# DEVELOPMENT OF AN INSTRUMENT TO ASSESS SELF-MANAGEMENT BARRIERS AMONG PATIENTS DIAGNOSED WITH TYPE 2 DIABETES IN RWANDA: A MIXED-METHOD STUDY

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**A thesis submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in fulfilment of the requirement for the degree of Doctor of Philosophy**

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## DECLARATION

I, Marie Claire Uwamahoro, declare that this research report (Human Research Ethics Clearance number **(M180432)** is my own work. It is being submitted for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

**Signed at Johannesburg**

On the 25 day of May 2021

## ABSTRACT

**Background:** There are several instruments to evaluate how type 2 diabetic patients perform self-management activities. However, little attention has been devoted to instruments assessing barriers that prevent patients from undertaking self-management activities.

**Aim:** The aim of this study was to develop an instrument to assess self-management barriers among patients with type 2 diabetes that can help health care providers, researchers and other stakeholders to understand the barriers of self-management in order to design appropriate interventions and give necessary support.

**Methodology:** A mixed-method approach using an exploratory sequential design was used. In the first phase, the study started with an integrative review from low-income countries and low-middle- income countries and a descriptive qualitative study conducted in 10 hospitals in Rwanda. They served to develop the new instrument. The content of the instrument was validated by 10 experts who established the Item Content Validity Index (I-CVI) and four patients who assessed the face validity. Similarly, 18 nurses and 2 medical doctors assessed its applicability in the clinical setting. In phase three, a descriptive cross section study was conducted and recruited 650 patients with type 2 diabetes from 10 hospitals to establish the construct validity. The Exploratory Factor Analysis (EFA) with Principal Component Analysis (PCA) was done to extract the appropriate number of factors.

**Findings:** The results of 25 articles from the integrative review and 23 individual interviews served to develop the pool of items. From an initial pool of 105 items, 63 were validated by experts with mean I-CVI ranging between 0.90-1. After the clinical utility study, one item was split into two bringing the number of items to 64. The EFA confirmed 51 items of Likert scale with 4 scores from strongly disagree = 1 to strongly agree = 4. The items loaded under nine factors explaining total variance of 53.8% with a factor loading ranging from .411- .710. The instrument was reliable with alpha Cronbach of .936 ranging from .601- .852 for each factor.

**Conclusion:** With regard to the results, the instrument developed was valid and reliable for assessing self-management barriers of type 2 diabetic patients in Rwanda. The findings of this research can help policy makers, researchers, health care providers and other stakeholders in planning, to enable the self-management activities as the most vibrant feature in diabetes management.



**Key words:** instrument, barriers, type 2 diabetes mellitus, self-management, Rwanda

## PRESENTATIONS ARISING FROM THIS STUDY

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## DEDICATION

I dedicate this thesis to:

My beloved husband Serge Nyirinkwaya for his support from the beginning to the end of this journey.

My beloved children Marie Faustine, Hervé and Ange Gabriella for their patience all the while I was away from home.

My late parents Evariste and Félicitée. You were my inspiration.

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## LIST OF ABBREVIATIONS AND SYMBOLS

BE-SEED2: Barriers to Self-management of type 2 Diabetes
BP : Blood Pressure
CHUB : Centre Hospitalier de Butare
CHUK : Centre Hospitalier de KIgali
CVI : Content Validity Index
DM : Diabetes Mellitus
DOQ : Diabetes Obstacles Questionnaire
DoQ-30 : Short version of the diabetes obstacles questionnaire
DSCB-OA: Diabetes Self-care Barriers in Older Adults
EBAS: Environmental Barriers to Diabetes-Regimen Adherence
EFA: Exploratory Factor Analysis
EFA: Exploratory Factor analysis
FPG: fasting plasma glucose
GNI: Gross National Income
HbA1: glycated hemoglobin
HIC: High Income Countries
I-CVI: Item Content Validity Index
KMO: Kaiser-Meyer-Olkin
LICs: Low Income Countries
LMICs: Low Middle Income Countries
MIC: Middle Income Countries
NCDs : Non-Communicable Diseases
PCA : Principal Component Analysis
PDDT: Patient-perceived difficulty in diabetes treatment
PDQ: Personal Diabetes Questionnaire
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QOL: Quality of life
r: correlation coefficient
S-CVI: Scale Content Validity Index
SMBG: Self-Monitoring of Blood Glucose
T1DM : Type 1 Diabetes Mellitus
T2DM : Type 2 Diabetes Mellitus
USA: Unites State of America

# CHAPTER 1: OVERVIEW OF THE STUDY

## 1.1 General introduction

People living with type 2 diabetes mellitus (T2DM) find themselves in a situation where they have to adopt a new lifestyle related to the nature and course of their disease. As T2DM is a chronic disease, patients are absolutely at the front line in management of the disease. For example, they will have to learn some medical skills like measuring blood glucose; they must learn how to adjust their diet; they will need to learn how to prevent complications as the illness progresses. All these different tasks can be referred to as self-management.

Given the complexity of T2DM, it is not surprising that patients find optimal self-management difficult to achieve, especially in low-income countries (LICs) and low- middle-income countries (LMICs) where there is a high incidence of low levels of literacy. Health care providers will only be able to identify the areas in which support is needed if they include the assessment of barriers to self-management in their daily routine care. This will be impossible without an appropriate instrument, the development of which is the overall purpose of this thesis. The development process will be done using a mixed-method approach with an exploratory sequential design (Creswell, 2009).

Chapter one introduces the reader to the background information on T2DM and self-management, the problem statement, the significance of the study, the research question, the purpose and objectives of the study, the conceptual framework and definitions. The chapter ends with the organisation of the thesis.

## 1.2 Background of the study

The prevalence of global diabetes mellitus (DM) was projected at 9.3 % i. e 463 million people in 2019, rising to 10,2 % i.e. 578 million by 2030 and 10.9 % i.e 700 million by 2045 (Saeedi *et al.*, 2019). The World Health Organization (WHO) revealed that DM was the seventh leading cause of death in 2016 (World Health organization, 2016)) where 46 % of diabetes-related deaths were attributed to LICs and LMICs. DM is categorised into two types; type 1 (T1DM) and T2DM. T2DM occurs most frequently worldwide and accounts for more than 90% of all diabetes cases in sub-Saharan Africa (American Diabetes Association, 2009; Hall *et al.*, 2011). It is a chronic metabolic non-communicable disease (NCD) characterised by high blood glucose as a result of decrease in insulin production or insulin resistance (Ozougwu *et al.*, 2013).

