* 2009; Swennen, Rutten, Kalkman *et al.* 2013), is a natural barrier to guideline adherence.

Some guidelines lead to extra work and thus increased complexity of a PHC practitioner's task. This is especially true if another set of forms has to be filled in or marked off, or if adherence to the guideline cannot be integrated practically into workflow (Almatar *et al.* 2016; Evans-Lacko *et al.* 2010; Reilly *et al.* 2007; Steyn *et al.* 2013). Formats that are not user-friendly (Austad *et al.* 2015) or those that are overwhelming (Khalifa & Alswailem 2015) are often seen as too complex to adhere to in the PHC setting.

In regards to *facilitators* linked to simplification factors, conciseness and clarity of guidelines and its language are highly praised (Abdelhamid *et al.* 2014; Almatar *et al.* 2016; Basedow *et al.* 2015; Carlsen *et al.* 2007; Evans-Lacko *et al.* 2010; Mazrou 2013; Vander Schaaf *et al.* 2015). A user-friendly format (Jabbour *et al.* 2018; Mazrou 2013) and practical usefulness to the local context (Evans-Lacko *et al.* 2010; Grimsmo *et al.* 2018; Harrison *et al.* 2010; Hashmi & Khan 2016; Reilly *et al.* 2007; Solà *et al.* 2014) were found to improve efficiency and efficacy (Rankin *et al.* 2015).

A new guideline that causes minimal duplication (Jabbour *et al.* 2018), while still leaving practitioners enough space to write their own notes and findings (Steyn *et al.* 2013), was found to be commendable, as this simplifies the work of PHC practitioners.

When guideline conclusions are clear and specific, with no grey areas or unintended loop holes (Swennen *et al.* 2013), PHC practitioners find it easier to apply guideline recommendations. Simplicity is also improved when there is clarity regarding which levels of personnel are responsible for which parts of the guideline (Sather, Svindseth, Crawford *et al.* 2018), as this factor minimises confusion.

Trust issues

Trust in a guideline encompasses both trust in its content, and trust in the compilers of the guideline. Some users of guidelines did not adhere to its recommendations, simply because they did not agree with the content of the guideline for various reasons (Hashmi & Khan 2016; Khalifa & Alswailem 2015; Lugtenberg *et al.* 2009; Taba *et al.* 2012; Zwolsman *et al.* 2012). Trust also becomes an issue when evidence is not supplied, or when evidence *is* supplied but not perceived by users to be relevant or applicable to the patient population

(Abdelhamid *et al.* 2014; Austad *et al.* 2015; Harrison *et al.* 2010; Hashmi & Khan 2016; Taba *et al.* 2012; Zwolsman *et al.* 2012). Evidence that is not up to date is also cited as a concern (Lugtenberg *et al.* 2009; Zwolsman *et al.* 2012) influencing adherence.

Trust in a guideline is facilitated by having a guideline that shows consistency with other available guidelines (Almatar *et al.* 2016) and also within itself, *i.e.* not giving contradictory advice within the same guideline (Donald *et al.* 2016). The imperative is that the guideline's quality must be high and its recommendations based on the best available evidence (Jabbour *et al.* 2018; Rankin *et al.* 2015; Vander Schaaf *et al.* 2015). End-users expressed a desire for more trustworthy guidelines, meaning that cited evidence in PHC guidelines should be specifically aimed at and sourced from studies done in the PHC settings (Abdelhamid *et al.* 2014). Evidence should also always be easily available (Mazrou 2013). Trust in a guideline is lastly enhanced if conclusions are unambiguous, with no grey areas of unclarity (Swennen *et al.* 2013), which is also linked to *simplification* issues.

4.4.3 Discussion of results of literature review

Now that the specific findings of the literature review have been presented, a further discussion of general comments is in order. The specific comments made by end-users of guidelines, as shown in the literature review (cf. Appendix K), provide valuable insight into the practical issues that end-users of guidelines can experience in PHC facilities.

As mentioned in Chapter 2, issues of multi-morbidity are of great concern in the PHC setting. The literature review re-iterated the need to make a special effort to integrate the guideline with a multi-disciplinary approach to each patient (Grimsmo *et al.* 2018).

Of special note for this research project, are the many mentions found in the reviewed literature of the educational responsibility and possibilities of a guideline: Donald *et al.* (2016) noted how a guideline can increase the PHC practitioners' confidence and knowledge in regards to their patients' management, and this sentiment was echoed by Elwyn, Rasmussen, Kinsey *et al.* (2018). The educational aspect of implementing a new guideline – usually by way of outreach efforts – is imperative, as it not only increases the competence of PHC practitioners, but also improves the uptake of the guideline (Kenefick *et al.* 2008; Rankin *et al.* 2015; Taba *et al.* 2012). Time should thus be allocated to staff members to participate in such training and outreach exercises (Khalifa & Alswailem 2015; Vander Schaaf *et al.* 2015).

Vander Schaaf *et al.* (2015) also suggests that a guideline should have a built-in method of improving quality. One way of ensuring enduring quality, is to have specific, scheduled reviews of the guideline (Mazrou 2013), and another may be to specify which clinical outcomes can be used to evaluate quality of care (Khalifa & Alswailem 2015).

Finally, during the literature study, a recurrent finding was also the emphasis that is put on the management and financial policies that should enable and support uptake of a guideline (Elwyn *et al.* 2018; Jabbour *et al.* 2018; Khalifa & Alswailem 2015; Zwolsman *et al.* 2012). The involvement of local stakeholders is mentioned in some studies (Carlsen *et al.* 2007; Palmer *et al.* 2018). However, as the management policies of the national and provincial departments of health were not the focus of this study, these stakeholder factors were not incorporated into the themes of the findings.

These findings regarding the qualities and characteristics of a feasible PHC guideline were, as far as possible, consciously incorporated into the new guideline during the planning and development process thereof.

4.5 PHASE IV: THE NEW FEASIBLE DIABETES MANAGEMENT GUIDELINE

The concluding phase of this research study consisted of the synthesis of the data generated in the first three phases of the study into a feasible guideline for the management of DM in PHC settings in the Free State. The methodology was discussed in Chapter 3 (cf. Section 3.2.4), and the findings, namely the product of the synthesis of all the collected data, will now be presented. The newly designed feasible DM management guideline consists of two sections, namely 1) how to manage a patient with DM at a follow-up visit, and 2) how to diagnose a patient with DM and/or manage the acutely ill patient who has DM; these two aspects will be presented separately.

4.5.1 The "Diabetes Follow-up" section of the new management guideline

The *Diabetes Follow-up* guideline that was synthesised and developed with the help of a qualified graphic designer, is attached as Appendix L. The final version, which is earmarked to be dispersed to the PHC setting during an implementation study, is an A1 paper size.

This proposed new guideline gives information on measures to evaluate and improve glucose control, but also on:

- Some common co-morbid conditions that can be associated with DM, *e.g.* HIV, hypertension, dyslipidaemia, peripheral vascular disease, and cardiovascular disease;
- Side-effects and alternatives to the common medications available to patients with DM in the Free State PHC setting;
- Which special investigations to do under which circumstances and how to interpret the results of the special investigations;
- A feasible flow to a consultation with a patient with DM;
- Preventative medicine, in the form of a vaccine schedule, patient appropriate cancer screening, as well as pregnancy and contraception planning; and
- Specific weight loss and exercise goals.

The information added to the guideline is presented in a mostly non-prescriptive way, in order to give the PHC practitioner multiple options when dealing with a complex case. By reminding the practitioner at the beginning of the consultation and once again at the end of the consultation to devote attention to the main complaint of the patient, the focus is kept on the patient-centeredness of the consultation, and not only on the management of the disease entity.

The guidance that is offered is referenced briefly in each text block, with the full reference available on the back of the poster. The details of the researcher, as well as the date on which the guideline should be reviewed, is also on the back of the poster. A list of abbreviations was made available on the front of the guideline for ease of use.

The guidance that was chosen by the researcher was adapted from the SEMDSA guidelines, to reflect the South African perspective of this research study. Where the guidance from the SEMDSA guidelines were not clear or lacked nuance - for example, in the case of the variation in HbA1C targets for different population groups - other sources were selected. Medication doses, side-effects and complications were presented in the new guidelines as obtained and discussed in the source documents, *e.g.* SEMDSA or the ADA guidelines, but was also verified through the South African Medicines Formulary (SAMF 2020).

Certain elements, such as the correct treatment for dyslipidaemia and the latest recommended vaccination schedule for adults, were sourced directly from the associations who publish the relevant guidelines, namely the Lipid and Atherosclerosis Society of South Africa (LASSA) (Klug *et al.* 2018) and the Centre for Disease Control's advisory committee on immunisation practices (Matanock, Lee, Gierke *et al.* 2019).

Colour-codes were used to represent the available medications and the different level of primary healthcare workers that can prescribe them. The colour coding (i.e. the range of colours used for coding) was done as described in the latest APC guidelines (RSA DOH 2019), with which the PHC practitioners in the public sector are already familiar. The colour coding consists of medication names printed in the following colours:

- Orange: can be prescribed by a professional nurse
- Purple: must be initiated by a doctor, but can then be re-prescribed by a professional nurse
- Blue: must be prescribed by a doctor.

Where some confusion may exist in the prescription of certain drugs; for instance, where the prescription of fast-acting insulin is allowed by a professional nurse in an emergency setting, but has to be prescribed by a doctor when it is used as part of a chronic treatment regimen, the guideline proposed a solution to the problem. In the table on the poster where medication is described, both the orange *and* the blue colour coding is used to describe the settings in which it can be prescribed.

A problematic area during the development of this new guideline was the recommendation concerning the eye evaluations of patients with DM. The international trends have been to move away from requiring the PHC setting practitioners to do a formal funduscopy and evaluate the findings themselves: all three guidelines evaluated during this research recommended that a formal eye picture should be done, which then should be evaluated by an expert (ADA 2019, IDF 2017; SEMDSA 2017). In large parts of South Africa, the Free State included, PHC services in regards to basic eye care is poor, with very little training in diagnosing eye conditions (Lilian, Railton, Schaftenaar *et al.* 2018) and very low referral rates for DM-related eye conditions (Cairncross *et al.* 2019). To continue to require PHC practitioners in the public sector to do an evaluation for which they are clearly not qualified, seems counter-productive. The solution to the problem is not yet evident, and large-scale support to this element of DM care is still needed.

4.5.2 The “Newly diagnosed diabetes and/or acutely ill patient with diabetes” section of the new management guideline

The section of the proposed new guideline to manage patients who are newly diagnosed with DM, or those patients with DM who are acutely ill, is attached as Appendix M. The guideline layout was designed by the same graphic designer and used the same basic

principles of colour coding, referencing and abbreviations as the follow-up guideline. The poster was designed to be an A2 size, and the details of the researcher, date of review of the guideline, and full reference list were also placed on the back of the poster.

This section of the guideline deals with the screening processes for DM, namely who to screen, how to screen, and how to interpret screening results. This section also advises on how to initiate DM treatment and which patients to refer urgently. The acute management of an acutely ill patient with DM, irrespective of whether the patient has a low or a high blood glucose, is also discussed briefly. The addition of the management of hypoglycaemia was adapted from the latest version of the APC (RSA DOH 2019).

A major addition to the guideline is the use of the OGTT to diagnose DM in cases where the diagnosis may not be clear. The diagnostic criteria, as well as the methods to do an OGTT, was sourced mostly from the SEMDSA guidelines (SEMDSA 2017).

A full protocol for the management of a Diabetic Keto-acidosis (DKA) was not included in the guideline; only the initial fluid and initial insulin management, as this is appropriate for the PHC setting. Once a patient arrives in a primary or secondary level hospital, established in-hospital protocols for the management of DKA exists and should be followed.

Of special note in this guideline, is the addition of guidance in regards to:

- Considerations of other causes that can mimic the signs and symptoms of DM;
- Clarity regarding the screening procedures for DM;
- Addition of the entities of Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT);
- Evaluation of causes for hypoglycaemia in patients who are known with DM; and
- The information regarding Metformin's doses, contra-indications, and side-effects are added to this guideline, to prevent practitioners from having to look for the information on the other guideline.

Due to the nature of acutely ill patients who have DM, as well as due to the nature of screening principles for patients with potential DM, this guideline is slightly more prescriptive: fewer choices are offered, and certain absolutes are given, e.g. the need for urgent referral to specialist services of all patients who are pregnant *and* has DM.

Regarding medication, Metformin is the only drug discussed in this aspect of the guideline,

due to Metformin being the drug of choice in the initiation of treatment in patients with Type 2 DM (SEMDSA 2017). Other medication is usually added during follow-up visits, and is therefore only discussed during the follow-up part of the guideline.

4.5.3 Discussion

While Kredo, Bernhardsson, Machingaidze and colleagues (2016) concede that a standard approach to guideline activity, *e.g.* guideline development, does not exist, some researchers have tried to address this issue. Machingaidze *et al.* (2018) suggest approaching guideline development in three tiers: in brief, the first tier consists of the evidence layer, the second tier of the assessment of the proposed guideline in terms of local feasibility, and the third tier of the guidance document itself. The documentation of the first two tiers needs to be comprehensive to enhance the credibility of the final guideline, irrespective of the format of the final guideline (Machingaidze *et al.* 2018). If this model is followed, the authors argue that the chances of developing a high-quality guideline, relevant to local South African conditions, becomes higher (Machingaidze *et al.* 2018). The first two layers of this three-tiered model are thus encompassed in this comprehensive study, and thus furthermore underpin the feasibility of the final product; namely, the proposed new guideline for the management of patients with DM in the Free State PHC setting.

During the development of the new guideline, the first three phases of the study yielded the information needed to make this new guideline a valuable one. Phase I (*cf.* Section 4.2) presented the minimum standards of care for patients with DM, while highlighting the glaring deficiencies in the *APC 2016/2017* guideline's DM management section (RSA DOH 2016). Phase II (*cf.* Section 4.3) showed that end-users of DM management guidelines in the PHC setting in the Free State agree that the *APC 2016/2017* is not adequate as a DM management guideline, neither in methodological quality nor in applicability to their work-setting, and showcased the methodological deficiencies of the *APC 2016/2017*. Phase III (*cf.* Section 4.4) produced the intrinsic feasibility factors prized by end-users of PHC setting guidelines that can enhance the uptake of a new guideline. The data thus gathered were then synthesised into the new guidelines (*cf.* Appendices L & M)

From Phase I, the following gaps in the *APC 2016/2017* are purposefully addressed in the new guideline:

- A more varied and personalised HbA1C target is espoused;
- Ways to adjust glucose targets according to the personalised HbA1C targets are

discussed;

- Specific exercise targets to assist with weight loss are mentioned;
- Medication descriptions, namely side-effects and contra-indications, are described more thoroughly;
- The presence of HIV in a patient with DM, and the drugs that can have a negative metabolic effect on patients with DM, are explored briefly;
- Important health promoters are discussed, e.g. vaccination and cancer screening, in addition to depression screening; and
- An OGTT section is included in the diagnostic processes, with instructions on how to do it in a PHC setting,

From Phase II, the following methodological and applicability problems were specifically targeted during the development of the new guideline:

- References of guidance are available;
- The credentials of the person who developed the guideline are stated on the guideline;
- A date to review and/or renew the guideline is clear;
- An attempt is made to involve a multi-disciplinary team in the management of patients with DM;
- An attempt is made to integrate the management of patients with DM who may have multi-morbid conditions;
- The guideline was designed to be easy to navigate and read; and
- To decrease to-and-fro paging, the guideline is in the format of a single-glance poster.

From Phase III, the following elements were mindfully included and/or excluded in this guideline, with some overlap from the findings in Phase II:

- The recommended medications available in the Free State;
- Unambiguous recommendations were made as far as possible, with the content made clear and non-contradictory;
- The language is kept clear and simple;
- No difficult calculations are required, with the BMI calculation being the only one needed;
- No extra paperwork is required of PHC practitioners using this guideline, for they can still use their normal note-making processes;
- Multi-morbidity as pertaining to patients with DM is addressed in the same guideline, by adding management options for hypertension, dyslipidaemia, geriatric patients,

thyroid testing, Vitamin B12 testing, and the presence of HIV, as well as other issues like depression screening and family planning;

- Evidence for guidance is supplied in the form of references, although the references section was placed on the back of the poster as to not interfere with the visual impact and flow of the guideline. The evidence supplied is from the most recent, available versions of highly acclaimed guidelines, as applicable to the PHC setting;
- Confusion between different guideline recommendations is purposefully minimised, with as little as possible grey areas and loopholes in recommendations;
- Options, choices and alternatives for different patients are given, in an attempt to minimise rigidity in recommendations;
- Colour coding is incorporated to clarify which drugs or interventions can be done by which level of PHC practitioner, and aligned with the colour coding already known to practitioners in the PHC setting in the Free State.
- An educational programme to pilot the guideline in the PHC setting in the Free State is planned as a separate research project.

For quality improvement purposes, a recommendation is made on the poster that the content of the guideline should be reviewed every 5 years, starting from 2026. The purpose of this review will be to evaluate whether any new drugs or technology has been made available to the PHC setting of the Free State, which should then be incorporated into the guideline.

The I.C.PAT checklist (Whittle *et al.* 2004) was completed as an additional way of quality control after completion of the guideline (cf. Appendix N).

4.6 THE INFLUENCE OF THE LATEST *ADULT PRIMARY CARE* GUIDELINE ON THIS RESEARCH STUDY

As mentioned in Chapter 1, the latest version of the *Adult Primary Care*, namely the 2019/2020 version, was made available in early 2020, after the data gathering for this study was already completed. The *Adult Primary Care 2019/2020*, which will now also be referred to as *APC 2019/2020*, is now stylised as a “clinical tool” (RSA DOH 2019), instead of a “guide” or an “integrated clinical management tool” (RSA DOH 2016).

Changes were made to the 2019 version of the *APC* when compared to the *APC 2016/2017*. The changes made specifically to the *APC 2016/2017* guideline’s DM management section are applicable to this study, and need to be discussed briefly. The three relevant pages of

the *APC 2019/2020*, namely pages 13, 112 and 113 (RSA DOH 2019) are attached as Appendix O.

A few of the systemic changes made to the *APC 2019/2020*, include that the colour coding of medication changed to three colours instead of two colours: purple was added for medication that must be initiated by doctors, but can then be continued by nurses according to their scope of practice. Another change was that the page dealing with the management of an acutely ill patient with DM is placed far from the follow-up pages: the three pages dealing with DM thus do not all follow each other consecutively. A new aspect on the same page dealing with the acutely ill patient with DM is the dedicated section detailing the management of hypoglycaemia.

The researcher reviewed the *APC 2019/2020* with the view of seeing how the content of the guideline differed from the *APC 2016/2017*. When the same guiding questions were asked as in Table 4.1, it was found that of the 41 questions, 23 still had the same answers as in the *APC 2016/2017*. In the case of three questions, the answers given had more substance than in the past, but were still not of the same standard as the guidance given by the ADA (2019) or SEMDSA (2017): these questions were the ones concerned with metformin and sulphonylurea side-effects and complications.

In six questions, the answers given by the *APC 2019/2020* were changed from the *APC 2016/2017*, but were still completely different from the other guidelines and not aligned with other guidelines. These questions had to do with HbA1C targets, fasting and 2-hour after meal glucose targets, frequency of testing blood glucose at home, and alternative treatment for patients with intolerance to ACE-inhibitors.

In the case of nine of the 41 questions, the *APC 2019/2020* improved their guidance substantially, to become much more in line with the guidance given by the ADA (2019) and/or SEMDSA (2017). These questions were those concerned with screening for DM, as well as with the special investigations needed to manage complications of DM and DM related conditions.

In a few cases, the guidance became more unclear and more confusing than in the past. Another visible change is that even more to-and-fro paging is required of users of the *APC 2019/2020*, with requirements to see other parts of the *APC 2019/2020* for more information, being abundant.

These changes reflect, on the whole, important improvements in the *APC 2019/2020* format. It is also the first time that the DM management section has seen any changes since the inception of the *PC101* (RSA DOH 2011) and its subsequent formats as the different editions of the *APC*. However, even though some of the problems of the *APC 2016/2017*, as exposed during this research study, were adjusted, most of the DM guidance section has not seen major improvement in its content, and important gaps still exist.

The researcher thus concluded that the need for the new proposed guideline, incorporating the findings of the different phases of the research study, was unchanged. The new guideline still consists of more, better integrated, and better aligned guidance in a simple, practical, more feasible format than both the *APC 2016/2017* and the *APC 2019/2020*. A comparison between the content of the *APC 2016/2017*, the *APC 2019/2020*, and the new proposed guideline, has been drawn up and attached as Appendix P. In this tabulated format (cf. Appendix P), the reader can evaluate the changes and improvements made by the new, proposed guideline in relation to both the *APC 2016/2017* and the *APC 2019/2020*.

4.7 CONCLUSION

Through a rigorous process, the end-product of the research study was developed. This newly developed guideline for the management of patients with DM was not designed to be slavishly followed for the most part. Its purpose is rather to *assist* with guidance and decisions-making by offering referenced treatment options and alternatives, as well as by giving additional information that can influence decisions, thus improving the feasibility of the guideline. In this way, the goal of providing higher quality, patient-centred, holistic care to our patients with DM in the PHC setting, can become one step closer in the Free State.

This concludes the results and discussion section of this research study. The final chapter, detailing conclusions and recommendations, will now follow.

CHAPTER 5

RECOMMENDATIONS AND CONCLUSIONS

5.1 INTRODUCTION

As the end of this mini-dissertation draws near, a short summary of the findings of this study is in order. These findings will be followed by a discussion of the strengths and limitations of the study. Finally, recommendations will be made, based on the findings of this study.

5.2 SUMMARY OF KEY FINDINGS

This research study consists of four phases, which each produced separate but interlinked findings.

Phase I consisted of a thematic comparative analysis of the content of three frequently referenced DM management guidelines with that of the DM management guideline of the *APC 2016/2017* (RSA DOH 2016). The findings of this phase of the study are that the *APC 2016/2017* compares very poorly to the guidance given by the ADA (2019) and SEMDSA (2017), with only 19.5% alignment with their content (cf. Table 4.3). Even when compared to an international guideline that is aimed at the management of DM at the PHC level (IDF 2017), the *APC 2016/2017* only demonstrated 31.7% positive alignment (cf. Table 4.3). In 43.9% of the questions posed regarding the management of DM, the *APC 2016/2017* offered no guidance at all (cf. Table 4.3). These findings may address the research problem of the poor quality of treatment that patients with DM receive in South Africa, as reported by the IDF (IDF 2015), and offer a possible explanation for this problem.

Phase II of this research study illuminated the quality of the *APC 2016/2017* guideline's DM management section, based on the perspectives of end-users regarding its applicability, rigour and completeness. The assessors in this research study scored the *APC 2016/2017* as only 26.8% compliant with rigour and completeness according to the iCAHE instrument (Grimmer *et al.* 2014), and 56.3% towards applicability to PHC setting in the Free State according to the CPGAE-V1.0 scale (Li *et al.* 2018) (cf. Sections 4.3.1 & 4.3.2.3). It was thus made clear that the DM management section of the *APC 2016/2017* does not conform to the best practice standards of guideline development either, in addition to its content limitations.

Phase III of this study revealed, by way of the findings of a literature review, that certain inherent features of a guideline can increase compliance with it in the PHC setting. These features, as well as the findings of the elements that can act as barriers to adherence, were identified thematically (cf. Section 4.4.2.1). The four themes identified are *autonomy of PHC practitioners*, *educational issues*, *the need for simplification*, and *trust issues*. These issues were noted, and the practical suggestions made by end-users of PHC setting guidelines were, where possible, actively incorporated into the development process of the new, proposed guideline.

Phase IV of the study is the culmination of the previous three phases, and consists of the proposed, new guideline for the management of patients with DM in the PHC setting in the Free State. The guidelines are captured in the format of two posters: one for the chronic and follow-up management of a patient already known with DM (cf. Appendix L), and one for the diagnosis of DM as well as the management of an acutely ill patient with DM (cf. Appendix M). In this proposed, new guideline, the identified gaps in guidance in the *APC 2016/2017* were addressed, and all guidance was aligned with existing best practice standards. The problematic areas in regards to rigour of development and applicability to the PHC setting in the Free State were also addressed. Lastly, suggestions found in the literature review of ways to improve the feasibility of the guideline were incorporated.

5.3 VALUE AND CONTRIBUTION OF THE RESEARCH

The goal of this research study was to address the problem of poor DM management in the Free State by developing a more feasible DM management guideline that can be used to improve patient care as well as PHC practitioners' competency in regards to DM management (cf. Sections 1.3 & 1.5.1). The main contribution of this study is thus the improved care and overall health that can be offered to the population of the Free State, especially those patients with DM. The development of this management guideline, which attempts to integrate the management of multi-morbid conditions with DM management and attends to the treatment and diagnostic gaps that existed in previous guidelines, is also a valuable contribution to patient care.

An important further aspect of this research study is that one of the goals of the development of the new, feasible management guideline was that it was to be designed for use as a tool for workplace learning (cf. Section 1.5.3). In workplace learning, PHC practitioners learn by working, and this is addressed by the new management guideline in two ways:

- Training will occur in the use of this guideline, both initially and during follow-up sessions. Training will occur in PHC facilities, and will consist of sessions during which the aligned PowerPoint® presentation will be discussed with PHC practitioners. This uniform training approach will help to ensure that all PHC clinics in the Free State receive the same quality information and training, even though different trainers might be responsible for the outreach programme.
- After training sessions, PHC practitioners can use the new management guideline as a quick reference to aid in decision-making regarding their patients with DM. Even though a PHC practitioner might not remember everything that was discussed during a training session, the management guideline is designed in such a way that it is user-friendly, and the necessary information is available at a glance.

By using this new feasible management guideline during training sessions and then on a daily basis, PHC practitioners will thus be learning while working. It will be possible for them to improve their practical and theoretical knowledge of DM by bridging any existing gaps in their knowledge. PHC practitioners' approach to DM management, as well as their competency and confidence, will consequently improve, which will loop back to the improved integrated care that patients with DM in the Free State will receive.

It is envisioned that the end-product of the study, namely the proposed, new, feasible DM guideline (cf. Appendices L and M) will affect the management and learning aspects of DM in a lasting and meaningful way when piloted and implemented. Patients with DM will therefore be the main beneficiaries of this end-product.

Another area where the study will contribute is that more than one article will be published regarding the findings and results of this research study.

5.4 STRENGTHS AND LIMITATIONS OF THE RESEARCH STUDY

This study has various strengths and limitations to acknowledge. One of the strengths lay in the strong underpinnings of trustworthiness (*i.e.* credibility, dependability, confirmability & trustworthiness) in the methodology used in this study. Furthermore, the conscious attempt to integrate the management of DM in the guideline with co-existing multi-morbid conditions is a major strength and a feature that is seemingly not often found in guidelines, but is highly coveted. The researcher's intrinsic knowledge of the Free State and its available support systems and structures was also an asset to the study.

In regards to the limitations that may influence the developed management guideline negatively, some aspects need to be acknowledged. The bulk of the guideline was developed mostly by one person, as part of a Master's degree project. While input from supervisors is included, the usual processes of guideline development have contributions from a large team. Another possible limitation of the study is that the evaluation of the guidelines in Phase II of the study was done by primary care doctors only, which means that no professional nurses took part in this evaluation. Furthermore, the implementation of this new guideline has not yet been piloted or implemented; this will form part of a different study that is already planned.

Additionally, a limitation of this study is that the financial implications of this new guideline on the Free State DOH were not explored. However, the new guideline does not recommend any special investigations that are not already recommended in the *APC 2019/2020* (RSA DOH 2019), except for occasional thyroid testing or haemoglobin testing if clinically indicated. The financial strain of the new guideline is consequently similar to that of the *APC 2019/2020*, a guideline that is already supposed to be implemented at provincial level.

5.5 CONCLUSIONS AND RECOMMENDATIONS

The findings of this study made clear the imperative to develop an improved guideline for the management of patients with DM in the Free State PHC setting. In accordance with Steyn *et al.* (2013), the new guideline was developed with the needs and specific circumstances of the target audience in mind, and with recommended medication and investigations being feasible and aligned with the resources of the Free State PHC setting.

Grant and Chika-Ezerioha (2014) state that the achievement of improved levels of education is one of the aspects of an integrated care pathway or guideline that is not only a goal of the pathway, but an aspect that must be evaluated after implementation of the pathway. PHC nurses can improve their knowledge regarding chronic disease management by being trained with a management guideline like the *APC 2016/17*, with the proviso that continuous training is needed to re-enforce the gained knowledge; this re-enforcement is not only vital to the retention of memory, but also in training new staff members who may have joined a clinic due to a high turnover of personnel (Naidoo *et al.* 2014). Additionally, training in the use of the new guideline will assist PHC practitioners in understanding the limitations of not only the diagnostic tests, but of the guideline itself (Barth *et al.* 2016). It thus follows that, although a more practical management guideline can address some of

the factors mentioned as causes of poor management of patients with DM, the educational component of a management guideline is an essential element to improve the understanding of PHC practitioners, and consequently of the care that patients receive. Training sessions during the piloting of this new guideline will be of the utmost importance to improve the knowledge of PHC practitioners and enhance their trust in this new guideline.

The researcher agrees with Barth *et al.* (2016:1134) that new guidelines “can only be of value if they are introduced, implemented and audited to ensure that old practices are discontinued”. The introduction and implementation processes represent an important educational process, and this ongoing process of training is of paramount importance if the new guideline is to have any impact on DM care in the PHC setting of the Free State.

The researcher recommends that a vigorous training programme be designed and implemented across all districts of the Free State to implement this new guideline. However, approval, input, and support from the provincial DOH will be essential. No initiative to improve the care of patients with DM can occur in isolation, and a team approach with the DOH as a major stakeholder and partner is essential for success.

A further recommendation is that, once the new guideline is implemented, the adherence and effect of the implementation of the new guideline be audited. As a number of measurable outcomes have been built into the new guideline, such an audit should be possible, although the baseline care that patients have been receiving *before* this new guideline may be difficult to evaluate. Austad *et al.* (2015) further warn that as mismatches between guideline targets and patients’ needs often exist, future studies that evaluate the efficacy of this management guideline should be layered and sensitive to these incongruities to produce useable data.

This management guideline should also be re-evaluated after a maximum of 5 years to add or withdraw any new medications or technology that may become available or non-available in the PHC setting of the Free State. Medication prescription codes also change from time to time, *e.g.* medication that could previously only be prescribed by a specialist that later become available to clinic level doctors. These kinds of changes should also be reflected when the guideline is renewed.

5.6 FURTHER STUDIES

Certain areas of possible future study were illuminated during this research study. Firstly,

there exists a large deficiency of data regarding the current state of DM in the Province. Studies that can gather baseline data from which future projections can be done are crucial and should be done as a matter of urgency.

Studies that test the impact of the new, proposed guideline after piloting and/or implementation will be valuable to review the uptake, outcomes, and efficacy of the new guideline.

A study regarding the use of point of care HbA1C meters, which can be made available in the PHC setting, can have a major influence on the feasibility of DM management guidelines and the care of patients with DM in general. Such a study can review data regarding the impact on DM care as well as the financial implications of the use of this type of technology.

5.7 FINAL CONCLUSION

This research project shows that the development of a new guideline for the management of a chronic condition, aligned with international standards but also to the local conditions in a cash-strapped province, is possible. However, as Widyahening and colleagues (2016) state, it is not enough to produce and disseminate guidelines when the goal is to implement evidence into practice; PHC practitioners should be made aware of these guidelines, and should agree with its content.

The modernisation of DM care is very rapid, and technology development is fast paced. The Free State still lags behind in these modernisation and technology fields, but this should not be used as an excuse for not providing improved care to our patients. We should try to do the best we can, with what we have.

Only if new guidelines are embraced, PHC practitioners are continually educated in these guidelines, and the provincial department of health supports these endeavours, will real change be seen in the care of patients with DM in this Province. Improved care will always be worthwhile in the long run.

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APPENDICES

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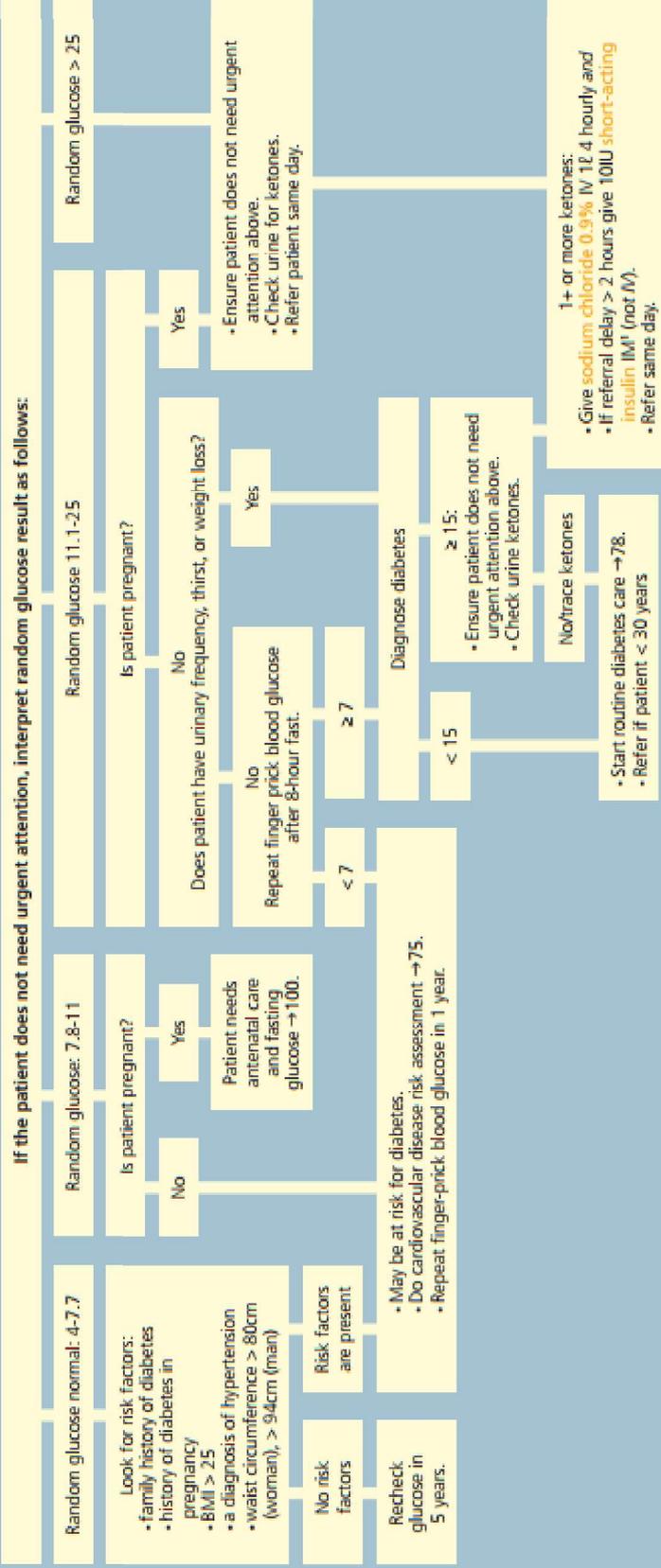
APPENDIX A Diabetes section of *Adult Primary Care 2016/2017* (pp. 77-79)

DIABETES: DIAGNOSIS

- Nausea and/or vomiting
 - Abdominal pain
 - Deep sighing breathing
- Recognise the patient with glucose ≥ 11.1 needing urgent attention:
- Temperature $\geq 38^{\circ}\text{C}$
 - Unconsciousness $\rightarrow 4$
 - Dehydration: systolic BP drop $> 20\text{mmHg}$ between lying and standing and poor urine output

Management:

- Rehydrate urgently: give sodium chloride 0.9% IV 1L in first hour then 1L over next 2 hours.
- Give 10IU short-acting insulin IM¹ (not IV).
- Refer urgently to hospital.



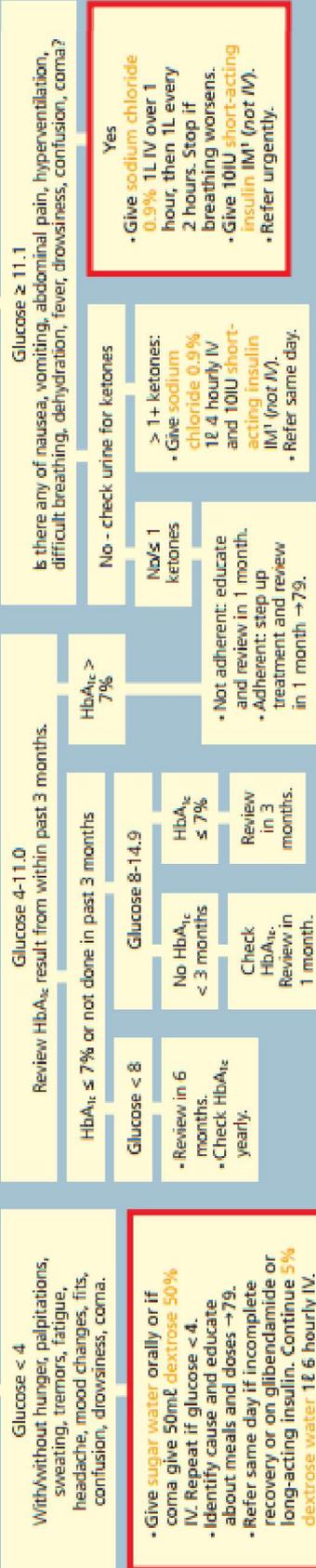
¹Do not give IV insulin without checking electrolytes, as it may cause low potassium and heart dysrhythmia.