T2DM is increasing in Rwanda. In 2014, 2,044 new cases were reported by the Ministry of Health Annual Health Statistics Booklet and increased to 3,490 cases in 2015 (Ministry of Health, 2016). The distribution according to urban and rural areas was not specified in the same booklet but some studies done showed that T2DM is a burden in both areas. A study by Tapela *et al.*(2016) conducted in the department of internal medicine of Butare Referral Hospital revealed that DM is among the major five causes leading people to seek health care and T2DM accounts for 86.4 % of all cases of diabetes in this unit. Another study reporting on the treatment of NCDs in rural areas indicated that diabetes is among 4 common NCDs with the majority of cases being T2DM cases (Tapela *et al.*, 2015).

Currently, the medical treatment of T2DM diabetes includes oral anti-diabetic medications or insulin therapy which can be administered to some T2DM patients whose diabetes cannot be controlled with oral diabetic medication (American Diabetes Association, 2019a). The overall goal of T2DM management is to maintain an optimal level of blood glucose (glycaemic control) to prevent or delay complications (Mancuso, 2015). As a life-long disease, treatment efficiency requires active participation by the patient in self-management activities which include which include adherence to self-medication(s), self-monitoring of blood glucose (SMBG) , healthy dietary practice, regular physical exercise, foot care and prevention of acute complications (Shrivastava, Shrivastava and Ramasamy, 2013). Thus, self-management represents the most important component of T2DM care and has a positive effect on glycaemic control and prevention of the complications of diabetes (Gao *et al.*, 2013).

Despite the importance of self-management, living with a life-long disease is challenging (Houtum, Rijken and Groenewegen, 2015). Patients are expected to assume roles that were initially carried out by trained health care providers and they may find it difficult and complex (Alrahbi, 2017). In addition, frustration may arise from other things such as lack of knowledge as regards self-management activities, financial constraints, lack of social and family support and other diabetes management complexities (Belue *et al.*, 2016; Foley and Belue, 2016; Musenge *et al.*, 2016).

Maintaining balance in the self-management of T2DM is an ongoing process. Subsequently, the needs and support for T2DM patients can change during illness and the course of life (Nam *et al.*, 2011). At times, patients may face medication adherence barriers, while at other times they may face barriers in changing their diet or understanding the information that has been given by health providers(Nam *et al.*, 2011). Besides, barriers accountered in self-management vary across individuals and context of which they live (Houtum, Rijken and Groenewegen, 2015). In the past decades research indicated that up to 40% of people diagnosed with T2DM fail to adhere to self-management activities (Perez, Alarez and Dilla, 2013) and a recent study by Bagonza, Rutebemberwa and Bazeyo (2015) showed that around 28.9% of patients living with T2DM in sub-Saharan Africa, do not properly adhere to self-management activities.

With this in mind, attention to and assessment of current barriers should be incorporated into disease management plans (Boateng, Neilands and Frongillo, 2018a). For this to happen, some studies, for example Ramezankhani *et al. (*2015) call for patient-centred mechanisms and advocate for an instrument that can identify essental areas related to individual barriers to self-management and thus requiring improvement through education and support.

### 1.3 Problem statement

A study conducted at Rwanda's national teaching hospital in Kigali found significant morbidity and complications among admitted and ambulatory diabetes patients (Rudasingwa, Amendezo and Twagirumukiza, 2012). It was also discovered that approximately 1,918 diabetes patients die per year due to macro and microvascular complications (Rudasingwa, Amendezo and Twagirumukiza, 2012; Rwanda Diabetes Association, 2015).

Self-management is related to T2DM outcomes (glycaemic control and management of complications) and strongly influences morbidity and mortality rates of patients diagnosed with T2DM (Schunk *et al.*, 2015). Despite this, the adherence to self-management activities in Rwanda is low. The barriers identified were low levels of knowledge and functional health literacy and illness perceptions (Nsereko *et al.*, 2013). These barriers were identified using instruments to assess how patients perform self-management and self-management barriers were measured as associated factors (Kamradt *et al.*, 2014; Lu, Xu and Zhao, 2016a).

Locally, an instrument that can be used specifically for that purpose is non-existent. The same case applies to the broader literature; there are no instruments for assessing self-management barriers as the main outcome in LICs and LMICs. It is critical that health providers learn which barriers hinder self-management and therefore, development of instruments to use routinely with high risk and high cost illnesses, such as T2DM, are needed (Ramezankhani *et al.*, 2015).

### 1.4 Significance of the study

In this study an instrument was developed and pilot tested to assess self-management barriers of patients diagnosed with T2DM in Rwanda. The instrument will enable the health care providers to implement patient-centered strategies through education and other available and relevant support which can be designed and implemented. This will contribute to a reduction in and delay of T2DM complications that are related to poor adherence and self-management activities, and ultimately a decrease in the mortality and morbidity of patients with T2DM. The new instrument, being the first to be developed in Rwanda and in the region, will contribute to the existing literature in the field of diabetes self-management and may be used by other researchers for future studies.

### 1.5 Research question

How can an instrument be developed to measure self-management barriers among patients diagnosed with T2DM in Rwanda?

### 1.6 Purpose of the study

The purpose of this study was to develop an instrument to assess self-management barriers among patients diagnosed with T2DM in Rwanda.

## 1.7 Phases of the study

The study was conducted in three phases. Each phase had its distinctive aims and objectives:

### 1.7.1 Phase 1

The aim for phase one was to conceptualise the construct of self-management and barriers. The objectives for this phase were:

- To explore current barriers to self-management of patients diagnosed with T2DM in low and middle-income countries through an integrative review
- To explore barriers to self-management of patients diagnosed with T2DM in Rwanda.

### 1.7.2 Phase 2

The aim for phase two was to develop a new instrument. It had two objectives:

- To identify a pool of items for the development of a new instrument to assess self-management barriers among T2DM patients.
- To design and refine items of the new instrument.

### 1.7.3 Phase 3

Phase 3 had the aim of validating and pilot testing the newly developed instrument and had two objectives:

- To describe the content validity of the newly developed instrument (using experts, patients and clinicians).
- To establish the construct validity of newly developed instrument.

## 1.8 Conceptual framework of type 2 diabetes mellitus self-management

The study adapted and applied the conceptual framework by Zeng *et al.* (2014) regarding T2DM self-management in Chinese Immigrants, United State of America (USA).

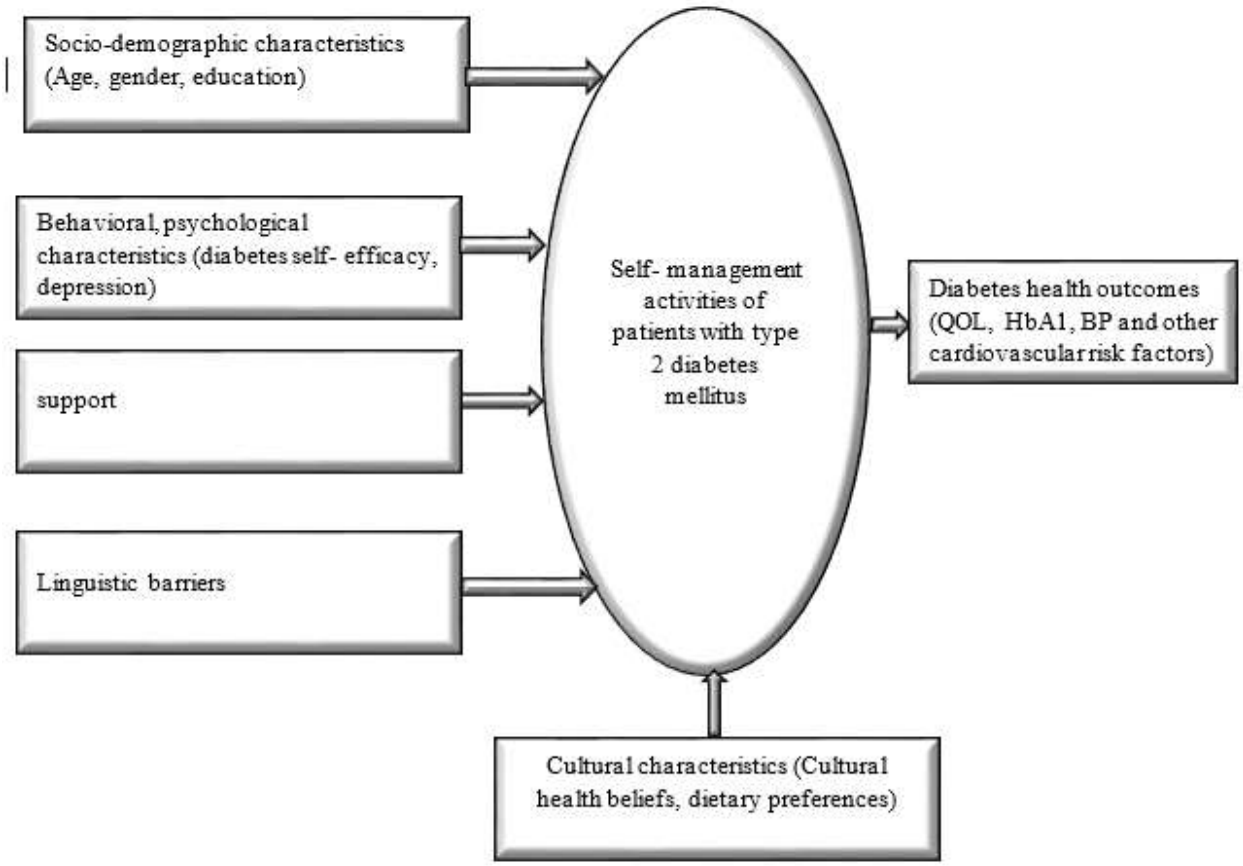


**Figure 1.1.: The original conceptual model for self-management of type 2 diabetes mellitus**

This conceptual model underlines the important role of self-management in predicting T2DM outcomes in a certain culture. The original model of Zeng *et al.* (2014) has seven key interrelated components which are: socio-demographic characteristics, behavioural and psychological characteristics, cultural characteristics, linguistic barriers, support, T2DM self-management and diabetes outcomes. The model assumes that the first five components impact on T2DM self-management which can predict diabetes outcomes. Even though this model is adopted from a HIC (USA), it is flexible as it does not prescribe specific cultural beliefs but rather has a component for cultural characteristics. This means that any cultural group can add their specific cultural beliefs in the model.

In the current study, the components of this model served as a lens to the structure of the integrative review and interview guide as well as the qualitative data analysis to find different barriers to self-management of T2DM. After being adapted, it also served to determine the content domain of the instrument.

The concepts of the conceptual framework are explained below:

### 1.8.1 Type 2 diabetes mellitus self-management

Self-management involves complex and comprehensive skills that patients with T2DM must learn to evaluate and integrate a variety of activities into their daily life to successfully perform self-management (Gasgow and Anderson, 1999). Most T2DM treatment relies on the ability of patients to perform these self-management behaviours correctly (Zeng *et al.*, 2014). Based on literature, T2DM self-management has been found to be critical to achieve good management of diabetes (Xu, Pan and Liu, 2011).

### 1.8.2 Socio-demographic characteristics

Different socio-demographic characteristics are described in the literature to influence self-management such as age, income and education (Xu, Pan and Liu, 2010).

### 1.8.3 Behavioural and psychological characteristics

Behavioural characteristics refer to motivation that a patient with T2DM can have to adhere to the medical and lifestyle regimen (Moss, 2014). Psychological characteristics refer to depression which is not uncommon in T2DM (Zeng *et al.*, 2014). Furthermore, people with sysmptoms of depression are unlikely to comply with appropriate self-management activities such as engaging in physical activities, taking drugs and adjusting diet (Mukeshimana and Mchunu, 2017).

### 1.8.4 Support

Support refers to assistance needed for "implementing and sustaining coping skills and behaviours needed to self-manage on an ongoing basis" (Powers *et al.*, 2016; p.1373). The support may be social, family, financial and may also come from health system (Powers *et al.*, 2016).

### 1.8.5 Cultural characteristics

This consists of health beliefs and dietary practices among the population.

### 1.8.6 Linguistic barriers

Language may be a barrier in understanding given instructions or a barrier to communication

### 1.8.7 Diabetes outcomes

Glycated hemoglobin (HbA1c), an index of glycaemic control that has been the best for years allows to show DM outcome. It is to be noted that international guidelines generally suggest that it should be either <6.5% or <7.0% (Saudek and Brick, 2009).

## 1.9 Conceptual definitions

### 1.9.1 Self-management

T2DM self-management activities in this study include foot care, diet, physical activity, medication adherence, and self-monitoring of blood glucose.

### 1.9.2 Low-income countries

In this study the definition of low-income economies was based on the Gross National Income (GNI) per capita, of $1,025 or less (World Bank, 2018) (ANNEXURE 1).

### 1.9.3 Low- middle-income countries

According to the World Bank (2018), lower middle-income countries are defined based on a GNI per capita between $1,026 and $4,035 (ANNEXURE 1).

### 1.9.4 Barriers

In this study a barrier is defined as any self-reported obstacle that hinders a patient diagnosed with T2DM diabetes in the performance of self-management activities.

### 1.9.5 Health care provider

In this study a health care provider is any health professional working in a clinical or hospital setting.