DIABETES: ROUTINE CARE

Assess the patient with diabetes

Assess	When to assess	Note
Symptoms	Every visit	Manage symptom as on symptom page. Ask about chest pain \rightarrow 19 and leg pain \rightarrow 40.
Depression	Every visit	if yes to \geq 1 \rightarrow 88: 1) During the past month, have you been down, depressed or hopeless? 2) During the past month, have you had little interest/pleasure in things?
BP	Every visit	Diagnose hypertension if $>$ 140/80 on 2 days. Treat to target: 120/70-140/80 \rightarrow 81.
BMI	At diagnosis, yearly or 3 monthly if trying to lose weight	BMI is weight (kg)/height (m) x height (m). Aim for BMI $<$ 25.
Waist circumference	At diagnosis, yearly or 3 monthly if trying to lose weight	Aim for $<$ 80cm in woman and $<$ 94cm in man.
Pregnancy status	Every visit	Discuss family planning needs \rightarrow 98. Refer for specialist care if pregnant.
Eyes for retinopathy	At diagnosis, yearly and if visual problems develop	Refer if new diabetes diagnosis, visual problems, cataracts or retinopathy.
Feet	At diagnosis, 3 months, then yearly, more often if high risk	Check for pain, pulses, sensation, deformity, skin problems. For foot screen and foot care education \rightarrow 41.
Random glucose	Every visit	Finger prick sample is adequate. See below: aim for $<$ 8.
Protein on urine dipstick	At diagnosis and yearly	• if no protein on dipstick, send urine to lab for microalbuminuria. • if albuminuria or proteinuria: start enalapril 10mg daily regardless of BP. Doctor to increase to 20mg after 1 month.
Ketones on urine dipstick	If glucose \geq 15	if glucose \geq 15 and \geq 1+ ketones, see below.
HbA _{1c}	6 monthly if HbA _{1c} $<$ 7% but 3 months after treatment change	Aim for HbA _{1c} $<$ 7%. HbA _{1c} reflects glucose control over past 3 months. See below.
eGFR	At diagnosis and yearly	Give patient's age and sex on form. If eGFR $<$ 60, refer to doctor.
Fasting total cholesterol, triglycerides	At diagnosis if not already done.	Refer to specialist if total cholesterol \geq 7.5 or triglycerides \geq 15.

Check random finger prick glucose at every visit and HbA_{1c} 6 monthly if HbA_{1c} \leq 7% but 3 months after change in glucose-lowering treatment.



*Do not give IV insulin without checking electrolytes, as it may cause low potassium and heart dysrhythmia.

Advise the patient with diabetes

- Help the patient to manage his/her CVD risk ↗ 76.
- Advise patient to adhere to treatment even if asymptomatic and to eat regular meals. Arrange adherence support if needed (helpline ↗ 111, community care, support groups).
- Ensure patient can recognise and manage hypoglycaemia:
 - If palpitations, sweats, headache or tremors, drink milk with sugar or eat a sweet or sandwich. Always carry something sweet. If fits, confusion or coma, rub sugar inside mouth.
 - Identify and manage the cause: increased exercise, missed meals, inappropriate dosing of glucose-lowering drugs, alcohol, intercurrent illness like diarrhoea.
- Educate the patient to care for his/her feet to prevent ulcers and amputation ↗ 41.

Treat the patient with diabetes

- Give aspirin 150mg daily if CVD or a family history thereof, hypertension, smoking, dyslipidaemia, albuminuria or > 40 years. Avoid if < 30 years, previous peptic ulcer or dyspepsia or BP ≥ 180/110.
- Give simvastatin 10mg regardless of cholesterol if patient has CVD, hypertension, smoking, obesity, and/or > 40 years.
- Give enalapril 10mg up to 20mg daily if albuminuria/proteinuria, and first line for hypertension. Avoid in pregnancy, angioedema or renal artery stenosis.
- Give glucose-lowering drugs in a stepwise fashion. Ensure patient is adherent before increasing treatment:

Step	Drugs	Breakfast	Lunch	Supper	Bed	Note
1	Start metformin	500mg 500mg 850mg 850mg	500mg 850mg 850mg	850mg		<ul style="list-style-type: none"> • Avoid in pregnancy, kidney or liver disease, recent heart attack, heart failure, alcoholism. • Take with meals. • Increase every 2 weeks if random glucose > 8 and patient is adherent. • If after 3 months on maximum dose, HbA_{1c} > 7%, move to step 2. • Continue metformin.
2	Add sulphonylurea: • glibenclamide if < 65 years or • gliclazide if ≥ 65 years	2.5mg 5mg 5mg 5mg 7.5mg 7.5mg 40mg 80mg 80mg 80mg 120mg 120mg 160mg 160mg		2.5mg 5mg 5mg 7.5mg 40mg 80mg 80mg 120mg 120mg 160mg		<ul style="list-style-type: none"> • Take with meals. • Avoid in pregnancy, severe kidney and liver disease, co-trimoxazole allergy. • Increase every 2 weeks if random glucose > 8 and patient is adherent. • If after 3 months on maximum dose, HbA_{1c} > 7%, move to step 3.
3	Dr Add basal insulin (intermediate or long acting)				Start dose: 8IU. Increase by 2IU. Max dose: 20IU.	<ul style="list-style-type: none"> • Continue metformin and sulphonylurea. • Patient to check fasting glucose on waking once a week. If ≥ 7 and patient is adherent, increase dose by 2 units. • Educate about insulin: injection technique and sites (abdomen, thighs, arms recommended), store insulin in fridge or a cool dark place, meal frequency, recognition of hypoglycaemia and hyperglycaemia, sharps disposal at clinic. • If after 3 months on maximum dose, HbA_{1c} > 7%, move to step 4. • Continue with metformin.
4	Dr Substitute with biphasic insulin	10IU 14IU 14IU 18IU		10IU 10IU 14IU 14IU		<ul style="list-style-type: none"> • Stop sulphonylurea and bedtime basal insulin. • Patient to check fasting glucose on waking once a week. If ≥ 7 and patient is adherent, increase dose by 4 units. • Educate about insulin as in step 3 above. • Refer if HbA_{1c} > 7% and > 30 units per day are needed.

APPENDIX B Rubric in blank format

	ADA 2019	IDF Clinical practice recommendations for managing T2DM in primary care 2017	SEMDSA 2017	APC 2016/2017
I. Diagnosis and screening				
1. Which patient population is described as "at risk" thus needs diabetes screening?				
2. Is doing an OGTT advised in certain circumstances?				
3. Is method to do OGTT correctly discussed?				
4. What are the diagnostic values of the OGTT?				
5. How should pre-diabetes be managed?				
6. How should pre-diabetes/high risk individuals be followed up/reviewed?				
II. Targets of Glucose Control and lifestyle changes				
7. Which target HbA1C is advised?				
8. How often is repetition of an HbA1C advised for a patient on treatment?				
9. Are factors influencing the interpretation of HbA1C discussed?				
10. What is the target fasting blood glucose (if HbA1C target is <7%) for patients on treatment?				
11. What is target 2hr post-prandial / random blood glucose for a patient on treatment?				
12. Is special populations discussed in terms of control targets/special considerations?				
13. How frequently is testing of blood glucose at home advised?				
14. Is hypoglycaemia explored?				
III. Discussion of glucose lowering treatment				
15. Metformin: Is contra-indications and/or complications discussed?				
16. Sulphonylureas: Is contra-indications and/or complications discussed?				
IV. Discussion of the complications of DM				
17. Is micro-albumin testing advised?				
18. How frequently is micro-albumin testing advised?				
19. What steps/treatment are advised when micro-albuminuria is present?				
20. Is side-effects/complications/ contra-indications for use of an angiotensin converting enzyme inhibitor (ACE-I) discussed?				
21. Is an alternative option to ACE-I explained or offered?				

Key to Rubric:

Discussed, with extensive detail (++++)

Discussed, with moderate detail (++)

Discussed, with minimal detail (+)

Not answered/discussed at all (-)

	ADA 2019	IDF Clinical practice recommendations for managing T2DM in primary care 2017	SEMDSA 2017	APC 2016/2017
22. Foot exam: How often advised? What to look for?				
23. Eye exam: How often advised? By whom should it be performed?				
24. Screening for depression / mental health recommended?				
25. Is autonomic neuropathy discussed?				
V. Related special investigations				
26. How frequently is urea, electrolytes and creatinine (U&E+Kr) testing advised?				
27. Is K (potassium) testing advised, and how frequently?				
28. Is Vitamin B12 testing advised or discussed?				
29. How often is Lipid testing advised?				
30. Which element of the lipogram is targeted for treatment? (Total cholesterol /LDL/HDL/Triglycerides)				
31. Which cholesterol lowering treatment is advised?				
32. What is the advised lipid treatment target?				
33. Is HIV testing advised in DM patient or <i>vice versa</i> ?				
34. Is thyroid function testing ever advised? (under which circumstances?)				
VI. Miscellaneous topics				
35. What is the target Body Mass Index (BMI) for patients with DM?				
36. Is cancer screening discussed?				
37. Are vaccinations recommended?				
38. Is smoking discussed?				
39. Point of care testing of HbA1C discussed?				
40. Injection site inspection for lipohypertrophy discussed?				
41. What is the recommended route for insulin in an emergency?				

Key to Rubric:

Discussed, with extensive detail (+++)

Discussed, with moderate detail (++)

Discussed, with minimal detail (+)

Not answered/discussed at all (-)

**APPENDIX C The International Centre for Allied Health Evidence (iCAHE)
instrument**

iCAHE Guideline Quality Check List

Guideline:

Guideline producer:

Link:

Availability	Comments
Is the guideline readily available in full text?	(1)
Does the guideline provide a complete reference list?	(1)
Does the guideline provide a summary of its recommendations?	(1)
Dates	
Is there a date of completion available?	(1)
Does the guideline provide an anticipated review date	(1)
Does the guideline provide dates for when literature was included?	(1)
Underlying Evidence	
Does the guideline provide an outline of the strategy they used to find underlying evidence?	(1)
Does the guideline use a hierarchy to rank the quality of the underlying evidence?	(1)
Does the guideline appraise the quality of the evidence which underpins its recommendations?	(1)
Does the guideline link the hierarchy and quality of underlying evidence to each recommendation?	(1)
Guideline developers	
Are the developers of the guideline clearly stated?	(1)
Does the qualifications and expertise of the guideline developer(s) link with the purpose of the guideline and its end users?	(1)
Guideline purpose and users	
Are the purpose and target users of the guideline stated?	(1)
Ease of use	
Is the guideline readable and easy to navigate?	(1)
Score	TOTAL /14

**International Centre for
Allied Health Evidence**

International Centre for Allied Health Evidence (iCAHE)
City East Campus, North Tce, Adelaide
University of South Australia

APPENDIX D The Clinical practice guideline applicability evaluation (CPGAE-V1.0) scale

ID □ □ □ □ □

Clinical Practice Guidelines Applicability Evaluation Scale

Guideline name: _____
Institution: _____
Name: _____
Major: _____
Professional title: _____
Engaged in the professional time: _____
Date: _____

Domain 1: Technical level

1. Compared to the country health care level.

Very good

4	3	2	1
---	---	---	---

 Very poor

Comment

2. Compared to the local health care level.

Very good

4	3	2	1
---	---	---	---

 Very poor

Comment

3. Compared to the unit health care level.

Very good

4	3	2	1
---	---	---	---

 Very poor

Comment

4. Compared to other related clinical and diagnosis programs.

Very good

4	3	2	1
---	---	---	---

 Very poor

Comment

Domain 2: Coordination of support

5. Coordinate with the contents of the relevant standards or guidelines.

Very good	4	3	2	1	Very poor
-----------	---	---	---	---	-----------

Comment

6. Coordinate with multidisciplinary.

Very good	4	3	2	1	Very poor
-----------	---	---	---	---	-----------

Comment

Domain 3: Structure and content

7. The scope of application is clear.

Very good	4	3	2	1	Very poor
-----------	---	---	---	---	-----------

Comment

8. The diagnostic point is accurate.

Very good	4	3	2	1	Very poor
-----------	---	---	---	---	-----------

Comment

9. The physico-chemical examination is reasonable.

Very good	4	3	2	1	Very poor
-----------	---	---	---	---	-----------

Comment

10. The structure is complete and reasonable

Very good	4	3	2	1	Very poor
-----------	---	---	---	---	-----------

Comment

11. The content is complete and reasonable.

Very good	4	3	2	1	Very poor
-----------	---	---	---	---	-----------

Comment

12. The content is clear.

Very good	4	3	2	1	Very poor
-----------	---	---	---	---	-----------

Comment

13. Technical contents support each other.

4	3	2	1
---	---	---	---

Very good

Very poor

Comment

14. There is no contradiction between the contents.

4	3	2	1
---	---	---	---

Very good

Very poor

Comment

15. The extensibility of the guideline

4	3	2	1
---	---	---	---

Very good

Very poor

Comment

Domain 4: The role of the guideline

16. The convenience of clinical application.

4	3	2	1
---	---	---	---

Very good

Very poor

Comment

17. Rational use of medical resources.

4	3	2	1
---	---	---	---

Very good

Very poor

Comment

18. The role of regulating medical management and guaranteeing medical service quality.

4	3	2	1
---	---	---	---

Very good

Very poor

Comment

19. The role of improving medical technology level.

4	3	2	1
---	---	---	---

Very good

Very poor

Comment

Explanations

Item 1, item 2, item 3 and item 4. The technical level stipulated in the guideline should be suitable for the current mainstream or average level of research, service, technical and management of the country/local/unit/ related health care level in this field.

Item 5. The guideline should be coordinated with the contents of the relevant standards or guidelines.

Item 6. The guideline should be coordinated with multidisciplinary implementation.

Item 7. The guideline should clearly indicate the scope of application and the population(s) that is affected by the recommendation(s).

Item 8. The guideline should accurately describe the main diagnosis and diagnostic methods of the disease for a brief statement.

Item 9. The physical and chemical examination indicators involved in the guidelines should have effective and feasible detection methods.

Item 10 and item 11. The structure and content of the guideline should be complete and reasonable for the medical staff to use. The problems in the technical content can be divided into the following situations: ①The content is scientific and reasonable. ②The content needs minor changes or additions. ③The content has some problems. ④The content has serious problems (e.g., the guideline conflicts with laws, regulations or mandatory standard).

Item 12. The content of the guideline should be clear and easy to understand by most clinicians.

Item 13 and item 14. Technical contents of the guideline should be support and coordinate with each other, without any inconsistency.

Item 15. With the development of medical technology, some technical indicators of the guideline need to be revised. The extensibility of the guideline means that the guideline should have certain space for updating its content and structure in the future.

Item 16. Clinical diagnosis and treatment program of guideline should be feasible and convenient.

Item 17. The implementation of guideline should help to use rational medical resources.

Item 18. The implementation of guideline should further to regulate medical management and guarantee service quality.

Item 19. Technical contents of the guideline should help improve the current medical technology level.

APPENDIX E A Participant Consent Form and Information Leaflet

of the study, and four names were chosen randomly from the list given by the Department of Family Medicine to be invited to participate in the study.

WHAT IS THE NATURE OF PARTICIPATION IN THIS STUDY?

If you choose to participate in this study, it will be expected of you to evaluate the diabetes management section of the current APC 2016/2017 guideline (as used in PHC clinics). The evaluation will take the form of two tools to be applied to the APC 2016/2017 guideline. The first tool has 14 questions that can be answered by Yes/No answers. The second tool has 19 questions, and answers are graded with a score of 1 to 4, with space left for comments should you like to give any additional comment. These two tools are used to evaluate the content, the developmental rigour and the applicability of the APC 2016/2017 guideline's diabetes section. To complete the two tools in question should take no longer than 30 to 45 minutes of time.

CAN THE PARTICIPANT WITHDRAW FROM THE STUDY?

Your participation in this study is strictly voluntary and there will be no penalty or loss of benefit for non-participation. Because your participation in this study is voluntary, you are under no obligation to consent to participation. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a written consent form. You are free to withdraw at any time and without giving a reason.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THIS STUDY?

Your honest assessment of the current APC 2016/2017 will assist in the identification of areas that can be improved upon regarding the care of patients with diabetes in the primary care setting. While you as participant in the study may possibly not see the end-result of a more feasible guideline for diabetes management soon, the plan is to distribute the new guideline to the primary care in the Free State in the future, which will improve the knowledge of practitioners, and thus improve the care given to patients with diabetes. Your participation in the study will be kept confidential, with only the researcher and study leaders having access to your name and telephone number.

WHAT IS THE ANTICIPATED INCONVENIENCE OF TAKING PART IN THIS STUDY?

The only anticipated inconvenience to participating in this study, is to sacrifice 30 to 45 minutes of your time in assessing the diabetes section of the APC 2016/2017 guideline. The researcher will have the responsibility of delivering and collecting the completed tools from you at a place of your convenience.

WILL WHAT I SAY BE KEPT CONFIDENTIAL?

The answer sheets that you will fill in, will be marked with your initials. However, your personal details (full names or any other details) will not be recorded anywhere. You will not be referred to in any way in any data, publications, or other research reporting methods such as conference proceedings, except to be identified anonymously as Participant 1/2/3/4. The completed answer sheets will only be accessed by the researcher herself, but may be reviewed upon request by people responsible for making sure that research is done properly, including the study leaders, examiner of the Master's degree, or members of the Research Ethics Committee. Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

HOW WILL THE INFORMATION BE STORED AND ULTIMATELY DESTROYED?

Hard copies of your answers will be stored by the researcher for a period of five years in a locked filing cabinet in her home for future research or academic purposes; electronic information will be stored on

a password protected computer. Future use of the stored data will be subject to further Research Ethics Review and approval if applicable. After five years of storage, the completed answer sheets will be destroyed firstly by shredding, and then by incineration. No harm or discomfort is anticipated for you as participant during this research study. If you are per chance identified as a participant in this study, risk to you in your personal capacity should be minimal, as no personally sensitive or harmful information regarding your own person will be sourced during this research project.

WILL I RECEIVE PAYMENT OR ANY INCENTIVES FOR PARTICIPATING IN THIS STUDY?

You will not receive any payment or incentive for participating in this study, but you will also not incur any costs. The researcher has the responsibility to deliver and collect the answer sheets from you personally at a place of your convenience.

HOW WILL THE PARTICIPANT BE INFORMED OF THE FINDINGS / RESULTS OF THE STUDY?

If you would like to be informed of the final research findings, please contact Dr MM Rossouw on 084 404 1200 or at rossouwmm@universitas.fs.gov.za. The findings will be accessible from April 2020. Should you require any further information or want to contact the researcher about any aspect of this study, please contact Dr MM Rossouw on 084 404 1200 or at rossouwmm@universitas.fs.gov.za. Should you have concerns about the way in which the research has been conducted, you may contact Dr A Adefuye at 073 943 5848 or at AdefuyeAO@ufs.ac.za.

Thank you for taking time to read this information sheet and for participating in this study.

CONSENT TO PARTICIPATE IN THIS STUDY

I, _____ (participant name), confirm that the person asking my consent to take part in this research has told me about the nature, procedure, potential benefits and anticipated inconvenience of participation.

I have read (or had explained to me) and understood the study as explained in the information sheet. I have had sufficient opportunity to ask questions and am prepared to participate in the study. I understand that my participation is voluntary and that I am free to withdraw at any time without penalty (if applicable). I am aware that the findings of this study will be anonymously processed into a research report, journal publications and/or conference proceedings.

I agree to participate in the evaluation of the diabetes section of the *APC 2016/2017* guideline by way of the two tools supplied.

I have received a signed copy of the informed consent agreement.