## 1.10 Organisation of the thesis

The thesis has nine chapters as described in Table 1.1

**Table 1.1: Organization of the thesis**

| Chapters | Content |
|---|---|
| **Chapter one:** Overview of the study | Introduction and the background of the study |
| **Chapter two**: Literature review | Literature review on diabetes, self-management and instruments that assess self-management barriers |
| **Chapter three**: Research methodology | Philosophic worldview, study setting or study context, study design, description and the summary of methods |
| **Chapter four**: Self-management barriers experienced by adult patients with T2DM in LICs and LMICs: an integrative literature review | Detailed methods and results of integrative review |
| **Chapter five**: Understanding self-management barriers experienced by adult patients with T2DM in Rwanda: a qualitative study | Detailed description of methods and results of individual interviews with adult patients in the self-management of T2DM in Rwanda to identify barriers |
| **Chapter six**: Development of an instrument to assess self-management barriers of patients with T2DM | Description of instrument development as well as the instrument itself |
| **Chapter seven:** Content validity of an instrument to assess self-management barriers of patients with T2DM | Description of steps taken to investigate the CV of the new instrument |
| **Chapter eight**: Investigation into construct validity of the instrument | Description of the process of construct validity |
| **Chapter nine:** Summary of main finding, conclusion and recommendations | Summarises the main results of the study, concludes and makes recommendations |

## 1.11 Conclusion

This chapter introduces the study and gives a description of T2DM and self-management in the Rwandan context. It includes the problem statement and the the purpose of the study. Objectives of different study phases are also presented in this chapter. Furthermore, the significance of the study and the conceptual definitions are discussed. Chapter one ends with a table that outlines the organisation of the thesis. In Chapter two, the literature review will be presented.

# CHAPTER 2: LITERATURE REVIEW

## 2.1 Introduction

There is a growing body of literature documenting the importance of self-management in the management of T2DM (Schillinger *et al.*, 2002; Bains and Egede, 2011; van der Heide *et al.*, 2014; Reisi *et al.*, 2016). However, more emphasis needs to be dedicated to support for patients with self-management barriers because their adherence to self-management is frequently low and this puts them at a higher risk of developing complications (Yamashita and Kart, 2011; Walker *et al.*, 2014; Abreu *et al.*, 2017; Zuercher, Diatta and Burnand, 2017). This chapter provides insight into diabetes descriptions, the self-management concept, T2DM and its complications, self-management with T2DM in particular and related barriers. This is followed by a description of instruments used to measure self-management barriers of T2DM patients and finally, a conclusion.

Electronic databases used include, PubMed, CINAHL, SCOPUS Science direct, Google Scholar and PsycInfo. The search was done between January 2008 and December 2018 although the literature was updated during the study. To source the literature, a combination of the broad key terms joined by Boolean "AND" and "OR" was used to conduct the search as follows:

(1) ("self-management" OR "self-care") AND "concept analysis"

(2) (barriers OR obstacles) AND ("self-management OR "self-care") AND, "type 2 diabetes".

(3) (instrument OR tool) AND (barriers OR obstacles) AND (self-management" OR "self-care") AND, "type 2 diabetes".

(4) ("systematic review" OR review) AND (instrument OR tool) AND ("self-management" OR "self-care") AND, "type 2 diabetes".

## 2.2 Definition and classification of diabetes mellitus

DM is a well known metabolic disease characterised by high levels of blood glucose resulting from a deficiency of pancreas b-cells and consequently compromising insulin actions, i.e. secretion of insulin, action of insulin or both) (Spellman, 2010; American Diabetes Association, 2010).

DM can be classified under four categories: The first category includes T1DM linked to autoimmune b-cell destruction and characterised by total insulin deficiency (Ozougwu *et al.*, 2013). The second category is known as T2DM and follows a progressive loss of b-cells, causing insulin resistance (Kahn, Cooper and Prato, 2014). The third category, gestational diabetes mellitus (GDM), is induced by pregnancy and frequently observed in the last trimesters of pregnancy (Kahn, Cooper and Prato, 2014). The last category includes other types of DM emanating from different causes, for example, HIV/AIDS medication, chemicals like glucocorticoid use and organ transplantation (American Diabetes Association, 2019b). This study focuses on T2DM that has proved to be most prevalent.

### 2.3 Pathophysiology of type 2 diabetes mellitus

Every day, during digestion, the so-called β cells of the pancreas in human beings, specifically in the islets of Langerhans, release about 40 – 51 U of insulin into the bloodstream (Lewis *et al.*, 2014). Insulin is said to mainly regulate and maintain the glycaemia acceptable levels of 70 to 120 mg/dl (Lewis *et al.*, 2014). When the levels of glucose increase, the insulin, as an anabolic hormone enables the storage of glucose as glycogen in the liver; the stored glucose will then be released when the the plasma levels of glucose decrease (American Diabetes Association, 2019b).

There are many insulin-dependent tissues in the human body. These tissues are mainly found in adipose tissue and skeletal muscle and contain insulin receptors (Yamashita and Kart, 2011; Olson, 2012; Lewis *et al.*, 2014; Walker *et al.*, 2014; Abreu *et al.*, 2017; Zuercher, Diatta and Burnand, 2017). The receptors are unlocked once insulin is released and facilitate the transport of glucose inside the cell for generating energy needed by the organism (Olson, 2012; Lewis *et al.*, 2014). Hormones like glucagon, growth hormones, epinephrine and cortisol commonly known as counter regulatory hormones oppose the activity of insulin (Kashan, Alta and Albayati, 2018; Rhyu *et al.*, 2019). Normally the blood glucose levels in the bloodstream are maintained by the activity of insulin and its counter regulatory hormones (Kahn, Cooper and Prato, 2014).

Unlike in T1DM, the pancreas in T2DM does not lose its total functioning capacity. It does secrete endogenous insulin but not in sufficient amounts to maintain blood glucose levels within normal ranges (Skyler *et al.*, 2017).

The actual problem is the resistance to insulin of the tissues mentioned above; thus, the difference between T1DM and T2DM resides in the presence of endogenous insulin in T2DM (Williams and Hopper, 2015). However, as the disease progresses, the literature has shown that a patient with T2DM may also need insulin as a result of pancreas deficiency.

Factors contributing the the onset of T2DM include obesity mainly abdominal and visceral adiposity, drugs, heredity and comorbidity (Zheng, Ley and Hu, 2018).

### 2.4 Clinical manifestations and diagnosis of type 2 diabetes mellitus

A person with T2DM may be asymptomatic for a long time and T2DM is sometimes called a "silent killer"; the diagnosis revealed only when complications have already arisen (Campbell 2001; World Health organization 2016). The classic symptoms shown in the literature include polyuria, polydipsia, and polyphagia (Lewis *et al.*, 2014; Skyler *et al.*, 2017; Zheng, Ley and Hu, 2018). There are additional symptoms like vision disturbances, recurrent infections, fatigue, candida infections and prolonged wound healing (Lewis *et al.*, 2014; Skyler *et al.*, 2017; Zheng, Ley and Hu, 2018).