Full Name of Participant: _____

Signature of Participant: _____ Date: _____

Full Name(s) of Researcher(s): _____

Signature of Researcher: _____ Date: _____

APPENDIX F The American Diabetes Association's "Decision cycle for patient-centered glycemic management in type 2 diabetes"

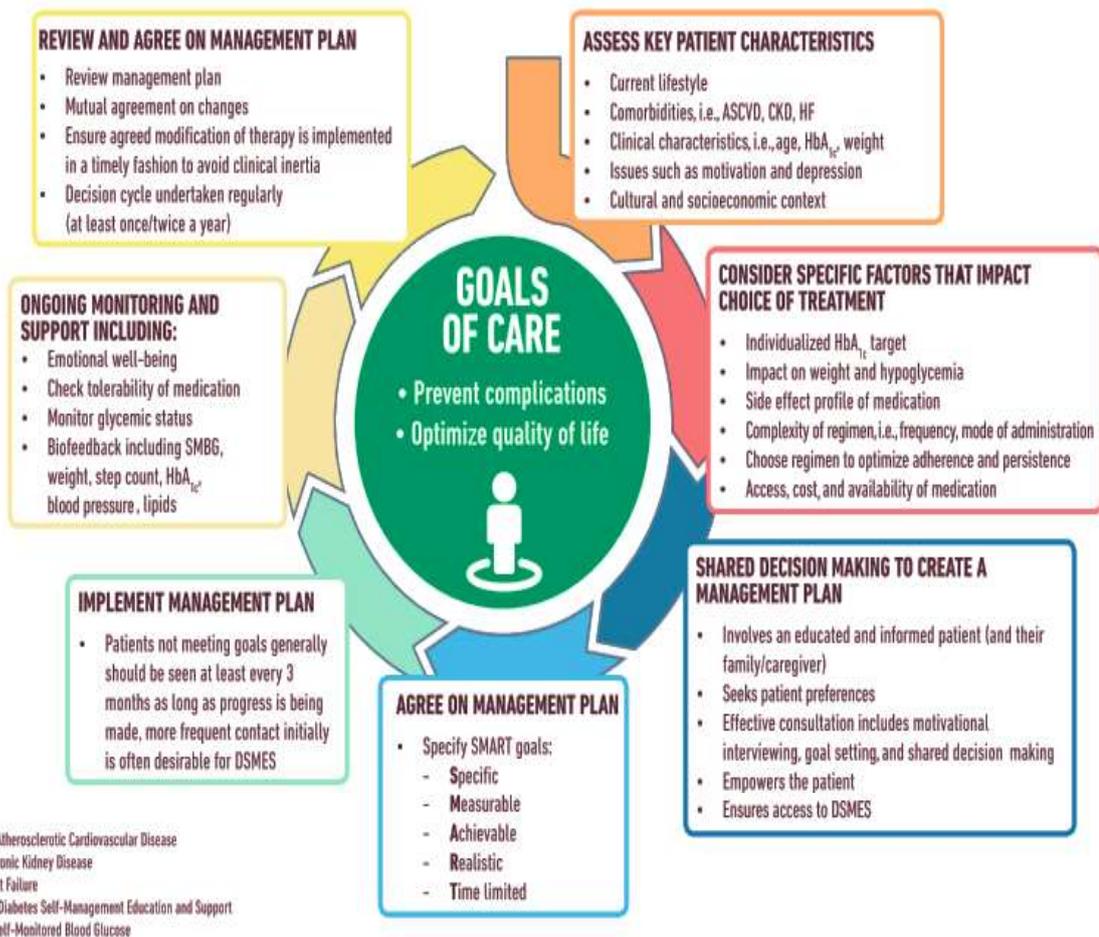


Figure 4.1—Decision cycle for patient-centered glycemic management in type 2 diabetes. Adapted from Davies et al. (119).

APPENDIX G The Integrated Care Pathways Appraisal Tool (I.C.PAT)

Integrated Clinical Pathway Checklist*

I. Content / Structure of ICP

- Have identified start and finish points
- Reflect a patient's journey (i.e. moving along a continuum of days/weeks/months/stages/objectives/programs)
- Reflect 24-hour continuous care/treatment (where appropriate)
- Form the record of care for an individual patient
- Allow documentation to be individualized to meet the patient's needs
- Outline the anticipated process of care/treatment

II. ICP Documentation

- Identify the relevant patients in the title of the ICP (e.g., ICP for Laparoscopic Cholecystectomy)
- Indicate the circumstances when a patient should come off or should not be put on (exclusion criteria)
- Meet local/national minimum standards for documentation (e.g. institution standards if exist)
- Include a reminder that says professional judgment must be applied while taking into account the patient's wishes & needs (i.e., the ICP is not a tramline and can be varied)
- Reference the evidence on which the content is based
- Include the date of development of the document on the ICP
- Include space for the identification of the individual patient on each page

III. The Development Process

- Record decisions made concerning the content of the ICP
- Record description/list staff involved in the development of the ICP
- Conduct a literature search to gather the evidence base for the clinical content of the ICP
- Record the rationale for including and excluding pieces of evidence/guidelines
- Pilot test the ICP and audit the ICP documentation after the pilot
- Consider clinical risk as part of the content of the ICP
- Consider training, education, and competency of staff as part of the content of the ICP
- Involve patient and/or their family members in the development of the ICP (by using focus groups/questionnaires/complaints/patient diaries, etc.)
- Take into account patients' and family members' multicultural needs

IV. The Implementation Process

- Establish an on-going training program for the staff
- Identify resources (individuals/time) to undertake the training on how to use the ICP
- Establish a system to feedback the variations of the ICP to the staff and patients/family members
- Agree on the location where the ICP documentation will be stored once finished
- Assess the risks involved in an ICP development before commencement
- Name an individual responsible for maintaining the ICP
- Provide training to staff when a change to the ICP content is made
- Provide regular training for new staff that will be using the ICP
- Set a review date of one year or less
- Get endorsement for the ICP development from the Trust Board/Clinical Governance Committee

Questions:

- Within the organization, is there a plan specifically for ICP development?
- Are ICPs evident in the organization's Clinical Governance Strategy?

*This checklist is adapted from *The Integrated Care Pathways Appraisal Tool (I.C.PAT)*¹, which provides a series of questions to ensure that the tool developed is an ICP, that the mechanism used to develop the ICP is robust, and that the ICP documentation meets at least the minimum legal requirements for clinical documentation. I.C.PAT uses the term "service user" where we have used the terms "patient" and "patient and/or family members."

¹Whittle C, McDonald PS, Dunn L, de Luc K. Developing the integrated care pathways appraisal tool (ICPAT): a pilot study. *J Integr Care Pathways* 2004; 8:77-81.

APPENDIX H University of the Free State Ethical approval



IRB nr 00006240
REC Reference nr 230408-011
IORG0005187
FWA00012784

05 September 2017

MARIA ROSSOUW
DEPT OF INTERNAL MEDICINE
FACULTY OF HEALTH SCIENCES
UFS

Dear Maria Rossouw,

HSREC 114/2017 (UFS-HSD2017/1172)

PRINCIPAL INVESTIGATOR: MARIA ROSSOUW

**PROJECT TITLE: A FEASIBLE DIABETES MANAGEMENT GUIDELINE FOR PRIMARY HEALTH CARE PRACTITIONERS
IN THE FREE STATE FOR WORKPLACE LEARNING**

APPROVED

1. You are hereby kindly informed that the Health Sciences Research Ethics Committee (HSREC) approved this protocol after all conditions were met. This decision will be ratified at the next meeting to be held on 26 September 2017.
2. The Committee must be informed of any serious adverse event and/or termination of the study.
3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.
4. A progress report should be submitted within one year of approval and annually for long term studies.
5. A final report should be submitted at the completion of the study.
6. Kindly use the **HSREC NR** as reference in correspondence to the HSREC Secretariat.
7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully

DR SM LE GRANGE
CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE



APPENDIX I Completed rubric

	ADA 2019	IDF Clinical practice recommendations for managing T2DM in primary care 2017	SEMDSA 2017	APC 2016/2017																																																												
I. Diagnosis and screening																																																																
1. Which patient population is described as "at risk" thus needs diabetes screening?	Obese (BMI >25) with First-degree relative with diabetes/ High-risk race/ethnicity / History of CVD/ Hypertension/ HDL cholesterol level < 0.90 mmol/L and/or a triglyceride level > 2.82 mmol/L /Women with polycystic ovary syndrome/Physical inactivity /Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans). Age ≥ 45 years. If any previous gest DM: screen every 3 years for life. (S18) (+++)	Age >40-45; Obese pts, increased waist circumference, hypertension, family history of DM. (If screen (+), do diagnostic test). (p9). (++)	All overweight adults with one other risk factor for DM: • Physical inactivity• Hypertension [Blood pressure (BP) ≥ 140/90 mmHg] or treatment for hypertension• First degree relative with diabetes• Dyslipidaemia• Polycystic ovarian syndrome• High-risk race/ethnicity (Asian Indian, Coloured)• Cardiovascular disease history• Gestational diabetes or baby > 4 kg• Previous IFG or IGT• Other conditions associated with insulin resistance (severe obesity, acanthosis nigricans). OR age >45 (S19). (+++)	Screening in asymptomatic pts not specifically mentioned. In section regarding symptomatic pts with normal random blood glucose: risk factors discussed: family history of DM, History of Gest DM, BMI >25, HT, Waist circumference of >94cm (men)/>80cm (women). "may be at risk, repeat random blood sugar after one year". (++)																																																												
2. Is doing an OGTT advised in certain circumstances?	Yes: to diagnose DM or pre-DM (S14) (++)	Yes, but not very clear WHEN. (+)	Yes: If pt asymptomatic but one screening test (+). Only way to diagnose IGT (S15); If HbA1C high but not diagnostic (S17); OGTT preferred test in high risk individual (S19). (+++)	No. (-)																																																												
3. Is method to do OGTT correctly discussed?	Yes. (S15) (+++)	Moderate detail. (p11) (++)	In detail. (S17) (+++)	N/A (-)																																																												
4. What are the diagnostic values of the OGTT?	<table border="0"> <tr> <td></td> <td>0hrs</td> <td>2hrs</td> <td>HbA1C</td> </tr> <tr> <td>Non-diabetic</td> <td>≤5.5</td> <td>and ≤7.7</td> <td>+ ≤5.6%</td> </tr> <tr> <td>IFG</td> <td>5.6-6.9</td> <td>and ≤7.7</td> <td>+ 5.7-6.4%</td> </tr> <tr> <td>IGT</td> <td>≤5.5</td> <td>and 7.8-11.0</td> <td>+"</td> </tr> <tr> <td>DM</td> <td>≥7.0</td> <td>OR ≥11.0</td> <td>OR ≥6.5%</td> </tr> </table> (S15; S18) (+++)		0hrs	2hrs	HbA1C	Non-diabetic	≤5.5	and ≤7.7	+ ≤5.6%	IFG	5.6-6.9	and ≤7.7	+ 5.7-6.4%	IGT	≤5.5	and 7.8-11.0	+"	DM	≥7.0	OR ≥11.0	OR ≥6.5%	<table border="0"> <tr> <td></td> <td>0hrs</td> <td>2hrs</td> <td>HbA1C</td> </tr> <tr> <td>Non-diabetic</td> <td>≤6.0</td> <td>and ≤7.7</td> <td></td> </tr> <tr> <td>IFG</td> <td>6.1-7.0</td> <td>and ≤7.7</td> <td></td> </tr> <tr> <td>IGT</td> <td>≤6.0</td> <td>and 7.8-11.0</td> <td></td> </tr> <tr> <td>DM</td> <td>≥7.0</td> <td>OR ≥11.0</td> <td>OR ≥6.5%</td> </tr> </table> (P11) (+++)		0hrs	2hrs	HbA1C	Non-diabetic	≤6.0	and ≤7.7		IFG	6.1-7.0	and ≤7.7		IGT	≤6.0	and 7.8-11.0		DM	≥7.0	OR ≥11.0	OR ≥6.5%	<table border="0"> <tr> <td></td> <td>0hrs</td> <td>2hrs</td> <td>HbA1C</td> </tr> <tr> <td>Non-diabetic</td> <td><5.6</td> <td>and <7.8</td> <td></td> </tr> <tr> <td>IFG</td> <td>6.0-6.9</td> <td>and <7.8</td> <td></td> </tr> <tr> <td>IGT</td> <td><5.6</td> <td>and 7.8-11.0</td> <td></td> </tr> <tr> <td>DM</td> <td>≥7.0</td> <td>OR ≥11.0</td> <td>OR ≥6.5%</td> </tr> </table> HbA1C of <6.5%: inconclusive (S16) (+++)		0hrs	2hrs	HbA1C	Non-diabetic	<5.6	and <7.8		IFG	6.0-6.9	and <7.8		IGT	<5.6	and 7.8-11.0		DM	≥7.0	OR ≥11.0	OR ≥6.5%	N/A (-)
	0hrs	2hrs	HbA1C																																																													
Non-diabetic	≤5.5	and ≤7.7	+ ≤5.6%																																																													
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Key to rubric:

Discussed, with extensive detail (+++)
Discussed, with moderate detail (++)

Discussed, with minimal detail (+)
Not answered/discussed at all (-)

	ADA 2019	IDF 2017	SEMDSA 2017	APC 2016/2017
5. How should pre-diabetes be managed?	Metformin if BMI >35/Age <60/Previous Gest DM. Lifestyle changes (Exercise 150mins per week - at least 3 x per week; weight loss 7-10% of initial bodyweight in first 6 months; decrease fat and caloric intake. (S31, S36) (+++)	Weight loss 5-7%; Exercise 150mins per week (intervals no longer than 48 hours); decrease caloric intake. (p10, p16) (++)	Aim >5% weight loss over 6 months. 150-250 minutes moderate intensity exercise per week to prevent weight gain; 4 hours exercise per week to lose weight. (S75) (++)	Not mentioned. (-)
6. How should pre-diabetes/high risk individuals be followed up/reviewed?	IFG or IGT: screen yearly for DM. If NEG OGTT in high risk pt: re-screen 3yearly. (S17). (+++)	If screen (+) but diagnostic test (-): implement lifestyle changes and repeat diagnostic test yearly. If screen (-) but risk factors (+): repeat screen 3 yearly. (p9) (+++)	If screen normal: repeat every 3 years, more frequently based on initial results and risk status (S19). (++)	If risk factors (-): re-screen in 5 years. If risk factors (+): repeat in one year. (+) Different from the others
II. Targets of Glucose Control and lifestyle changes				
7. Which target HbA1C is advised?	Individualise, re-assess periodically. Most non-pregnant patients: <7%; Selected patients for more stringent control: <6.5%; Multiple co-morbidities: <8% (S63); Elderly with multiple co-morbidities/cognitive impairment: <8-8.5%. (S140; S142) (+++)	General target: <7% (p12); <8%: Multiple medications, short predicted survival, cognitive impairment, CKD, severe CVD (p13) (++)	Chapter 8 (S34-38): Individualise. Newly diagnosed and healthy: <6.5%; Most pts: <7%; Elderly, frail, multiple co-morbidities, severe CVD, advanced CKD, severe hypo's, hypoglycaemic unawareness: 7.1-8.5%. (+++)	<7% (+)
8. How often is repetition of an HbA1C advised for a patient on treatment?	At diagnosis, at every follow-up visit, and yearly (S38) (+++)	Not specifically mentioned. (-)	Every 6 months if stable, 3 months after treatment intensified. (S21) (+++)	Every 6 months, 3 months after treatment changed. (+++)
9. Are factors influencing the interpretation of HbA1C discussed?	Yes, HIV also mentioned (S14-S15) (+++)	No (-)	Yes. (S142) (+++)	No. (-)

Key to rubric:

Discussed, with extensive detail (+++)
Discussed, with moderate detail (++)

Discussed, with minimal detail (+)
Not answered/discussed at all (-)

	ADA 2019	IDF 2017	SEMDSA 2017	APC 2016/2017
10. What is the target fasting blood glucose (if HbA1C target is <7%) for patients on treatment?	5.0 - 7.2 (S142) (+++)	<6.0 (p 13) (++)	4.0-7.0 (S36) (+++)	Not mentioned specifically. (+)
11. What is target 2hr post-prandial / random blood glucose for a patient on treatment?	For HbA1C of <7%: ≤10.0 (S142) (++)	For HbA1C of <7%: <10.0 (p13) (++)	For HbA1C <6.5%: <8; HbA1C <7%: <10; HbA1C <8: <12 (S36) (+++)	Unclear: Random 4-14.9, also <8. (+)
12. Is special populations discussed in terms of control targets/special considerations?	Yes (elderly, cognitive impairment, kidney disease, end-of-life care etc.) (S140; S142) (+++)	Yes: short survival life, advanced CKD, cognitive impairment, established CVD etc (P13) (++)	Yes, detailed. (S35-36) (+++)	No (-)
13. How frequently is testing of blood glucose at home advised?	Intensive insulin regimes: 6-10 x per day. Basal insulin: once a day (Fasting). Oral treatment only: not needed if controlling. (S73) (+++)	Glucose self-testing is "mandatory for patients using insulin" (p13); no recommendations made regarding frequency. (+)	Oral treatment: no testing at home needed except in individualised cases. Intensive insulin regimes (2-4 injections per day): test at least 3x per day. Once daily insulin: test once daily on waking. If HbA1C high with normal fasting glucose: check also after largest meal of day (thus twice per day). Test more frequently in acute illness/pregnancy etc. (S37) (+++)	If on insulin: check fasting glucose upon waking once a week. (+)
14. Is hypoglycaemia explored?	Yes, severity scale and risks for hypoglycaemia (S39; S66-68) (+++)	Superficially (p12; p16) (+)	Yes: Risk factors (S52). Whole Chapter 8 (S60-63). (+++)	"Educate on signs and symptoms of hypoglycemia, how to treat", "Identify and manage cause". Examples of symptoms, causes and treatment offered. (++)

Key to rubric:

Discussed, with extensive detail (+++)
Discussed, with moderate detail (++)

Discussed, with minimal detail (+)
Not answered/discussed at all (-)

	ADA 2019	IDF 2017	SEMDSA 2017	APC 2016/2017
III. Discussion of glucose lowering treatment				
15. Metformin: Is contra-indications and/or complications discussed?	Yes: eGFR <30: contra-indicated. (S93 + S96). Other s/e discussed. (+++)	CKD stage 3A: reduce dose; Stage 3B, 4 and 5: contra-indicated (p18; p21). Other s/e not mentioned. (++)	Yes (S39, S57). eGFR 30-45 ml/min: reduce dose. eGFR <30: contra-indicated. (++)	Contra-indicated in pregnancy, kidney/liver disease, recent heart attacks, heart failure, alcoholism. No complications discussed. (+)
16. Sulphonylureas: Is contra-indications and/or complications discussed?	Yes: DKD neutral, risk of hypoglycaemia, increased CVD deaths in studies on older Sulphonylureas; efficacy; effect on weight, cost (S93). (+++)	CKD stage 3A and 3B: caution, higher risk. CKD stage 4 + 5: contra-indicated (p21). Complications: Hypoglycaemia (p18). (+++)	S91: Stage 3 and 4 CKD: initiate low dose Glimepiride. Sulphonylurea allergy is NOT a contra-indication. Avoid in advanced liver disease. (+++)	Avoid in pregnancy, severe kidney and liver disease, co-trimoxazole allergy. No complications discussed. (+)
IV. Discussion of the complications of DM				
17. Is micro-albumin testing advised?	Yes, as spot protein-creatinine ration (S38) (+++)	Yes, but as albuminuria or albumin-creatinine ratio (p27). (+++)	Yes, as albumin/creatinine ratio (S21). (+++)	Yes (+++)
18. How frequently is micro-albumin testing advised?	Spot prot:creat ratio at diagnosis, then yearly (S38). (+++)	Yearly. (p27) (+++)	Albumin-creatinine ratio initially, then yearly. Urine dipstix for protein at every visit, then yearly. (S21) (+++)	At diagnosis, and yearly. (Send for micro-albumin if no protein on urine dipstix) (+++)
19. What steps/treatment are advised when micro-albuminuria is present?	Start ACE-inhibitor (ACE-I) OR ARB at maximum tolerated dose indicated for blood pressure treatment (S107). (++)	Treat persistent micro-albuminuria with ACE-I or ARB. (p27) (+)	Exclude other causes for raised albumin-creatinine ratio (S90), then ACE-I/ARB (S91). (+++)	For both micro-albuminuria AND frank proteinuria: start Enalapril 10mg dly and increase to 20mg dly after one month irrespective of BP. (+)