According to the American Diabetes Association (2020), the diagnosis of diabetes mellitus can be made through one of the following four methods: (1) glycated hemoglobin (HbA1c) of 6.5% or higher, (2), fasting plasma glucose (FPG) level greater than or equal to 126 mg/dL (7.0 mmol/L), (3) two-hour plasma glucose level greater than or equal to 200 mg/dL (11.1 mmol/L) and (4) a random plasma glucose greater than or equal to 200 mg/dL (11.1 mmol/L) in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis. The prediabetes diagnosis is made by a FPG of 5.1 mmol/L HbA1c of 5.0% (31 mmol/mol) (Lee *et al.*, 2019).

### 2.5 Complications of poorly managed diabetes

The complications of diabetes can be classified into 2 categories; acute complications and chronic complications (Lewis *et al.*, 2014). Hypoglycaemia, hyperglycaemia and hyperosmolar hyperglycaemic syndrome, diabetic ketoacidosis (DKA) are among the acute complications.

Chronic complications include angiopathy, diabetes retinopathy, neuropathy, nephropathy, foot problems, integumentary complications and recurrent infection (Lewis *et al.*, 2014; Skyler *et al.*, 2017; Zheng, Ley and Hu, 2018).

In addition to the physical complications, T2DM is associated with psychological issues linked to serious chronic health complications and change in routine habits (Lewis *et al.*, 2014). Studies have shown that T2DM can be associated with emotional stress and depression that may decrease patients' adherence to self-management activities (Gopichandran *et al.*, 2012; Nsereko *et al.*, 2013; Jackson *et al.*, 2015). Thus, diabetes management is a complex process and various aspects must be considered when planning interventions (Zheng, Ley and Hu, 2018).

## 2.6 Management of type 2 diabetes mellitus

The management of diabetes requires multifactorial strategies including medication, self-management activities like a healthy diet, physical exercise and other behaviours (American Diabetes Association, 2020). From this perspective, it is clear that an active partnership between the health care provider and the diabetic patient will be imperative.

### 2.6.1 Medication of type 2 diabetes mellitus

There are different medications for the treatment of T2DM and the American Diabetes Association (2020) sets out some recommendations to be followed but suggests that countries should adapt the recommendations based on contextual realities. Considerations include cardiovascular comorbidities, hypoglycaemia risk, impact on weight, cost, risk for side effects and patient preferences (American Diabetes Association, 2020). Metformin is the preferred initial pharmacologic agent for the treatment of T2DM. Early combination therapy can be considered in some patients at treatment initiation with the aim of extending the time before treatment fails (American Diabetes Association, 2020). The medication regimen and medication-taking behaviour should be re-evaluated at regular intervals (every 3–6 months) and adjusted as needed (American Diabetes Association, 2020).

### 2.6.2 Self-management of type 2 diabetes mellitus

#### 2.6.2.1 An overview of the concept of self-management

Starting mid-1900s, there was a shift in disease patterns during which the world found itself moving from acute to chronic diseases including T2DM. This prompted the need for people to take a lead and responsibility in the management of their own health (Wilkinson and Whitehead,

2009a). Despite their preventable risky behaviours, chronic diseases create a global and huge financial burden and account for a high percentage of all health care spending. Therefore, self-management became the cornerstone in the prevention of those risky unhealthy behaviours (Kawi, 2012).

There is confusion between terms synonymous with self-management such as self-care and a consistent definition for differentiating between them has not been demonstrated in the literature. Some scholars prefer the word 'self-care' (Piwonka and Merino, 1999), to 'self-management' (Legorreta, Leung and Berkbigler, 2000) to mean essentially the same thing.

Self-care in the area of health was first defined back in 1983 by WHO as follows; "the activities individuals, families and communities undertake with the intention of enhancing health, preventing disease, limiting illness, and restoring health" (Webber, Guo and Mann, 2013). Later in 1998, the WHO updated the definition to become more specific in several areas of self-care and more emphasis was placed on the responsibility of the patient in self-care and clearly stated; "Self-Care is what people do for themselves to establish and maintain health, and to prevent and deal with illness" (Webber, Guo and Mann, 2013). This updated definition included a detailed explanation of related concepts, namely hygiene (general and personal), nutrition (type and quality of food eaten), lifestyle (sporting activities, leisure etc.), environmental factors (living conditions, social habits, etc.), socio-economic factors (income level, cultural beliefs, etc.) and self-medication (Webber, Guo and Mann, 2013).

Again in 2009, the WHO revised its definition and added an important element of self-care, namely independence. However, considering the nature of most chronic diseases, this definition of self-care was criticised and found unsuitable for management of a chronic disease seen that efficient management cannot be achieved without external support(Wilkinson and Whitehead, 2009b). Meanwhile, compared to self-care, self-management was associated with independence in conjunction with multifaceted units like family, community and health care providers, to successfully manage the physical, psychosocial, cultural and spiritual aspects of a long-term chronic disease (Wilkinson and Whitehead, 2009b). Therefore, self-management considers the autonomy of the person in need, but continuous support from family and health professionals are essential (Wilkinson and Whitehead, 2009b).

In some literature self-care was presented as a complex concept with two interrelated elements: the first one being the capability for health and secondly, as a process for health and health development. As health capability, self-care refers to action capability, more akin to the description of self-management; as a process, self-care refers to an individual health development process related to illness and well-being (Wilkinson and Whitehead, 2009b).

Therefore, since the intention of the current study was to look into self-care activities, the researcher chose to use self-management and retained the idea of Richard and Shea (2011) who argue that self-management is more specific than self-care and embedded in the broad concept of self-care which is an elusive and complex term.

Lorig and Holman (2003) operationalised self-management in chronic illness in terms of tasks and skills with self-efficacy for patients to make decisions and engage in behaviours toward managing their chronic illness state. It is influenced by a variety of individual characteristics, physical limitations, knowledge, environment, financial status, need for social and emotional support and multiple realities with medications. Self-management is affected by health care systems, policies and health care providers who are not trained in the management of chronic care complexities (Kawi, 2012). Culture and context are also associated with self-management. Slamah *et al*. (2020) highlight that cultural and context adaptation of self-management barriers of T2DM should be taken into consideration before designing and planning specific interventions.

#### 2.6.2.2 Type 2 diabetes mellitus self-management activities

Analysing the broad literature related to self-management and diabetes, common elements in the definitions across various healthcare disciplines include recognition that self-management involves the ability to make decisions and perform actions, thus acknowledging autonomy of the patient. It includes different activities that may vary. Gopichandran *et al.* (2012) revealed that self-management includes activities such as diet, exercise, monitoring of the disease, drug adherence, positive coping skills, problem-solving skills and risk-reducing behaviours.

However, in their studies, some behaviours became difficult to measure and only four of these behaviours were studied, namely adherence to diet, blood glucose monitoring, adherence to medication and exercise.