Key to rubric:

Discussed, with extensive detail (+++)
Discussed, with moderate detail (++)

Discussed, with minimal detail (+)
Not answered/discussed at all (-)

	ADA 2019	IDF 2017	SEMDSA 2017	APC 2016/2017
20. Is side-effects/complications/ contra-indications for use of an angiotensin converting enzyme inhibitor (ACE-I) discussed?	Yes. Monitor K at least annually (S 107) (++) Very little about contra-indications.	No (-)	Contra-indications: pregnancy (S109). Check K and Kr 2 weeks after initiation. (S92) (+++)	Avoid in pregnancy, angio-oedema and renal artery stenosis. <i>Complications not discussed.</i> (+)
21. Is an alternative option to ACE-I explained or offered?	If drug not tolerated, substitute with another class (S107). (++)	Yes. ACE-I OR ARB. (p27) (+++)	Yes, ACE-I OR ARB. (S91) (+++)	No (-)
22. Foot exam: How often advised? What to look for?	At diagnosis, annually for visual inspection, pulses and sensation (temp, vibration/pinprick, monofilament) (S38). At every visit if has decreased sensation or previous ulcers (S133). (+++)	Screen with monofilament. Inspect feet every visit if foot is at risk (p28). (+)	Initial, then annually: monofilament, vibration, ankle jerks and pulses. (S21) (+++)	At diagnosis, after 3 months, then yearly. More often if at risk. Look for pain, pulses, deformity. If skin problems: "go to page 41". (++)
23. Eye exam: How often advised? By whom should it be performed?	At diagnosis, then every 1-2 years if no disease. Yearly if retinopathy. By eye specialist. (S38, S129) (++)	Screen every 1-2 years, preferably with non-mydiatic retinal photography, interpreted by expert, OR direct ophthalmoscopy (dilated) by trained health professional (p27). (++)	Visual acuity: initial, then annual. Retinal exam: initial, then annual (preferably with dilated retinal photography, interpreted by properly certified examiner) (S93-S95). (++)	At diagnosis, then yearly, or if visual problems develop. "Refer if new diagnosis, visual problems or retinopathy". (+) (Completely different answer than other 3)
24. Screening for depression / mental health recommended?	Screen for anxiety, depression and disordered eating (S42-43). Screening tool not provided. (+++)	Yes (p26), screening tool given. (++)	Screen at initial visit, at 3-6 monthly visits and annually. (S21). Little detail, no tool. (++)	Yes, screen at every visit. If present "go to page 88". (++)
25. Is autonomic neuropathy discussed?	Yes (S131-S132). (+++)	Not specifically. (-)	Test at initial visit, then annual (S21). No specifics mentioned. (+)	No. (-)

Key to rubric:

Discussed, with extensive detail (+++)

Discussed, with minimal detail (+)

Discussed, with moderate detail (++)

Not answered/discussed at all (-)

	ADA 2019	IDF 2017	SEMDSA 2017	APC 2016/2017
V. Related special investigations				
26. How frequently is urea, electrolytes and creatinine (U&E+Kr) testing advised?	Kr and eGFR: at diagnosis, then yearly (S38) (+++)	Measure yearly if other risk factors present (eg HT) OR once albuminuria detected (p27) (+++)	Kr and eGFR: initial, then annually (S21). (+++)	eGFR: at diagnosis and yearly. (+)
27. Is K (potassium) testing advised, and how frequently?	If pt is on diuretics, ARBs or ACE-I: test at diagnosis and then yearly. (S38) (+++)	No (-)	Test at initial visit, then annual (S88) (+++)	No (-)
28. Is Vitamin B12 testing advised or discussed?	Yes (S31): "Consider monitoring", especially in presence of anaemia +/-peripheral neuropathy. (++)	Not mentioned. (-)	Not to test routine. Only if anaemia or peripheral neuropathy (S39). (+++)	No. (-)
29. How often is Lipid testing advised?	Test Total Cholesterol, LDL, Triglycerides and HDL: at diagnosis and yearly. S109: Test every 5 years until the age of 40, then yearly. (S38) (+++)	Not specifically mentioned, no need to retest even if high risk and at high intensity treatment: confusing. (p24) (+)	TC, LDL, HDL and Triglycerides: test at initial visit, three months after treatment started or changed, then annually when on target. (S78) (+++)	At diagnosis only. Total cholesterol and Triglycerides. (+)
30. Which element of the lipogram is targeted for treatment? (Total cholesterol/LDL/HDL/ Triglycerides)	(Triglycerides and LDL (S38) (+++)	Triglycerides and LDL (p24) (+++)	LDL and Triglycerides (S78) (+++)	Fasting Total Cholesterol and Triglycerides (+) Completely different answer than other three.
31. Which cholesterol lowering treatment is advised?	LDL: statins (response vs s/e, thus maximum dose in high risk patients (S104-110); Triglycerides: lifestyle and / fibrates (S112) (+++)	Statins: high intensity at maximum advised dose (advised atorva or rosuvastatin); Triglycerides: fibrates (p24) (++)	Statins: Simva, atorva or rosuva; Fibrates and diet for Triglycerides (S78-S81). (++)	Simvastatin 10mg dly, regardless of cholesterol if CVD, HT, smoking, obese or >40 years: (+) Completely different answer than other three.

Key to rubric:

Discussed, with extensive detail (+++)

Discussed, with minimal detail (+)

Discussed, with moderate detail (++)

Not answered/discussed at all (-)

	ADA 2019	IDF 2017	SEMDSA 2017	APC 2016/2017
32. What is the advised lipid treatment target?	Unclear. (S109-S110). Many details, aim for % reduction, stratified according to risk. (+++)	Primary prevention: \leq 2.5; Secondary prevention: \leq 1.8 (LDL) (p24). Answers not very clear. Triglycerides: treat if 5.7-11.4 (++)	LDL $<$ 1.8 (S80) (+++)	Not mentioned, not for re-testing once on 10mg Simva. (-)
33. Is HIV testing advised in DM patient or vice versa?	In patients with HIV: screen for DM with fasting glucose before initiation of ARVs, when changes treatment, and 3-6 months after treatment started or changed. Then screen for DM yearly if normal. (S41) (+++)	No (-)	Yes, test of HIV at initial DM visit. Whole chapter 25 (S115-118) about HIV in diabetes. (+++)	No. No mention in DM section of HIV testing, no mention in HIV section of DM screening. (-)
34. Is thyroid function testing ever advised? (under which circumstances?)	T1DM: screen with TSH (S38). Screen if dislipidemia present, especially high Triglycerides (S112). If peripheral neuropathy present (S131). If unexplained glycaemic variability (S152). (+++)	Not mentioned. (-)	When investigating the secondary causes for hyperlipidaemia (S81) (+)	Not mentioned. (-)
VI. Miscellaneous topics				
35. What is the target Body Mass Index (BMI) for patients with DM?	$<$ 25. Measure at each encounter (S17; S81). (+++)	Not specifically mentioned. (-)	Unclear target. Measure at each visit (S21). (+)	$<$ 25, measure at each visit. (+++)
36. Is cancer screening discussed?	Recommend age-appropriate cancer screening (S39). (++)	No (-)	No (-)	No (-)
37. Are vaccinations recommended?	Influenza, pneumococcal, Hep B, and PPSV23 (pneumococcal polysaccharide vaccine) (S36). (+++)	Not mentioned. (-)	Initial and annual: pneumococcal and influenza vaccine (S20). (++)	Not mentioned. (-)

Key to rubric:

Discussed, with extensive detail (+++)
Discussed, with moderate detail (++)

Discussed, with minimal detail (+)
Not answered/discussed at all (-)

	ADA 2019	IDF 2017	SEMDSA 2017	APC 2016/2017
38. Is smoking discussed?	Yes (S53). (++)	Yes (p16). (++)	Yes, discuss every visit (S20). (++)	No, only as part of CVD risk stratifying for statins. (-)
39. Point of care testing of HbA1C discussed?	"Provides opportunity of more timely treatment changes", provided that is used for monitoring and not diagnosis. (S15; S61) (++)	"A standardised HbA1C test should be available in every primary care clinic" (p11), but no clear if referencing a point of care test. (+)	Point of care testing of HbA1C OR glucose should not be used for diagnosis of DM, only for follow-up monitoring (S17). (++)	No (-)
40. Injection site inspection for lipohypertrophy discussed?	Yes (S91) (++)	No (-)	Yes (S21; S61). (++)	No (-)
41. What is the recommended route for insulin in an emergency?	IM should not be used as has variable absorption and effect. Only use IM if no other access. (S91) (++)	Not mentioned. (-)	Use IV or SC in emergency, only use IM if according to institution protocol. (S66) (++)	MUST inject IM during hyperglycemic emergencies "to prevent hypokalaemia". (+) Completely different answer than other two.

Key to rubric:

Discussed, with extensive detail (+++)
Discussed, with moderate detail (++)

Discussed, with minimal detail (+)
Not answered/discussed at all (-)

APPENDIX J **List of guiding questions not answered by the *Adult Primary Care*
2016/2017**

LIST OF QUESTIONS NOT ANSWERED BY THE ADULT PRIMARY CARE 2016/2017

Section I:

2. Is doing an oral glucose tolerance test (OGTT) advised in certain circumstances?
3. Is method of doing OGTT correctly discussed?
4. What are the diagnostic values of the OGTT?
5. How should pre-diabetes be managed?

Section II:

9. Are factors influencing the interpretation of HbA1C discussed?
12. Is special populations discussed in terms of control targets/special considerations?

Section III: Nil

Section IV:

21. Is an alternative option to ACE-I explained or offered?
25. Is autonomic neuropathy discussed?

Section V:

27. Is K (potassium) testing advised, and how frequently?
28. Is Vitamin B12 testing advised or discussed?
32. What is the advised lipid treatment target?
33. Is HIV testing advised in DM patients or vice versa?
34. Is thyroid function testing ever advised? (Under which circumstances?)

Section VI:

36. Is cancer screening discussed?
37. Are vaccinations recommended?
38. Is smoking discussed?
39. Point of care testing of HbA1C discussed?
40. Injection site inspection for lipohypertrophy discussed?

APPENDIX K Completed literature study

Author(s), year of publication.	Name of article/publication	Barriers identified	Facilitators/Enablers identified	Other related comments made
Abdelhamid <i>et al.</i> (2014)	Primary care evidence in clinical guidelines: a mixed methods study of practitioners' views	Large number of available guidelines; time constraints; evidence limited in applicability to patients	The evidence provided with the guideline should be clearly relevant to the primary setting to make usage of guideline more likely. Guidelines should be in a brief, clear, accessible format.	"Primary care practitioners rarely looked at the evidence behind the recommendations unless the recommendation seemed very different from their normal practice" (e722); guidelines in primary care not always practical, as it "mostly addressed the management of specific conditions post-diagnosis, while primary care practitioners predominantly deal with comorbidities and symptoms diagnosis" (e723-724).
Almatar <i>et al.</i> (2016)	Clinical Pathway and Monthly Feedback Improve Adherence to Antibiotic Guideline Recommendations for Community-Acquired Pneumonia	Inadequate integration of guideline into clinical workflow; time limitations; complex calculation scores to assess severity of a condition; high turnover of junior doctors who must learn about the guideline; feedback too general.	If implemented guideline is consistent with latest versions of nationally available guidelines; if "key local opinion leaders" are involved in the process (p 6/9); concise versions of guidelines had better concordance; Feedback should be given very specifically and not more frequently than once a month.	"educational interventions alone have a limited impact" (p 6/9)

Author(s), year of publication.	Name of article/publication	Barriers identified	Facilitators/Enablers identified	Other related comments made
Austad <i>et al.</i> (2015)	General practitioners' experiences with multiple clinical guidelines: A qualitative study from Norway	Adherence difficult due to overload of guidelines, large and inaccessible format, mismatch between needs of patients and recommendations in guidelines. Multimorbidity in patients cause application difficulty.		Clinical judgement is used to overcome treatment dilemmas; More focus on current complaints and quality of life, instead of on guideline adherence.
Basedow <i>et al.</i> (2015)	Australian GP attitudes to clinical practice guidelines and some implications for translating osteoarthritis care into practice	The wide field of general practice cause it to be difficult to be familiar with and apply all available guidelines.		Short format of guidelines are preferred: 2-3 page summaries OR flowcharts/algorithms OR single page checklists.
Carlsen <i>et al.</i> (2007)	Thou shalt versus thou shalt not: a meta-synthesis of GP's attitudes to clinical practice guidelines	Rigid guidelines that disregard complex patient circumstances. Lack of time to assess and implement recommendations. Lack of convenience, skills and resources.	More positive attitudes towards guidelines developed by peers or which has been approved by local population.	Should be short, simple and include leaflets to give to patients.

Author(s), year of publication.	Name of article/publication	Barriers identified	Facilitators/Enablers identified	Other related comments made
Deutsch <i>et al.</i> (2018)	Adressing Human Papillomavirus Prevention During Pediatric Acute Sexual Assault Care	"healthcare provider, institution, and guideline- or patient-specific factors, including biases, issues of autonomy, or lack of education/knowledge around the specific medical condition/diagnosis" (p 159)		
Donald <i>et al.</i> (2016)	Development and implementation of an online clinical pathway for adult chronic kidney disease in primary care: a mixed methods study		Consistency in provided information	More patient handouts are needed; a guideline/tool can "increase knowledge and confidence in the care of patients" (7 of 11)
Elwyn <i>et al.</i> (2018)	On a learning curve for shared decision making: Interviews with clinicians using the knee osteoarthritis Option Grid	Perceived lack of time.	Management policies to support use of pathways/tools.	Use of tool increase confidence and competence in health care workers; empowerment of patients.
Evans-Lacko <i>et al.</i> (2010)	Facilitators and barriers to implementing clinical care pathways	Lack of involvement of staff, lack of awareness of guideline, lack of time; overly prescriptive guideline; leads to additional work; difficult or unclear language; insufficient staff; high staff turnover; perceived increase in cost.; resources constrained.	Involvement of staff in design; clear language; specific to context; outcomes to interventions can be measured. Flexibility allowed; If staff has been trained adequately.	

Author(s), year of publication.	Name of article/publication	Barriers identified	Facilitators/Enablers identified	Other related comments made
Grimsmo <i>et al.</i> (2018)	Disease-specific clinical pathways – are they feasible in primary care? A mixed-methods study	Multiple chronic diseases cause difficulty in implementing individual pathways for each disease	Health care practitioners must be able to tailor treatment to patients' needs and preferences; should be practically usable; should have broad multi-disciplinary approach in some instances.	Guidelines rarely discuss relevance, safety and applicability in regards to patients with multimorbidity, also rarely discuss quality of life effects/functional ability/additional burdens caused by treatment.
Harrison <i>et al.</i> (2010)	Adapting clinical practice guidelines to local context and assessing barriers to their use	Rigidity of guideline; lack of staff; guideline seen as inapplicable to the population served; patient preferences not aligned with reconcilable with guideline.	Customise the guideline to the specific organisation/level of care	
Hashmi & Khan (2016)	ADHERENCE TO DIABETES MELLITUS TREATMENT GUIDELINES FROM THEORY TO PRACTICE: THE MISSING LINK	Health care practitioner Factors: disagreement with context of guideline and application to patients; lack of knowledge and training; work overload; lack of time, lack of concensus in/about guideline. Patient Factors: Education, socio-economic status and presence of co-morbid conditions. System Factors: lack of availability of training, infrastructure and financial resources.		Guidelines should be seen as valid, reliable, applicable. Should be disseminated in effective manner to all involved stakeholders.

Author(s), year of publication.	Name of article/publication	Barriers identified	Facilitators/Enablers identified	Other related comments made
Jabbour <i>et al.</i> 2018	Defining barriers and enablers for clinical pathway implementation in complex clinical settings	High turnover of staff trained / not trained in guideline; threatens doctor autonomy/pressure for conformity.	Health care practitioners must know that pathway exist, must believe in its high quality and basis in best available evidence; easily available; user-friendly; cause minimal duplication.	The system, team and individual must all support the adoption of the pathway.
Kenefick <i>et al.</i> (2008)	Improving Physician Adherence to Clinical Practice Guidelines: Barriers and Strategies for Change	HCP barriers: culture, beliefs and habits; Lack of transparency in the development process of guidelines; insufficient flexibility and clinical relevance. Not reflecting of complexity and context of decision making.		Encourage innovation; Enable HCPs with training in guidelines.
Khalifa & Alswailem 2015	Clinical Pathways: Identifying Development, Implementation and Evaluation Challenges	Previous bad/failed guidelines; perceptions of time wasting; overwhelming guideline in regards to prompts and evidence; unconvincing content; staff and time shortages, financial shortages. High turnover of staff; inadequate training.	Time allocated for staff training in regards to every guideline.	Financial resources should be allocated for successful guideline implementation. Quality of care outcomes should be monitored: user satisfaction, clinical outcomes.

Author(s), year of publication.	Name of article/publication	Barriers identified	Facilitators/Enablers identified	Other related comments made
Khunti <i>et al.</i> (2019)	Therapeutic inertia in type 2 diabetes: prevalence, causes, consequences and methods to overcome inertia	Inertia is major barrier to effective use of guidelines. Inertia found to be due to HCP factors: lack of time, knowledge inadequacies, variations in recommendations of various guidelines, perceptions/fears regarding medication side-effects, inadequate experience with management of specific condition. System factors: costs, variance between different levels/settings in healthcare; availability of recommended medication. Patient factors: fear of new regimes; presence of multi-morbidity.		
Lugtenberg <i>et al.</i> (2009)	Why don't physicians adhere to guideline recommendations in practice? An analysis of barriers among Dutch general practitioners	HCP barriers: lack of agreement with recommendations made by guideline, inadequate skills/training, poor expectancy of outcomes, unwillingness of change previous management habits, perception about pt preference not matching guideline recommendation. Lack of time and resources. Guidelines: unclear/confusing; not up to date; not comprehensive enough; too complex.		

Author(s), year of publication.	Name of article/publication	Barriers identified	Facilitators/Enablers identified	Other related comments made
Mazrou (2013)	Expected benefits of clinical practice guidelines: Factors affecting their adherence and methods of implementation and dissemination		Use clear, precise, unambiguous language; user-friendly format; links to evidence.	"Should be representative of all key disciplines and interests (including patients), clinically applicable with a clear definition of the target population and identify where exceptions to the recommendations lie"(p143). Should have scheduled reviews and lead to health improvement and HCPs treating similar patients similarly. Quality evaluated if similar product will be produced by other group using the same evidence.
Mercuri <i>et al.</i> (2015)	When Guidelines Don't Guide: The Effect of Patient Context on Management Decisions Based on Clinical Practice Guidelines	Contextual factors in patients cause HCPs to deviate from guidelines.		
Palmer <i>et al.</i> (2018)	Standardising costs or standardising care? Qualitative evaluation of the implementation and impact of a hospital funding reform in Ontario, Canada	Complex pathways more difficult to adopt	Involvement and consultation with stakeholders	External support is needed to implement pathways and policies

Author(s), year of publication.	Name of article/publication	Barriers identified	Facilitators/Enablers identified	Other related comments made
Papanikitas & Lunan (2018)	Inside general practice ethics: guidelines 'and' or 'for' good clinical practice			When developing guideline, should include considerations of when to follow and when to deviate from guideline.
Rankin <i>et al.</i> (2015)	Everybody wants it done but nobody wants to do it: an exploration of the barrier and enablers of critical components towards creating a clinical pathway for anxiety and depression in cancer	Lack of resources; Difficulty integrating with other sectors of health services; patient reluctant to admit to diagnosis	Ownership of pathway by and engaged team improves uptake; education and presentation of a good evidence base improves acceptability of pathway; should demonstrate efficacy and efficiency of pathway.	Education and training regarding pathway should be performed as part of implementation
Reilly <i>et al.</i> (2007)	Implementation of a first presentation psychosis clinical pathway in an area mental health service: the trials of a continuing quality improvement process	Inadequate evidence base; task relevance seen as lacking; increased work-load; excessive duplication of documents; lack of support needed; lack of outcome evaluation; staff turnover.	Training of staff in use of pathway.	Pathways should be applicable to the local setting.
Sather <i>et al.</i> (2018)	Care pathways in the transition of patients between district psychiatric hospital centres (DPCs) and community mental health services	Lack of responsible personnel; insufficient protocols and systematic plans; system challenges.	Identification of which personnel is responsible for which parts of pathway; patient involvement.	Information is needed from hospital level if patient is discharged, thus good communication is key.

Author(s), year of publication.	Name of article/publication	Barriers identified	Facilitators/Enablers identified	Other related comments made
Solà <i>et al.</i> (2014)	Attitudes and Perceptions about Clinical Guidelines: A Qualitative Study with Spanish Physicians	If guideline is not seen to be useful or if HCP is not knowledgeable about guideline, has poor uptake.	If guideline is seen as practical and pragmatic, not only theoretically strong, has better uptake.	Recommendations made by guideline must be implementable and context specific.
Steyn <i>et al.</i> (2013)	Implementation of national guidelines, incorporated within structured diabetes and hypertension records at primary level care in Cape Town, South Africa: a randomised controlled trial	Severe workload of HCPs; budget constraints. Some recommendations not feasible in setting (e.g. ECG); Implementation should not cause duplication of work, should not be an extra piece of paper to fill in. Guideline should not exclude holistic care of patient.		HCPs should always have enough space to write extra notes, guideline printed as a structured record to be filled in will thus be problematic. When guidelines are available, it can prompt HCPs to screen for neglected health issues.
Swennen <i>et al.</i> (2013)	Do general practitioners follow treatment recommendations from guidelines in their decisions on heart failure management? A cross-sectional study	HCP avoid recommended drugs if had previous negative experiences with same drug OR if recommendations confusing or unclear OR if different guidelines (e.g. pulmo vs cardio) recommend opposing views.		Guideline conclusions should be stated explicitly.

Author(s), year of publication.	Name of article/publication	Barriers identified	Facilitators/Enablers identified	Other related comments made
Taba <i>et al.</i> (2012)	Barriers and facilitators to the implementation of clinical practice guidelines: A cross-sectional survey among physicians in Estonia	Perceptions that guidelines were not evidence-based; guideline not relevant to the population or not correct for the needs/characteristics of specific patients; too complex. Disagreement with guideline recommendations. Lack of time + resources to implement recommendations.	Easily found guideline, even online. Training courses in use of specific guidelines.	Barriers to guidelines should be targeted and adapted to local conditions. HCPs still need training in use and appraising guidelines.
Van der Schaaf <i>et al.</i> (2015)	Translating Clinical Guidelines Into Practice: Challenges and Opportunities in a Dynamic Health Care Environment	Guideline lacking in support from management; poor quality improvement skills. HCPs difficulty in handling multiple detailed recommendations. Preference for personalised care based on patient context and own knowledge and experience.	If guideline includes quality improvement methods.	Increase evidence-based approach; health systems must support implementation of guideline; provide education, e.g. by outreach efforts. Decrease complexity of guidelines.
Zwolsman <i>et al.</i> (2012)	Barriers to GPs' use of evidence-based medicine: a systematic review	Lack of knowledge or skills; Personal experiences with conditions over course of career; Resources lacking (especially technological resources); Available evidence is lacking/inadequate quality/contradictory/not up to date/too much.	Attitudes of colleagues can influence use of evidence-based guidelines (positively or negatively);	Implementation of guidelines needs financial inputs.

APPENDIX L The “Diabetes follow-up” section of the new management guideline, in poster format

A CONTROL: HbA1C Targets:

- Did it change from before?
- Re-tests periodically (see HbA1C interpretation)
- (Hb B12, transferrin, HbA1c, renal function etc)

Young healthy, non-pregnant patient	≤ 7%
Planning pregnancy, selected other patients	≤ 6.5%
Established ischaemic heart disease, multiple comorbidities	4.0-7.0
Eligible for medical therapy, selected others	4.0-7.0

Ref: SMO2019.007

B Target glucoses to maintain HbA1C

HbA1c target	Fasting glucose	2h post meal glucose
≤ 6.5%	4.0-7.0	< 8
≤ 7%	4.0-7.0	< 10
≤ 8%	4.0-7.0	< 12

Ref: SMO2019.007

C TREATMENT OPTIONS

Name	Dose	Contra-Indication	Side effects
ORAL TREATMENT			
AGLIFLOZIN	Start 500mg bd Escalate to 1g bd (ability/cost/pt)	Renal failure (see eGFR, reduce in dose column) Liver function impairment Alcoholics	Severe diarrhoea (reduce dose, then stop if does not improve) Vitamin B12 deficiencies Lactate acidosis (rare)
GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RA)	Start 0.5mg bd Escalate to 1mg bd Max dose: 500mg bd	Renal failure (see eGFR, reduce in dose column) Liver function impairment Fragility elderly patients Pregnancy	Prolonged hypoglycaemic events
INSULIN	Use 30 minutes pre-meal OR As a sliding scale when blood glucose high after a meal	Inject ABDOMEN and thighs only Use with care in renal impairment: hypoglycaemias become more severe	Hypoglycaemia Weight gain Lipodystrophy at injection sites
PROTEINASE INHIBITORS	Use twice a day, 30 minutes before meals Usually lower doses in morning, lower dose at night. Dose is weight dependent and pt profile dependent (0.2-0.6U/kg/dy)	Use with care in renal impairment: hypoglycaemias become more severe	Hypoglycaemia Weight gain Lipodystrophy at injection sites

D LIPID TREATMENT

NAME	DOSE	SIDE-EFFECTS
Simvastatin	20mg noct 40mg noct (maximum) 80mg noct (maximum)	Muscle pain (CK) as seen Joint pain and stiffness Liver impairment Gastro-intestinal disturbances
Atorvastatin	10mg noct 20mg noct 40mg noct (maximum)	If has severe side-effects on simvastatin If has poor response on maximum simvastatin Indicated when patient is also on statins without specialist consult
TRIGLYCERIDES specialist	If Triglycerides >15 BEFORE DM treatment initiated >5 IN CONTROLLED diabetic specialist Treatment aim < 1.6	
Fibrate (bezafibrate)	200mg dy 400mg dy 400mg dy	Do not COMBINE fibrates and statins without specialist consult.

Ref: SMO2019.017

E Hypertension medication: most common available options

DRUG NAME (Class)	Doses available	Contra-Indications	Complications/ side-effects and alternatives
Ridag (Hydrochlorothiazide)	12.5 - 25mg dy	eGFR <30	High serum-calcium (side effects: dehydration and hypokalaemia)
Enalapril (ACE-inhibitor)	5mg dy 10mg dy 10mg bd 20mg dy	Hyperkalaemia Renal artery stenosis Previous angio-angina Pregnancy	Angio-oedema (STOP or reduce dose) Angio-oedema (STOP, change to ARB) Chronic cough (Reduce dose OR change to ARB if needed) Alternative: Losartan (ARB)
Amlodipine (calcium channel blocker)	5mg dy 10mg dy (can be given as nocte dose)		Peripheral oedema Dizziness/orthostatic hypotension Alternative: Amlodil XL (specialist)
Losartan (ARB) (specialist)	50mg dy 100mg dy	Hyperkalaemia	Reduce dose (STOP or reduce dose)
Amlodil (Beta-blocker)	2.5mg dy 5mg dy 50mg bd 100mg dy	Asthma Bradycardia/heart blocks Severe peripheral vascular disease	Bradycardia Asthma Alternative: Carvedilol 3.125 mg dy/bd 6.25mg dy/bd 12.5mg dy/bd
Aspirin	75-150mg dy	Peptic ulcer disease Kidney dysfunction Severe liver dysfunction	PUD, haematuria, upper GI bleed Alternative: Clopidogrel (specialist)

Ref: SMO2019.017

F Peripheral vascular examination

Examine periphery, more frequently if new problems develop

Temperature

Tissue loss

Ulcers

Claudication.

Ref: SMO2019.017

G Exercise

To improve glucose control and for weight loss:

- 150-250 minutes per week, moderate intensity, no longer than 40 hours interval between days.
- For weight loss: 4 hours exercise per week

Ref: SMO2019.017

H MEALS:

Ask about:

- Timing of medication in terms of meals.
- Frequency of meals.
- Intake and sugar intake.

I Escalation of treatment: (Also see C)

Start Metformin: escalate to maximum tolerated dose, if not controlling

Add Glimepiride: escalate to maximum tolerated dose, if not controlling

Add Pioglitazone once a day: Start with 25 in morning, 17.5 at night; increase as needed.

Patients on insulin MUST have a glucometer, then get glucose test strips, needles and syringes on prescription!

Check fasting glucose to see if improving. (See B)

Ref: SMO2019.017

J DYSLIPIDAEMIA TREATMENT OPTIONS

NAME	DOSE	SIDE-EFFECTS
Simvastatin	20mg noct 40mg noct (maximum) 80mg noct (maximum)	Muscle pain (CK) as seen Joint pain and stiffness Liver impairment Gastro-intestinal disturbances
Atorvastatin	10mg noct 20mg noct 40mg noct (maximum)	If has severe side-effects on simvastatin If has poor response on maximum simvastatin Indicated when patient is also on statins without specialist consult
TRIGLYCERIDES specialist	If Triglycerides >15 BEFORE DM treatment initiated >5 IN CONTROLLED diabetic specialist Treatment aim < 1.6	
Fibrate (bezafibrate)	200mg dy 400mg dy 400mg dy	Do not COMBINE fibrates and statins without specialist consult.

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H MEALS:

Ask about:

- Timing of medication in terms of meals.
- Frequency of meals.
- Intake and sugar intake.

I Escalation of treatment: (Also see C)

Start Metformin: escalate to maximum tolerated dose, if not controlling

Add Glimepiride: escalate to maximum tolerated dose, if not controlling

Add Pioglitazone once a day: Start with 25 in morning, 17.5 at night; increase as needed.

Patients on insulin MUST have a glucometer, then get glucose test strips, needles and syringes on prescription!

Check fasting glucose to see if improving. (See B)

Ref: SMO2019.017

J DYSLIPIDAEMIA TREATMENT OPTIONS

NAME	DOSE	SIDE-EFFECTS
Simvastatin	20mg noct 40mg noct (maximum) 80mg noct (maximum)	Muscle pain (CK) as seen Joint pain and stiffness Liver impairment Gastro-intestinal disturbances
Atorvastatin	10mg noct 20mg noct 40mg noct (maximum)	If has severe side-effects on simvastatin If has poor response on maximum simvastatin Indicated when patient is also on statins without specialist consult
TRIGLYCERIDES specialist	If Triglycerides >15 BEFORE DM treatment initiated >5 IN CONTROLLED diabetic specialist Treatment aim < 1.6	
Fibrate (bezafibrate)	200mg dy 400mg dy 400mg dy	Do not COMBINE fibrates and statins without specialist consult.

Ref: SMO2019.017

A CONTROL: HbA1C Targets:

- Did it change from before?
- Re-tests periodically (see HbA1C interpretation)
- (Hb B12, transferrin, HbA1c, renal function etc)

Young healthy, non-pregnant patient	≤ 7%
Planning pregnancy, selected other patients	≤ 6.5%
Established ischaemic heart disease, multiple comorbidities	4.0-7.0
Eligible for medical therapy, selected others	4.0-7.0

Ref: SMO2019.007

B Target glucoses to maintain HbA1C

HbA1c target	Fasting glucose	2h post meal glucose
≤ 6.5%	4.0-7.0	< 8
≤ 7%	4.0-7.0	< 10
≤ 8%	4.0-7.0	< 12

Ref: SMO2019.007

C TREATMENT OPTIONS

Name	Dose	Contra-Indication	Side effects
ORAL TREATMENT			
AGLIFLOZIN	Start 500mg bd Escalate to 1g bd (ability/cost/pt)	Renal failure (see eGFR, reduce in dose column) Liver function impairment Alcoholics	Severe diarrhoea (reduce dose, then stop if does not improve) Vitamin B12 deficiencies Lactate acidosis (rare)
GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RA)	Start 0.5mg bd Escalate to 1mg bd Max dose: 500mg bd	Renal failure (see eGFR, reduce in dose column) Liver function impairment Fragility elderly patients Pregnancy	Prolonged hypoglycaemic events
INSULIN	Use 30 minutes pre-meal OR As a sliding scale when blood glucose high after a meal	Inject ABDOMEN and thighs only Use with care in renal impairment: hypoglycaemias become more severe	Hypoglycaemia Weight gain Lipodystrophy at injection sites
PROTEINASE INHIBITORS	Use twice a day, 30 minutes before meals Usually lower doses in morning, lower dose at night. Dose is weight dependent and pt profile dependent (0.2-0.6U/kg/dy)	Use with care in renal impairment: hypoglycaemias become more severe	Hypoglycaemia Weight gain Lipodystrophy at injection sites

D LIPID TREATMENT

NAME	DOSE	SIDE-EFFECTS
Simvastatin	20mg noct 40mg noct (maximum) 80mg noct (maximum)	Muscle pain (CK) as seen Joint pain and stiffness Liver impairment Gastro-intestinal disturbances
Atorvastatin	10mg noct 20mg noct 40mg noct (maximum)	If has severe side-effects on simvastatin If has poor response on maximum simvastatin Indicated when patient is also on statins without specialist consult
TRIGLYCERIDES specialist	If Triglycerides >15 BEFORE DM treatment initiated >5 IN CONTROLLED diabetic specialist Treatment aim < 1.6	
Fibrate (bezafibrate)	200mg dy 400mg dy 400mg dy	Do not COMBINE fibrates and statins without specialist consult.

Ref: SMO2019.017

E Hypertension medication: most common available options

DRUG NAME (Class)	Doses available	Contra-Indications	Complications/ side-effects and alternatives
Ridag (Hydrochlorothiazide)	12.5 - 25mg dy	eGFR <30	High serum-calcium (side effects: dehydration and hypokalaemia)
Enalapril (ACE-inhibitor)	5mg dy 10mg dy 10mg bd 20mg dy	Hyperkalaemia Renal artery stenosis Previous angio-angina Pregnancy	Angio-oedema (STOP or reduce dose) Angio-oedema (STOP, change to ARB) Chronic cough (Reduce dose OR change to ARB if needed) Alternative: Losartan (ARB)
Amlodipine (calcium channel blocker)	5mg dy 10mg dy (can be given as nocte dose)		Peripheral oedema Dizziness/orthostatic hypotension Alternative: Amlodil XL (specialist)
Losartan (ARB) (specialist)	50mg dy 100mg dy	Hyperkalaemia	Reduce dose (STOP or reduce dose)
Amlodil (Beta-blocker)	2.5mg dy 5mg dy 50mg bd 100mg dy	Asthma Bradycardia/heart blocks Severe peripheral vascular disease	Bradycardia Asthma Alternative: Carvedilol 3.125 mg dy/bd 6.25mg dy/bd 12.5mg dy/bd
Aspirin	75-150mg dy	Peptic ulcer disease Kidney dysfunction Severe liver dysfunction	PUD, haematuria, upper GI bleed Alternative: Clopidogrel (specialist)

Ref: SMO2019.017

F Peripheral vascular examination

Examine periphery, more frequently if new problems develop

Temperature

Tissue loss

Ulcers

Claudication.

Ref: SMO2019.017

G Exercise

To improve glucose control and for weight loss:

- 150-250 minutes per week, moderate intensity, no longer than 40 hours interval between days.
- For weight loss: 4 hours exercise per week

Ref: SMO2019.017

H MEALS:

Ask about:

- Timing of medication in terms of meals.
- Frequency of meals.
- Intake and sugar intake.

I Escalation of treatment: (Also see C)

Start Metformin: escalate to maximum tolerated dose, if not controlling

Add Glimepiride: escalate to maximum tolerated dose, if not controlling

Add Pioglitazone once a day: Start with 25 in morning, 17.5 at night; increase as needed.

Patients on insulin MUST have a glucometer, then get glucose test strips, needles and syringes on prescription!

Check fasting glucose to see if improving. (See B)

Ref: SMO2019.017

J DYSLIPIDAEMIA TREATMENT OPTIONS

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Ref: SMO2019.017

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- Did it change from before?
- Re-tests periodically (see HbA1C interpretation)
- (Hb B12, transferrin, HbA1c, renal function etc)

Young healthy, non-pregnant patient	≤ 7%
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Eligible for medical therapy, selected others	4.0-7.0

Ref: SMO2019.007

B Target glucoses to maintain HbA1C

HbA1c target	Fasting glucose	2h post meal glucose
≤ 6.5%	4.0-7.0	< 8
≤ 7%	4.0-7.0	< 10
≤ 8%	4.0-7.0	< 12

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Name	Dose	Contra-Indication	Side effects
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INSULIN	Use 30 minutes pre-meal OR As a sliding scale when blood glucose high after a meal	Inject ABDOMEN and thighs only Use with care in renal impairment: hypoglycaemias become more severe	Hypoglycaemia Weight gain Lipodystrophy at injection sites
PROTEINASE INHIBITORS	Use twice a day, 30 minutes before meals Usually lower doses in morning, lower dose at night. Dose is weight dependent and pt profile dependent (0.2-0.6U/kg/dy)	Use with care in renal impairment: hypoglycaemias become more severe	Hypoglycaemia Weight gain Lipodystrophy at injection sites

D LIPID TREATMENT

NAME	DOSE	SIDE-EFFECTS
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Atorvastatin	10mg noct 20mg noct 40mg noct (maximum)	If has severe side-effects on simvastatin If has poor response on maximum simvastatin Indicated when patient is also on statins without specialist consult
TRIGLYCERIDES specialist	If Triglycerides >15 BEFORE DM treatment initiated >5 IN CONTROLLED diabetic specialist Treatment aim < 1.6	
Fibrate (bezafibrate)	200mg dy 400mg dy 400mg dy	Do not COMBINE fibrates and statins without specialist consult.