According to a recent systematic review on the adherence to diabetes self-management behaviour in low- and middle-income countries, the common self-management behaviours that were assessed were diet, exercise, SMBG, medication use and foot care (Mhpe *et al.*, 2019). Self-management guidelines are freely available for persons with T2DM and clearly described (American Diabetes Association 2019).

For example, physical activity, walking (150 min/week) is the most popular choice and has been shown to reduce the relative risk of T2DM by 60% (American Diabetes Association 2019). Recommendations regarding diet include counting the number of carbohydrates, reducing total fat in a meal and increasing food rich in fibre based on food accessibility (American Diabetes Association 2019). In addition, patients should avoid red meat and replace it with white meat. Literature showed that self-monitoring of glucose can give baseline information according to which self-management activities can be adjusted and should be performed at least once daily coupled with glycated haemoglobin (A1C) at least twice per year (Pinzur et al. 2005; American Diabetes Association 2019). Feet should be inspected at every visit for patients with evidence of sensory loss or prior ulceration or amputation and comprehensive foot evaluation for others at least annually to identify risk factors for ulcers and amputations (American Diabetes Association 2019). Medication should be taken according to prescription by the health care providers and should be combined with other self-management activities (American Diabetes Association 2019).

#### 2.6.2.3 Type 2 diabetes mellitus self-management barriers

Although guidelines for self-management of diabetes are available, it does not mean it is easy for all to adhere to them and to incorporate them into their daily lives. Difficulties with diabetes self-management activities are found across all age groups and shifting from one life style to another like changing food habits and exercise would be challenging for most individuals (Kawi, 2012). Some patients may do it adequately, others scarcely, but most of the time, there are certain barriers to self-management.

A qualitative study using a descriptive phenomenology design by Putra Yasa *et al.* (2018) in Indonesia showed three barriers to self-management; lack of knowledge of diabetes management, lack of glycaemic control and management of complications of diabetes.

However, in this study self-management was not clearly defined to understand which activity or dimension of self-management was most affected.

In a qualitative study done in Portugal to assess the facilitators, barriers and expectations in the self-management of T2DM (Laranjo *et al.*, 2015), self-management was not defined. However, the results revealed that participants had barriers that were grouped into three themes which are diet, physical exercise and glycaemic control. Participants of the study expressed that diet was the most problematic barrier. Healthy food was expensive and they struggled to implement dietary requirements in their daily eating patterns. Regarding physical exercise, the barriers were motivation and co-morbidities making exercise hard. Glycaemic control was affected by anxiety and lack of understanding regarding sudden blood sugar rises. Information and knowledge and family and social support cut across the barriers of diet, physical exercise and glycaemic control.

In a qualitative study done in Canada by Banasiak *et al.* (2020), participants struggled with adhering to dietary recommendations and the costs of medications and supplies. Although participants pointed to issues of stigma, challenges with physical activity, relationships with their health care providers, the struggles with diet and cost were most prevalent in the interviews. However, the dimensions of self-management measured, were not stated.

Another qualitative study done in Senegal, Africa by Belue *et al.* (2013) indicated that financial challenges related to accessing medical care and adhering to the prescribed diabetic diet were the main barriers to diabetes management. Family dynamics served as both supportive and inhibiting forces that influence the aforementioned barriers. A cross-sectional quantitative study conducted in Rwanda by Mukanoheli *et al.* (2020) among T2DM patients at a Teaching University Hospital in Kigali, investigated the association between functional health literacy and self-care behaviours (diet, foot care, blood glucose testing, exercise and smoking). It was concluded that less self-care behaviours were performed by those with low functional health literacy. However, the study sample was relatively small (n=233) and conducted in one hospital.

The literature has shown that the majority of studies assessing barriers of self-management are qualitative in nature (Pun, Coates and Benzie, 2009; Sohal *et al.*, 2015; Foley and BeLue, 2017; Putra Yasa *et al.*, 2018; Slamah *et al.*, 2020). This is probably due to the lack of instruments that assess self-management barriers as the main construct. There are, however, quantitative studies

that used statistical methods to identify barriers of self-management as associated factors (socio-demographic characteristics, depression, illness perception, self-efficacy) but not as the outcome (Nsereko *et al.*, 2013; Basu *et al.*, 2015; Mukeshimana and Mchunu, 2017). There is an urgent need to develop and validate instruments that can be used to assess barriers to self-management.

#### 2.6.2.4 Instrument for self-management barriers for type 2 diabetes mellitus

This section describes the globally existing instruments on self-management barriers in T2DM found in literature.

A systematic review conducted by Lu, Xu and Zhao (2016a) to examine the characteristics and psychometric properties of the instruments used to assess self-care behaviours among persons with T2DM between 1990 – April 2014, came up with 30 instruments identified in 75 articles published in English. The study considered both instruments measuring more than one dimension of self-management (21 instruments) and those measuring a single dimension (nine instruments). However, among 30 instruments, none of them assessed the barriers to self-management. The review also concluded that instruments had been applied to studies with incomplete psychometric profiles and insufficient explanation of scoring.

Another systematic review was conducted by Caro-bautista, Mart and Morales-asencio (2013). It was undertaken to retrieve published studies about instruments for evaluating self-care behaviours or barriers to diabetes self-care in T2DM from January 1990 – December 2012. The review did not take into account instruments that explored only partial (single) dimensions of living with diabetes. The review included 16 instruments that met all the inclusion criteria. Of the 16 only four assessed barriers of self-management, namely the Environmental Barriers to Diabetes-Regimen Adherence (EBAS, 60 items) (Irvine *et al.*, 1990), the Diabetes Obstacles Questionnaire (DOQ, 77 items) by Hearnshaw *et al.* (2007), Diabetes Self-care Barriers in Older Adults (DSCB-OA, 12 items) by Tu, Barchard and Tu (1993) and Patient-perceived difficulty in diabetes treatment (PDDT) scale by Tamir *et al.* (2012).

#### 2.6.2.4.1 The Environmental Barriers to Diabetes-Regimen Adherence instrument

The "Environmental Barriers to Diabetes-Regimen Adherence **(**EBAS)" is a 60-item scale with four sub-scales (factors); medications (13 items), diet (18 items), glucose testing (13 items) and exercise (16 items). Responses to each item are recorded on a five point Likert scale ranging from 1 (never) to always (5), developed by Irvine *et al*. (1990) in Virginia, United States of America (USA). The instrument was tested for content validity, criterion validity, discriminant validity, internal consistency and test-retest reliability. The discriminant validity (construct validity) was only assessed by correlating the EBAS with other instruments; no factor analysis was conducted and therefore the reliability of sub-scale has not been validated. In addition to that, the instrument was validated using a small sample size (214) with type 1 diabetes mellitus (T1DM) and T2DM without distinction between the two types. Although the content and face validity were assessed by health professionals the results of the experts' agreement were not presented. The instrument only assessed the environmental barriers and excluded social and emotional barriers.