Ref: SMO2019.017

E Hypertension medication: most common available options

DRUG NAME (Class)	Doses available	Contra-Indications	Complications/ side-effects and alternatives
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Enalapril (ACE-inhibitor)	5mg dy 10mg dy 10mg bd 20mg dy	Hyperkalaemia Renal artery stenosis Previous angio-angina Pregnancy	Angio-oedema (STOP or reduce dose) Angio-oedema (STOP, change to ARB) Chronic cough (Reduce dose OR change to ARB if needed) Alternative: Losartan (ARB)
Amlodipine (calcium channel blocker)	5mg dy 10mg dy (can be given as nocte dose)		Peripheral oedema Dizziness/orthostatic hypotension Alternative: Amlodil XL (specialist)
Losartan (ARB) (specialist)	50mg dy 100mg dy	Hyperkalaemia	Reduce dose (STOP or reduce dose)
Amlodil (Beta-blocker)	2.5mg dy 5mg dy 50mg bd 100mg dy	Asthma Bradycardia/heart blocks Severe peripheral vascular disease	Bradycardia Asthma Alternative: Carvedilol 3.125 mg dy/bd 6

APPENDIX M **The “Newly diagnosed diabetes and/or acutely ill patient with diabetes”
section of the new management guideline, in poster format**

Free State

DIABETES DIAGNOSIS and the acutely ill patient with Diabetes Mellitus (DM)

Adults
Non-pregnant patients

Abbreviations (2)
IFG: Impaired fasting glucose
IGT: Impaired glucose tolerance
IV: Intra-venous
NGT: Naso-gastric tube
OGTT: Oral glucose tolerance test
sds: subcutaneous
tds: three times per day
U&E + Kr: Urea, electrolytes and creatinine
UTI: Urinary tract infection

A Fluid management of DKA in PHC clinics while awaiting transfer

- Resuscitate with 2 large peripheral lines.
- Fluids: Sodium chloride (0.9%) OR Ringer's Lactate 1 litre over 60 minutes then 200-250ml per hour for 6 hours
- Short acting insulin (Actrapid) boluses every 1hour, give s.c. according to sliding scale (doctor to advise: 0.14U/kg)

B Pregnancy and DM

Any pregnant patient who is diagnosed with DM or Any patient with DM who is diagnosed as being pregnant must be DISCUSSED on the SAME DAY with the local High Risk clinic.

C Possible causes for hypoglycaemia in patient with diabetes:

- Missed meals)
- Pregnancy or breastfeeding
- Sepsis or infection
- Overdose of diabetes medication (unintentional or intentional)
- Glimepiride use
- Renal function impairment with insulin retention (either with injectable insulin or with oral diabetes treatment)
- Liver function impairment
- Alcohol use

Ref: SEMDSA 2017

D METFORMIN (take during/after main meals of the day)

DOSE	Contra-indications	Side-effects
<ul style="list-style-type: none"> Start 500mg bds Escalate to 1g bd (elderly) 1g tds (younger pts) 850mg bds max dose 500mg bd If eGFR ≥ 145: If eGFR ≤ 30: do not use 	<ul style="list-style-type: none"> Renal failure (see 1) eGFR doses in dose column) Liver function impairment * Alcoholics * In HIV (+) patient: presence of HIVAN, liver disease, use of stavudine, didanosine 	<ul style="list-style-type: none"> Severe diarrhoea (reduce dose, then stop if does not improve) * Vll B12 deficiencies * Lactate acidosis (rare)

Ref: ADA 2019 & SAMF 2020

E At first follow-up:

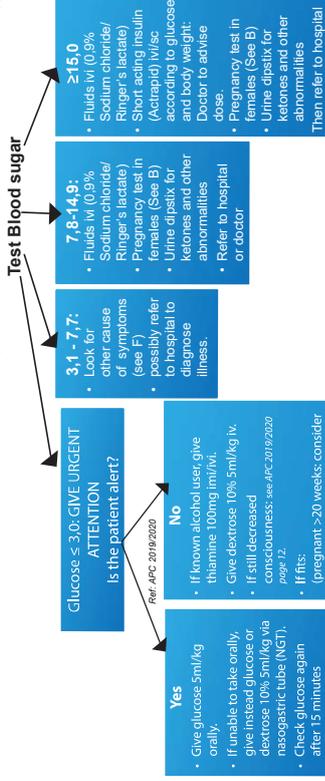
- Check results of baseline bloods (if it was indicated) and if any contra-indications to treatment exist.
- Review response to initial treatment and if side-effects developed.
- Evaluate patient's co-morbid conditions/risk factors
 - * Hypertension
 - * Dyslipidaemia
 - * HIV etc.
- Review weightloss program.
- Book scheduled general diabetes follow up according to current response.

Ref: ADA 2019 & SEMDSA 2017

SYMPTOMATIC PATIENTS (Polyuria/Polydipsia/Polyphagia/Weightloss)

ACUTELY ILL PATIENT -New DM or known DM-

(Tachypnoea / Fever / Dehydrated / Ketone odour / Vomiting)



Glucose ≤ 3.0 : GIVE URGENT ATTENTION

- Is the patient alert?
- Yes**
 - Give glucose 5ml/kg orally.
 - if unable to take orally, give instead glucose or dextrose 10% 5ml/kg via nasogastric tube (NGT).
 - Check glucose again after 15 minutes
 - No**
 - if known alcohol user, give thiamine 100mg im/iv.
 - Give dextrose 10% 5ml/kg iv.
 - if still decreased consciousness: see APC 2019/2020 page 12.
 - if fits: (pregnant >20 weeks: consider eclampsia: see APC 2019/2020 p 138)
 - Consider head injuries.
 - If not pregnant: stop fit with diazepam/midazolam (up to 2 doses, 5 minute interval).
 - If still fits after 2 doses of diazepam/midazolam: doctor to add Phenytoin loading dose and refer.
 - Check glucose after 15 minutes.

Overt Diabetes

- INITIATION OF DIABETES TREATMENT**
- Metformin (See D)
 - Lifestyle changes (See G+H)
 - Baseline bloods: U&E+Kr, HbA1C, Hb/FBC, Lipogram, urine albumin (if no protein on urine dipstick)
 - Book follow-up date in \pm two weeks (See E)
- If fasting bloodsugar ≥ 15 or HbA1C $\geq 10\%$ also do the above - but consider initiating insulin faster!

IF OGTT shows IF/IGT

- Consider Metformin if no contra-indications (See D)
- Life-style changes (See G+H)
- Book-Follow up (See E)
- Re-screen in 1 year (stop Metformin two weeks before repeating OGTT)

Negative for diabetes

- Consider other causes for symptoms (See F)
- Re-screen in 3 years *if risk still present.*
- Life-style changes (See G+H)

NOT ACUTELY ILL

- SCREEN THE PATIENT FOR DIABETES**
- If Asymptomatic: Pick TWO methods (See K)
 - If Symptomatic: Pick ONE method (See K)
 - Pregnancy test in females (See B)
- Remember: When in doubt, do oral glucose tolerance test (OGTT) (See J+K)

ASYMPTOMATIC PATIENTS Who are at risk to develop DM?

- Patients who must be screened:**
- Symptoms of DM
 - Age ≥ 45
 - Obese patients (BMI >30)
 - Previous cardiovascular event
 - Abnormal cholesterol
 - Family history of DM
 - Previous baby of >4 kg
 - Previous proven gestational DM
 - Pregnant patient.
 - Acanthosis nigricans \pm skin tags in neck/skin folds
 - Patient with HIV and on ART^s: if any of above risk factors present
 - HIV (+) patients: before initiation or changing of treatment regimen

K HOW TO SCREEN FOR DM

- Pick TWO tests: do on separate days in a two-week period.
- Fasting glucose
 - Random glucose
 - HbA1C: $\geq 6.5\%$ is diagnostic (See I)
 - OGTT (See J)
- Fingerpricks MUST be confirmed with Grey Top
- to interpret result: same as OGTT result (See J)

Ref: SEMDSA 2017

J OGTT METHODS (for non-pregnant patients)

- 75g of glucose diluted in hot water cooled down.
- Patient come fasting to the clinic
- 0hrs: Grey Top tube for glucose
- 2hrs: Grey Top tube for glucose
- * Specimens should reach the laboratory the same day.*

HOW TO INTERPRET THE OGTT RESULTS:

Non-diabetic	0hr value	2hr value
	≤ 5.6	and ≤ 7.7
Impaired fasting glucose (IFG)	5.7-6.9	but ≤ 7.7
Impaired glucose tolerance (IGT)	≤ 5.6	but > 7.7
Diabetic (overt)	≥ 7.0	or ≥ 11.1

Ref: SEMDSA 2017

I HbA1C for diagnosis

- $\leq 5.6\%$: Probably no DM
- 5.7 - 6.4%: Possible IFG/IGT, confirm with OGTT
- $\geq 6.5\%$: Diagnostic for DM, can confirm with OGTT

Ref: ADA 2019

G Exercise

- To improve glucose control and for weight loss:
- Aim for 5% reduction in weight over 6 months.
- In general:
- 150-250 minutes per week, moderate intensity, no longer than 48 hours interval between days.
 - For weight loss: 4 hours exercise per week
 - Aim for BMI < 25

Ref: SEMDSA 2017

F Some other causes for polyuria/polydipsia/polyphagia

- Pregnancy
- Hyperthyroidism
- Hypercalcaemia
- Helminthes infestations
- UTI
- Urinary tract obstruction (e.g. prostate enlargement etc.)
- Medication (Amiloripine etc)
- Malignancies and more

H Lifestyle changes

- Exercise (see G)
- Weightloss (see G)
- Dietician
- Social worker
- Support groups

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Guideline to be reviewed:
2025

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APPENDIX N The Integrated Care Pathways Appraisal Tool (I.C.PAT) checklist

Integrated Clinical Pathway Checklist*

I. Content / Structure of ICP

- Have identified start and finish points Yes
- Reflect a patient's journey (i.e. moving along a continuum of days/weeks/months/stages/objectives/programs) Yes
- Reflect 24-hour continuous care/treatment (where appropriate) Not applicable
- Form the record of care for an individual patient? *No, poster format. Usual clinical notes can be made with guideline as a prompt.*
- Allow documentation to be individualized to meet the patient's needs Yes
- Outline the anticipated process of care/treatment Yes

II. ICP Documentation

- Identify the relevant patients in the title of the ICP (e.g., ICP for Laparoscopic Cholecystectomy) Yes
- Indicate the circumstances when a patient should come off or should not be put on (exclusion criteria) Yes (contra-indications and side-effects of treatment)
- Meet local/national minimum standards for documentation (e.g. institution standards if exist) Standard to be clarified with Department of Health prior to pilot or implementation
- Include a reminder that says professional judgment must be applied while taking into account the patient's wishes & needs (i.e., the ICP is not a tramline and can be varied) Yes
- Reference the evidence on which the content is based Yes.
- Include the date of development of the document on the ICP Yes
- Include space for the identification of the individual patient on each page Not applicable.

III. The Development Process

- Record decisions made concerning the content of the ICP Yes, as part of mini-dissertation
- Record description/list staff involved in the development of the ICP Yes
- Conduct a literature search to gather the evidence base for the clinical content of the ICP Yes, as part of mini-dissertation
- Record the rationale for including and excluding pieces of evidence/guidelines Yes, as part of mini-dissertation
- Pilot test the ICP and audit the ICP documentation after the pilot Planned as separate study
- Consider clinical risk as part of the content of the ICP Yes, imbedded with HbA1C targets, treatment option discussions.
- Consider training, education, and competency of staff as part of the content of the ICP Yes
- Involve patient and/or their family members in the development of the ICP (by using focus groups/questionnaires /complaints/patient diaries, etc.) No
- Take into account patients' and family members' multicultural needs Not really.

IV. The Implementation Process

- Establish an on-going training program for the staff Yes, as part of implementation and outreach programme.
- Identify resources (individuals/time) to undertake the training on how to use the ICP Not yet explicitly identified.
- Establish a system to feedback the variations of the ICP to the staff and patients/family members Part of the training.
- Agree on the location where the ICP documentation will be stored once finished Mini-dissertation document storage
- Assess the risks involved in an ICP development before commencement Yes: ethical considerations were done.
- Name an individual responsible for maintaining the ICP To be decided upon in conjunction with Department of Health
- Provide training to staff when a change to the ICP content is made Yes
- Provide regular training for new staff that will be using the ICP Should happen on yearly basis.
- Set a review date of one year or less No, 5 years.
- Get endorsement for the ICP development from the Trust Board/Clinical Governance Committee Received from HSREC of the UOFS

V. Questions:

- Within the organization, is there a plan specifically for ICP development? In the UOFS organization, not the DOH FS
- Are ICPs evident in the organization's Clinical Governance Strategy? Yes, as part of the APC guidelines for PHC.

*This checklist is adapted from *The Integrated Care Pathways Appraisal Tool (I.C.PAT)*¹, which provides a series of questions to ensure that the tool developed is an ICP, that the mechanism used to develop the ICP is robust, and that the ICP documentation meets at least the minimum legal requirements for clinical documentation. I.C.PAT uses the term "service user" where we have used the terms "patient" and "patient and/or family members."

¹Whittle C, McDonald PS, Dunn L, de Luc K. Developing the integrated care pathways appraisal tool (ICPAT): a pilot study. *J Integr Care Pathways* 2004; 8:77–81.

APPENDIX O **Diabetes section of *Adult Primary Care 2019/2020* (pp.13, 112 & 113)**

ASSESS AND MANAGE GLUCOSE

If known diabetes → 112.

Interpret and manage random fingerprick glucose:

Glucose < 3
Patient has hypoglycaemia.

Give urgent attention

Is patient alert?

Yes

- Give **glucose**[†] 5mL/kg orally.
- If unable to take orally, give instead **glucose**[†] or **dextrose** 10%[‡] 5mL/kg via nasogastric tube (NGT).
- Check glucose after 15 minutes:

No

- If known alcohol user, give **thiamine** 100mg IM/IV.
- Give **dextrose** 10%[‡] 5mL/kg IV.
- If decreased consciousness → 12.
- If fits > 15.
- Check glucose after 15 minutes:

< 3

Give further **glucose**[†] or **dextrose** 10%[‡] 2mL/kg orally/kg orally/ via NGT and discuss/ refer.

≥ 3

Look for cause. Return to symptom page.

- Give **dextrose** 10%[‡] 2mL/kg IV.
- Then give **dextrose** 5% 1L IV 6 hourly.
- Refer.

Glucose 3-6.0

Does patient have BMP ≥ 25 and ≥ 1 of:

- Physical inactivity
- Hypertension
- Parent or sibling with diabetes
- Polycystic ovarian disease
- Indian ethnicity
- Cardiovascular disease
- Diabetes during pregnancy
- Previous big baby > 4000g
- Previous impaired fasting glucose
- TB in past year

No

Recheck glucose 3 yearly once over 45 years.

Yes

Check fasting plasma glucose after an 8-hour overnight fast.

< 6.1

Repeat fasting plasma glucose after 3 years or 1 year if CVD[†] or hypertension.

6.1-6.9

- Patient has impaired fasting glucose.
- Repeat fasting plasma glucose after 1 week.

< 7

Repeat fasting plasma glucose 1 week later.

> 7

Repeat fasting glucose after 1 year.

Assess CVD risk ≥ 110.

Glucose ≥ 11.1

Check if patient needs urgent attention:

- Decreased consciousness → 12
- Chest pain → 33
- Fits > 15
- Drowsiness
- Confusion
- Nausea or vomiting
- Abdominal pain
- Rapid deep breathing
- Temperature ≥ 38°C
- Dehydration[§]

No

Check urine for ketones.

No ketones

Has patient had weight loss, thirst (especially at night) or been passing excessive amounts of urine often?

Yes

No

Ketones present

- Give **sodium chloride** 0.9% 20mL/kg IV over the first hour, then 10mL/kg/hour thereafter. Stop if breathing worsens.
- If referral delay > 2 hours: give **short-acting insulin** 0.1 units/kg IM (not IV)*. Avoid using insulin needle to give IM insulin. Use 22-25 gauge needle depending on weight of patient.
- Refer urgently.

[†]Three teaspoons sugar (15g) in 1 cup (200mL) water. [‡]If dextrose 10% unavailable: mix 1 part dextrose 50% to 4 parts water for injection to make dextrose 10% solution. [§]BMI = weight (kg) ÷ height (m). [¶]Cardiovascular disease (CVD) includes ischaemic heart disease, peripheral vascular disease and stroke/TIA. ^{††}Thirst, dry mouth, poor skin turgor, BP < 90/60, pulse ≥ 100. ^{‡‡}World IV Insulin as may cause low potassium and heart dysrhythmia. Monitoring needed.

DIABETES: ROUTINE CARE

<ul style="list-style-type: none"> • Chest pain → 33. • Fitting → 15. • Decreased consciousness, drowsiness 	<p>Give urgent attention to the patient with diabetes and any of:</p> <ul style="list-style-type: none"> • Confusion or unusual behaviour • Weakness or dizziness • Shaking <p>Check random fingerprick glucose:</p>	<ul style="list-style-type: none"> • Sweating • Nausea or vomiting • Abdominal pain • Thirst or hunger <p>Temperature $\geq 38^{\circ}\text{C}$ Dehydration: dry mouth, poor skin turgor, BP < 90/60, pulse ≥ 100</p>
<p>Glucose < 4 with/without symptoms</p>	<p>Glucose ≥ 11.1 with symptoms</p>	<p>Glucose ≥ 11.1 without symptoms</p>
<ul style="list-style-type: none"> • If alert: give glucose¹ 5mL/kg orally. If unable to take orally, give instead glucose¹ or dextrose 10%² 5mL/kg via nasogastric tube. • If decreased consciousness: give dextrose 10%² 5mL/kg IV. If known alcohol user, give thiamine 100mg IM/IV before dextrose. • Recheck glucose after 15 minutes: if still < 4, give further 2mL/kg. For IV: once glucose ≥ 4, continue dextrose 5% 1L IV 6 hourly. • Identify cause and educate about meals and doses → 113. • If incomplete recovery or on glimepiride, glibenclamide or insulin, refer same day. 	<p>Check urine for ketones.</p> <p>Ketones present</p> <p>No ketones</p> <p>Give routine diabetes care below.</p>	<p>Check urine for ketones.</p> <p>Ketones present</p> <p>No ketones</p> <p>Give routine diabetes care below.</p>

Assess	When to assess	Note
Symptoms	Every visit	Manage symptoms as on symptom pages. Ask about chest pain → 33 and leg pain → 56.
Depression	At diagnosis and if control poor	In the past month, has patient: 1) felt down, depressed, hopeless or 2) felt little interest or pleasure in doing things? If yes to either → 125.
Alcohol/drug use	At diagnosis and if control poor	In the past year, has patient: 1) drunk ≥ 4 drinks/session, 2) used illegal drugs or 3) misused prescription or over-the-counter medications? If yes to any → 124.
BP	Every visit	If known hypertension → 115. If not, check BP: if $\geq 140/90$ → 114.
BMI and waist circumference	• Weight: at every visit • BMI, waist circumference: at diagnosis	• BMI = weight (kg) + height (m) ² • Aim for BMI ≤ 25 and waist circumference < 80cm (woman) or < 94cm (man).
Eyes	At diagnosis, yearly and if visual problems	Check visual acuity and fundoscopy. If visual problems, cataracts or retinopathy, refer.
Feet	At diagnosis, yearly and more often if problems	Check for pain, pulses, sensation, deformity, skin problems. For foot screen and foot care education → 57.
Family planning	Every visit	Assess patient's contraceptive needs → 136. If pregnant or planning pregnancy, refer for specialist care.
Glucose	If adjusting glucose-lowering medication	If fasting glucose > 8 or non-fasting glucose taken 2 hours after eating > 10, step up treatment → 113.
HbA _{1c} (glucose control over past 3 months)	• Yearly if HbA _{1c} $\leq 8\%$ • 3 months after treatment change	• If HbA _{1c} $\leq 8\%$: diabetes controlled , continue same treatment for diabetes. • If HbA _{1c} > 8%: diabetes uncontrolled . If adherent, step up treatment → 113. If not adherent, give support and repeat HbA _{1c} after 3 months.
Urine dipstick	At diagnosis and yearly	• If protein, start enalapril if not already on it → 113. • If no protein and not on enalapril, send urine to lab for albumin/creatinine ratio. If ratio > 3, start enalapril → 113.
Creatinine (eGFR)	• At diagnosis, then yearly • If on enalapril: at baseline and 4 weeks ^a	• Give age and sex on form. If eGFR < 60, discuss with doctor. If eGFR < 30, refer. • If creatinine increases by > 20%, stop enalapril and refer to doctor.
Potassium	If on enalapril: at baseline, 4 weeks ^a , then yearly	If potassium > 5.0, avoid/stop enalapril and refer to doctor.
Lipids	At diagnosis	Check fasting total cholesterol, triglycerides, HDL/LDL. Assess CVD risk → 110. If total cholesterol > 7.5 or triglycerides > 10, refer/discuss.

¹Three teaspoons sugar (15g) in 1 cup (200mL) water. ²If dextrose 10% unavailable: mix 1 part dextrose 50% to 4 parts water to make a dextrose 10% solution. ^aVoid IV insulin as it may cause low potassium and heart dysrhythmia. Avoid using an insulin needle to give IM insulin. ^bOne drink is 1 tot of spirits, or 1 small glass (125mL) of beer. ^cIf eGFR < 60, repeat instead at 2 weeks.

Advise the patient with diabetes

- Help the patient to manage his/her CVD risk 211. Educate on foot care to prevent ulcers and amputation 257.
- Discuss diet: avoid white/brown sugar and honey, use artificial sweetener instead. Cut down on starch (rice, noodles, bread, potato, sweet potato, butternut, mielies, pap, samp).
- Explain importance of adherence and to eat regular meals. If newly diagnosed or poor adherence or attendance, refer for community care worker support.
- Ensure patient can recognise and manage hypoglycaemia (shaking, sweating, palpitations, weakness, hunger):
 - Drink milk with sugar or eat a sweet. Always carry something sweet. If not in clinic and fits, confusion or coma, rub sugar inside mouth and call ambulance. Go to clinic if illness (like diarrhoea).
 - Identify and manage the cause: increased exercise, missed meals, inappropriate dosing of glucose-lowering medications, alcohol, infections.
- If on/starting insulin, educate on how to use it:
 - Discuss injection technique and sites (abdomen, thighs, arms), store insulin in fridge/cool dark place, meal frequency, recognising hypoglycaemia/hyperglycaemia, sharps disposal at clinic.
 - Advise that if unwell and vomiting/not eating as usual, to increase fluid intake, check glucose 3 times a day if possible and adjust insulin dose if necessary (avoid stopping insulin).

Treat the patient with diabetes

- If known with CVD*: give **simvastatin**² 40mg² and **aspirin** daily. Avoid simvastatin if pregnant and avoid aspirin if peptic ulcer, dyspepsia, kidney disease. Avoid both if liver disease.
- If not known with CVD* but CVD risk > 20%, eGFR < 60, known with diabetes > 10 years or age > 40 years, give **simvastatin**² 10mg daily. Avoid if pregnant or liver disease.
- If albuminuria/proteinuria, give **enalapril**⁴ 5mg 12 hourly, regardless of BP. If proteinuria persists and systolic BP > 100, increase up to 10mg 12 hourly, if tolerated.
- Give glucose-lowering medication using stepwise approach as in table below. Ensure patient is adherent before increasing treatment. If not adherent, refer for community care worker support.

Step	Medication	Breakfast	Supper	Bed	Note
1	Metformin	500mg 500mg 850mg 1g	500mg 850mg 1g		<ul style="list-style-type: none"> • Avoid if eGFR < 30, liver disease, uncontrolled heart failure, alcoholism. • Take with meals. If on duloxetine or eGFR 30-60, halve dose, up to maximum of 500mg 12 hourly. • May cause self-limiting nausea, abdominal cramps or diarrhoea. Advise patient not to stop treatment. • Increase monthly if fasting glucose > 8 (or postprandial⁵ glucose > 10) or HbA_{1c} > 8%, and patient is adherent. • If up to 2g needed daily, metformin may be given as 850mg 8 hourly instead of 1g twice daily. • If after 3 months on maximum dose HbA_{1c} > 8%, move to step 2.
2	Add glibenclamide or glibenclamide	1mg 2mg 3mg 4mg 2.5mg 5mg 5mg 5mg 7.5mg 10mg			<ul style="list-style-type: none"> • Continue metformin. • Take glibenclamide with breakfast. Take glibenclamide 30 minutes before breakfast. Avoid missing meals. • Avoid in pregnancy, severe kidney (eGFR < 60) and liver disease, co-trimoxazole allergy. Avoid glibenclamide if > 65 years. • Increase every 2 weeks if fasting glucose > 8 (or postprandial⁵ glucose > 10) or HbA_{1c} > 8%, and patient is adherent. • If after 3 months on maximum dose HbA_{1c} > 8%, move to step 3.
3	Add basal insulin (intermediate or long acting)			Start at 10IU. If fasting glucose > 8, increase by 2-4units each week.	<ul style="list-style-type: none"> • Stop glibenclamide/glibenclamide but continue metformin when starting insulin. • Educate about insulin as above and issue meter: patient to check fasting glucose on waking 3 times a week. • If > 20IU needed or if patient having episodes of hypoglycaemia, discuss/refer to doctor.
4	Substitute with biphasic insulin	0.2IU/kg 0.2IU/kg + 4IU 0.2IU/kg + 4IU 0.2IU/kg + 8IU 0.2IU/kg + 8IU	0.1IU/kg 0.1IU/kg 0.1IU/kg + 4IU 0.1IU/kg + 4IU 0.1IU/kg + 8IU 0.1IU/kg + 8IU etc		<ul style="list-style-type: none"> • Continue with metformin. Stop glibenclamide/glibenclamide and basal insulin. • Start with 0.3units/kg/day. Patient to give two-thirds of total daily insulin dose 30 minutes before breakfast and one-third of total daily insulin dose 30 minutes before supper. • Patient to check fasting glucose on waking 3 times a week. If ≥ 8 and patient adherent, increase morning dose by 4 units. If still ≥ 8 after one week, increase evening dose by 4 units. • Educate about insulin as above. • If fasting glucose still ≥ 8 or HbA_{1c} > 8% after 3 months, discuss with specialist.

Review the patient with diabetes 6 monthly once stable.

Cardiovascular disease (CVD) includes ischaemic heart disease, peripheral vascular disease and stroke/TIA. ²If HIV positive on lopinavir/ritonavir or atazanavir/ritonavir, avoid simvastatin, give instead atorvastatin 10mg daily. ³If on amiodipine, reduce simvastatin dose to 10mg daily. ⁴Avoid in pregnancy, angioedema or renal artery stenosis. If not tolerating enalapril (e.g. persistent cough), refer to doctor to consider alternative. ⁵Two hours after eating.

APPENDIX P **Tabulated comparison of diabetes sections of *Adult Primary Care 2016/2017*, the *Adult Primary Care 2019/2020*, and the new proposed guideline**

	APC 2016/2017	APC 2019/2020	NEW GUIDELINE																				
I. Diagnosis and screening																							
1. Which patient population is described as "at risk" thus needs diabetes screening?	Screening in asymptomatic pts not specifically mentioned. In section regarding symptomatic pts with normal random blood glucose: risk factors discussed: family history of DM, History of Gest DM, BMI >25, HT, Waist circumference of >94cm (men)>80cm (women). "may be at risk, repeat random blood sugar after one year".	BMI More than/equal to 25 AND one/more of the following: *Physical inactivity/HT/Parent or sibling with DM/PCOS/Indian ethnicity/CVD/DM during pregnancy/Prev Big baby >4kg/Prev IFG/TB in past year.	One ore more risk factors present: BMI >25, family history of DM, previous baby >4kg, symptoms of DM, previous proven gestational DM, pregnancy, pt with HIV on ARTs, acanthosis \pm skin tags in neck/skinfolds, age \geq 45.																				
2. Is doing an OGTT advised in certain circumstances?	No.	No	Yes, whenever uncertain of diagnosis.																				
3. Is method to do OGTT correctly discussed?	N/A	N/A	Yes, in moderate detail.																				
4. What are the diagnostic values of the OGTT?	N/A	N/A	<table border="0"> <tr> <td></td> <td>0hrs</td> <td>and</td> <td>2hrs</td> </tr> <tr> <td>Non-diabetic</td> <td>\leq5.6</td> <td></td> <td>\leq7.7</td> </tr> <tr> <td>IFG</td> <td>5.7-6.9</td> <td>but</td> <td>\leq7.7</td> </tr> <tr> <td>IGT</td> <td>\leq5.6</td> <td>but</td> <td>7.8-11.0</td> </tr> <tr> <td>DM</td> <td>\geq7.0</td> <td>OR</td> <td>\geq11.0 O</td> </tr> </table>		0hrs	and	2hrs	Non-diabetic	\leq 5.6		\leq 7.7	IFG	5.7-6.9	but	\leq 7.7	IGT	\leq 5.6	but	7.8-11.0	DM	\geq 7.0	OR	\geq 11.0 O
	0hrs	and	2hrs																				
Non-diabetic	\leq 5.6		\leq 7.7																				
IFG	5.7-6.9	but	\leq 7.7																				
IGT	\leq 5.6	but	7.8-11.0																				
DM	\geq 7.0	OR	\geq 11.0 O																				
5. How should pre-diabetes be managed?	Not mentioned.	Not mentioned	Consider Metformin, Lifestyle changes, rescreen.																				
6. How should pre-diabetes/high risk individuals be followed up/reviewed?	If risk factors (-): re-screen in 5 years. If risk factors (+): repeat in one year.	If fasting glucose normal, repeat fasting glucose after 3 years, or if CVD/HT: repeat after 1 year	If screen normal but risk stays present: rescreen in 3 years. If IFG/IFGT: repeat OGTT/screen in 1 year.																				

II. Targets of Glucose Control and lifestyle changes	APC 2016/2017	APC 2019/2020	New guideline
7. Which target HbA1C is advised?	<7%	<8%	Variable (\leq 6.5% - 8.5%), according to circumstances.
8. How often is repetition of an HbA1C advised for a patient on treatment?	Every 6 months, 3 months after treatment changed.	3 months after treatment change	3 Months after changed treatment, otherwise 6 monthly if stable.
9. Are factors influencing the interpretation of HbA1C discussed?	No.	No	Yes, shortly.
10. What is the target <u>fasting</u> blood glucose (if HbA1C target is <7%) for patients on treatment?	Not mentioned specifically.	Fasting glucose <8	4.0-7.0
11. What is target <u>2hr post-prandial</u> / random blood glucose for a patient on treatment?	Unclear: Random 4-14.9, also <8.	Glucose <10	For HbA1C <6.5%: <8; HbA1C <7%: <10; HbA1C <8: <12
12. Is special populations discussed in terms of control targets/special considerations?	No	No	Yes.
13. How frequently is testing of blood glucose at home advised?	If on insulin: check fasting glucose upon waking once a week.	If on insulin: Check 3 times per week on waking .	If not on insulin: no need to check glucose at home yet. If on insulin: check 2-3 times per day, more often when sick/unwell.

	APC 2016/2017	APC 2019/2020	New guideline
14. Is hypoglycaemia explored?	"Educate on signs and symptoms of hypoglycemia, how to treat", "Identify and manage cause". Examples of symptoms, causes and treatment offered.	"Educate on signs and symptoms of hypoglycemia, how to treat", "Identify and manage cause". Examples of symptoms, causes and treatment offered.	Yes, in detail.
III. Discussion on glucose lowering treatment			
15. Metformin : Is contra-indications and/or complications discussed?	Contra-indicated in pregnancy, kidney/liver disease, recent heart attacks, heart failure, alcoholism. No complications discussed.	Take with meals. Self-limiting nausea and cramps/diarrhoea. Max dose of 500mg bd if GFR of 30-60 OR if on dolutegravir.	Take with meals. Reduce / stop depending on eGFR. Other complications and contra-indications discussed.
16. Sulphonylureas : Is contra-indications and/or complications discussed?	Avoid in pregnancy, severe kidney and liver disease, co-trimoxazole allergy. No complications discussed.	Take 30 mins pre-meal; Avoid in pregnancy, severe kidney (eGFT <60) and liver disease, co-trimoxazole allergy.	Take 30 mins before main meal. Complications and contra-indications discussed.
IV. Discussion on the complications of DM			
17. Is micro-albumin testing advised?	Yes	Albumin/creatinine ratio if no protein on dipstick AND not on enalapril. (no mention of follow-up)	Yes. Alb/creatinine ratio.
18. How frequently is micro-albumin testing advised?	At diagnosis, and yearly. (Send for micro-albumin if no protein on urine dipstick)	Dipstick: on diagnosis and yearly. Assumption is to send for alb/cr ratio only as indicated above, thus ?yearly.	At diagnosis, then yearly if no protein on urine dipstick.

	APC 2016/2017	APC 2019/2020	New guideline
19. What steps/treatment are advised when micro-albuminuria is present?	For both micro-albuminuria AND frank proteinuria: start Enalapril 10mg dly and increase to 20mg dly after one month irrespective of BP.	If alb/creat ratio >3: start enalapril, start on 5mg bd irrespective of BP, increase if proteinuria persists and Systolic BP >100.	Consider UTI, consider ACE/ARB
20. Is side-effects/complications/ contra-indications for use of an angiotensin converting enzyme inhibitor (ACE-I) discussed?	Avoid in pregnancy, angio-oedema and renal artery stenosis. <i>Complications not discussed</i> .	Avoid in pregnancy, angio-oedema and renal artery stenosis. If not tolerating enalapril (e.g. persistent cough), refer to doctor to consider alternative.	Avoid in pregnancy, hyperkalemia, angio-oedema and renal artery stenosis. Complications: hyperkalemia, angioedema, cough.
21. Is an alternative option to ACE-I explained or offered?	No	No, doctor to consider alternative.	Yes: Losartan.
22. Foot exam: How often advised? What to look for?	At diagnosis, after 3 months, then yearly. More often if at risk. Look for pain, pulses, deformity. If skin problems: "go to page 41".	At diagnosis, yearly, and more often if has problems. Pain, pulses, sensation, deformity skin problems. For foot screen and foot care education: go to page 57.	At diagnosis, then yearly/more often if problems.
23. Eye exam: How often advised? By whom should it be performed?	At diagnosis, then yearly, or if visual problems develop. "Refer if new diagnosis, visual problems or retinopathy".	At diagnosis, yearly and if visual problems: Check visual acuity and fundoscopy. If visual problems, cataracts or retinopathy: refer.	At diagnosis, then yearly/more often if problems. To be done by trained professional (dilated fundoscopy/retinal photograph)
24. Screening for depression / mental health recommended?	Yes, screen at every visit. If present "go to page 88").	At diagnosis and if poor control. Two question screening tool, refer to page 125.	Yes. Small screening tool.
25. Is autonomic neuropathy discussed?	No.	No.	Yes.

	APC 2016/2017	APC 2019/2020	New guideline
V. Related special investigations			
26. How frequently is urea, electrolytes and creatinine (U&E+Kr) testing advised?	eGFR: at diagnosis and yearly.	Kr/eGFR: At diagnosis, then yearly. If on enalapril: at baseline and 4 weeks. If eGFR <60: repeat instead after 2 weeks.	U&E +Kr: At diagnosis, yearly, per indication (one month after initiating ACE-I/ARB).
27. Is K (potassium) testing advised, and how frequently?	No	If on enalapril: at baseline, 4 weeks, then yearly. (if eGFR <60: repeat instead at 2 weeks)	As part of U&E: at diagnosis, yearly, indication (one month after starting ACE-I/ARB))
28. Is Vitamin B12 testing advised or discussed?	No.	No	Yes. If symptoms present or anaemic, especially if on Metformin.
29. How often is Lipid testing advised?	At diagnosis only. Total cholesterol and Triglycerides.	At diagnosis.	At diagnosis, then yearly.
30. Which element of the lipogram is targeted for treatment? (Total cholesterol/LDL/HDL/ Triglycerides)	Fasting Total Cholesterol and Triglycerides	Total cholesterol, triglycerides, HDL/LDL.	LDL and triglycerides.
31. Which cholesterol lowering treatment is advised?	Simvastatin 10mg dly, regardless of cholesterol if CVD, HT, smoking, obese or >40 years.	Simvastatin 10mg dly: if CVD rslt >20%, eGFR <60, Known with DM <10years, age >40 years. Atorva if HIV (+) on lopinavir/ritonavir or atazanavir/ritonavir.	Simva; Atorva for special cases; Diet and fibrates for triglycerides.

	APC 2016/2017	APC 2019/2020	New guideline
32. What is the advised lipid treatment target?	Not mentioned, not for re-testing once on 10mg Simva.	No target. No re-testing.	Primary prevention: ≤ 2.5 ; Secondary prevention: ≤ 1.8 (LDL); Trigs: <1,8 (consult specialists mostly in Trigs)
33. Is HIV testing advised in DM patient or vice versa?	No. No mention in DM section of HIV testing, no mention in HIV section of DM screening.	No. No mention in DM section of HIV testing, no mention in HIV section of DM screening.	Yes: in patients with DM: confirm status, review ART types if already on treatment.
34. Is thyroid function testing ever advised? (under which circumstances?)	Not mentioned.	No	Yes, if difficult to control DM or Lipids.
VI. Miscellaneous topics			
35. What is the target Body Mass Index (BMI) for patients with DM?	<25, measure at each visit.	<25	<25
36. Is cancer screening discussed?	No	No	Yes, age appropriate
37. Are vaccinations recommended?	Not mentioned.	No	Yes, Influenza, PPSV23 and PCV13
38. Is smoking discussed?	No, only as part of CVD risk stratifying for statins.	No	Yes.
39. Point of care testing of HbA1C discussed?	No	No	No
40. Injection site inspection for lipohypertrophy discussed?	No	No	Yes.

	APC 2016/2017	APC 2019/2020	New guideline
41. What is the recommended route for insulin in an emergency?	MUST inject IM during hyperglycemic emergencies "to prevent hypokalaemia"	MUST inject IM during hyperglycemic emergencies "to prevent hypokalaemia"	iv/sc

APPENDIX Q Letter from Language Editor

19 August 2020

To whom it may concern

This is to certify that I lightly language-edited the mini-dissertation of Maria Magdalena Rossouw electronically using track changes and comments, excluding references and appendices. The author effected the changes. In this way, both linguistic excellence and the author's ownership of her text were ensured.

Sincerely

Dr Luna Bergh

Language and Writing Specialist

APPENDIX R Turn-it-In Report

A FEASIBLE DIABETES MANAGEMENT GUIDELINE FOR PRIMARY HEALTH CARE PRACTITIONERS IN THE FREE STATE FOR WORKPLACE LEARNING

by Maria Rossouw

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