#### 2.6.2.4.2 The Diabetes Obstacles Questionnaire

The "Diabetes Obstacles Questionnaire (DOQ)" was developed by Hearnshaw *et al.* (2007) in the United Kingdom (UK), It has 77 items, Likert Scale with five categories (strongly disagree =1 strongly agree = 5). It measures eight dimensions of self-management; medication, self-monitoring, knowledge and beliefs, diagnosis, relationships with healthcare professionals, lifestyles changes, coping and advice and support. Regarding the validation process, the instrument employed content validity, criterion validity, construct validity and internal consistency. The content validity was assessed by 21 professionals and unidentified lay persons through extensive feedback. However, the mean of agreement on the items was not specified. The construct validity used a sample of 176 T2DM patients. The instrument was developed in a high-income country (HIC) and there were many items with non-specific activities of self-management. For example, the self-monitoring dimension is not specific and it is not clear how it differs from the entire spectrum of self-management. The process of how the items were chosen by the researchers' team before starting the validation process is not well described.

#### 2.6.2.4.3 Diabetes Self-care Barriers in Older Adults instrument

The "Diabetes Self-care Barriers in Older Adults (DSCB-OA)" instrument measures three dimensions of self-management; diet, exercise, and blood glucose monitoring barriers with 12 items without any specified scale for measurement. It was developed by Tu, Barchard and Tu (1993) in the United Kingdom, a HIC. The instrument was validated for content validity, construct validity, internal consistency and interrater reliability. The sample was small with 149 participants and the validation included both T1DM and T2DM participants. The instrument did not include items on medication and foot care and it is not clear how the members of the research team decided on the items. The instrument was also limited to the elderly from 55 years old and above.

#### 2.6.2.4.4 Patient-perceived difficulty in diabetes treatment scale

The "Patient-perceived difficulty in diabetes treatment (PDDT) scale" was developed in Israel by Tamir *et al.* (2012) with one factor including self-care, drug, management, glycaemic self-monitoring, diet, relation with health providers and costs. It has 12 items Likert Scale with five categories (1= very difficult, 5 = not difficult at all). It was validated for content validity, criterion validity and construct validity. The internal consistency was not assessed with a sample of 984 participants. However, the validation process used both T1DM and T2DM patients. The detail of items generation was not described by the researchers' team.

Apart from the instruments identified in the systematic reviews, scrutiny of different databases named in the introduction of this chapter, yielded three additional instruments which are discussed below.

#### 2.6.2.4.5 A scale of perceived barriers to self-care in patients with type 2 diabetes mellitus

This "scale of perceived barriers to self-care in patients with T2DM" is a 11- item with a point 5 Likert scale (1 = strongly agree, 5 = strongly disagree) developed by Ramezankhani *et al.* (2015) It included 400 patients with T2DM who were covered by the health centres in Isfahan (Iran) in 2015. The validation was done for content validity, construct validity and internal consistency. After EFA, 11 items fell into three factors (lateral effects, facilities and resources, patient's diagnosis barriers). However, the items are too general and one item would include two outcomes. The development process of the scale was not clearly documented.

#### 2.6.2.4.6 The short version of the diabetes obstacles questionnaire

The "short version of the diabetes obstacles questionnaire (DoQ-30)" is a short form of the Diabetes Obstacles Questionnaire (DOQ-77) discussed above. It was developed by Pilv *et al.* (2016) analysing data from six HIC countries in Europe; Belgium, France, Estonia, Serbia, Slovenia, and Turkey. The selection of items for the short version of the DOQ was achieved with construct validity. The instrument reduced the number of items from the original instrument (from 77 items to 30 items) but in the process, essential items related to financial constraints and cultural aspects were lost.

#### 2.6.2.4.7 The Personal Diabetes Questionnaire

The **"**Personal Diabetes Questionnaire (PDQ)" was developed by Stetson *et al.* (2011) in the USA, a HIC. It has two parts. The first part describes diabetes self-care behaviours under four major domains: (1) nutritional management, (2) medication utilization problems, (3) blood glucose, monitoring, and (4) exercise and physical activity, and the second part describes the barriers to self-care behaviours. The instrument was reviewed by multidisciplinary diabetes care providers and items subsequently revised until the measure provided complete coverage of the diabetes care domains using as few items as possible. However, the content validity index indicating the experts' agreement was not calculated. To design the items for self-care behaviours barriers, two local qualitative studies were used (Schlundt, Pichert, *et al.*, 1994; Schlundt, Rea, *et al.*, 1994). However, those two qualitative studies only covered the obstacles of diet adherence and one of them assessed dietary barriers in adolescents but in the validation process they only recruited adults from USA. The instrument was put through other validation processes such as construct validity and criterion validity with a sample of 790 adults; 205 with type 1 and 585 with T2DM in the USA. The study setting was limited to a single clinic, mainly servicing patients with high incomes and high levels of education. The number of items was not clearly stated.

#### 2.6.2.4.8 Summary of the instruments for type 2 diabetes mellitus barriers to self-management

Table 2.1 provides a summary of the instruments described above. It indicates the country and the level of income. These are imperative considerations as it is assumed that barriers to self-management differ from country to country.

Sample sizes of the validation of the instruments were also considered since results are unreliable if the sample is too small. Reliability and validity aspects were noted if the information was available as this would assist the researcher in avoiding poor design when developing a new instrument which is the aim of this study. The instruments that were considered will guide the researcher in the next phase of this study when a new instrument will be developed for better items generation.

**Table 2.1: Instruments assessing self-management barriers among type 2 diabetes mellitus patients**

| Instrument | Country and level of income | Number of factors or sub-scales, items, scores and mode administration | Population, sample | Psychometrics |
|---|---|---|---|---|
| 1. The "Environmental Barriers to Regimen Adherence (EBAS)" | Virginia, USA. High-income Country | 1. 4 factors: diet, exercise, glucose testing and medication<br>2. 60 items, 5 point Likert scale<br>Self-administered | T1DM and T2DM (n=214) | 1. Content validity: 5 professionals reviewed the questionnaire and assessed its face validity. No I-CVI calculated.<br>2. Criterion validity: Correlating EBAS with the Barriers to Diabetes Adherence Scale (BAS), BAS - Portion of Diabetes-Care Profile (DCP-BAS) scale and the Diabetes Self-Care Behavior (DSCB) scale. For correlating with BAS r = 0,63; for correlating with DCP-BAS r = 0.51; for DSCB: r = -0.33–0.52; for HbA1c r = 0.28<br>3. Discriminant validity: two ways: 1. DSCB not measuring by EBAS, r = -0.18 (0.01). 2. Sub-scale EBAS with total score EBAS r = 0-73–0.86<br>4. Internal consistency: Cronbach's alpha = 0.94 (0.84–0.91)<br>5. Test–retest reliability: r = 0_80 (0.59–0.74) after 6 weeks |
| 2. "The Diabetes Obstacles Questionnaire (DOQ), 77 items" | United King-dom High-income Country | 1. 8 Factors: medication, self-monitoring, knowledge and beliefs, diagnosis, relationships with healthcare professionals, lifestyle changes, coping and advice and support. Responders also completed a quality-of-life questionnaire (ADDQoL) and the | T2DM (n = 176), Age (mean): 62.2 years | 1. Content validity: The items generated from focus group and literature review. The content validity assessed by panel of 21 members through extensive feedback<br>2. Criterion validity range: r = 0.383–0.706<br>3. Construct validity: KMO test range = 0.712–0.903. Correlation between HbA1c and 4 dimensions DOQ, r = 0.184–0.34; Correlation between ADDQoL and 3 dimensions DOQ, r = 0.169–0.271.<br>4. Internal consistency: Cronbach's alpha range = 0.766–0.937<br>5. Floor/ceiling effect: Eliminated 18 items (with >90% of responses in one category of each item), but no reported dates. |

| | | | | |
|---|---|---|---|---|
| | | Problem Areas in Diabetes (PAID) scale.<br>2. 77 items. Likert Scale with 5 categories | | |
| 3. "Diabetes Self-care Barriers in Older Adults (DSCB-OA)" | Alabama, USA<br>HIC | 1. 3 Factors: diet, exercise and blood glucose monitoring barriers<br>2. 12 items<br>Non-specified scale for measurement | T2DM (n = 82)<br>T1DM (n = 65)<br>Age (mean): 68 years | 1. Content validity: Items generated from literature review, panel of lay people and professionals reviewed the instrument<br>2. Construct validity: factor analysis with varimax rotation, 3 factor solution (47.1% of total variance).<br>3. Internal consistency: Cronbach's alpha = 0.69 (0.60–0.86)<br>4. Interrater reliability: 95% (2 interviewers) |
| 4. "Patient-perceived difficulty in diabetes treatment (PDDT) scale" | Israel<br>HIC | 1. 1 Factor including: self-care, drug management, glycaemic self-monitoring, diet, relation with health providers and costs.<br>2. 12 items<br>Likert Scale with 5 categories (1 = very difficult, 5 = not difficult at all). | T1DM (n = 384)<br>T2DM (604)<br>Age (mean): 60 years | 1. Content validity: Items generated from literature review, 4 focus groups with 24 T2DM patients, cognitive interview with 34 T2DM. Items reviewed by experts in epidemiology and diabetes care<br>2. Criterion validity with HbA1c, r range: 0.12–0.20; Holistic Quality of life, r range: 0.11–0.36; Diabetes-specific Quality of life, r range: 0.31–0.46.<br>3. Discriminant validity differences between scores groups by type of treatment for 11 over 12 items<br>4. Interpretability = 3 groups were presented (T1DM, T2DM only tablet-treated and T2DM diet-treated) |
| 5. "Perceived barriers to self-care in patients with T2DM" | | 1. 3 Factors: lateral effects, patient's diagnosis barriers, facilities and resources<br>2. 11 items (1 = strongly agree, 5 = strongly disagree) | T2DM (n = 400) | 1. Content validity: opinions of an expert panel, CVI = 0.84.<br>2. Construct validity: The KMO value 0.71, Bartlett's test of sphericity was significant ($p < 0.001$, 311.36),<br>Factor analysis confirmed the validity of the 11 items and 3 factors of the developed scale. The factor loading ranged from 0.46 to 0.78. These three factors together explained 40.28% of the total variance.<br>3. The overall reliability Cronbach's alpha= 0.79 (0.82 to 0.93). |

| | | | | |
|---|---|---|---|---|
| 6. “Short version of the diabetes obstacles questionnaire (DOQ-30) ” | Belgium, France, Estonia, Serbia, Slovenia, and Turkey<br>High-income countries | 30 items in nine Factors | T2DM (n=853) mean age was 64 | 1.EFA: resulted in item-to-factor loadings from 0.42 to 0.85 and 18 factors with an eigenvalue 41 explaining 51.5% of items’ variance<br>Scree plot, eigenvalues, and content analysis indicated nine meaningful sub-scales with four items in the first six and two in the last three altogether 30 items.<br>The Kaiser–Meyer–Olkin measure of sampling adequacy was 0.92, and Bartlett’s test of sphericity was significant (P50.001),<br><br>Cronbach’s alpha 0.52 0.52–0.89<br>Pearson correlation between scale scores of the DOQ and the DOQ-30 r = 0.58–0.99. |
| 7. “The Personal Diabetes Questionnaire (PDQ)” | USA<br>High-income country | The care behaviours, perceptions and barriers<br>Number of items not clear | 790 adults (205 with type 1 and 585 with T2DM) | Reliability (Cronbach a = .650 –.834) |

## 2.7 Conclusions

Self-management is crucial in the management of T2DM. Patients need support to overcome barriers and challenges. There have been few quantitative studies to identify barriers to self-management due to the lack of validated instruments. Most instruments did not focus on the barriers to self-management and lacked a rigorous development process. Patients do self-manage and are being told to do so, but the question is: what is affecting them while self-managing? Clarification and measurement of self-management barriers is necessary for health care providers in order to better support their patients. It is also recommended that studies be conducted in LICs and LMICs to adapt the approach to self-management barriers to the local culture and context. Therefore, there is a need to develop and validate an instrument to assess self-management barriers among T2DM in LICs and LMICs.

# CHAPTER 3: PHILOSOPHICAL WORLDVIEW AND CONSEQUENT RESEARCH METHODOLOGY

## 3.1 Introduction

This chapter gives an overview of the underlying philosophy and assumptions of the research. It further describes the context and setting of research, and briefly explains the exploratory sequential design that was used. It ends with a figure summarising the research methods. The detail of other methods used with each objective are described in the respective chapters.

## 3.2 Philosophical worldviews guiding the current research

In order for the researchers to decide on the nature and design of the research to be used, they have to take a given stance vis-à-vis the philosophical worldview that underlines their inquiry. The terms *paradigm* and *world views* are synonymous; they speak of the set of beliefs or philosophical assumptions that researchers make in their study and guide the actions that they will take (Creswell, 2009). There are various paradigms or worldviews; Creswell (2009) discusses four, namely postpositive, aiming at theory verification; the constructivist, aiming at theory generation; the participatory which is change orientated; and the pragmatist, focusing on the real-world practice orientated view.

The worldviews or paradigms of scientific research have some common ground. However, each has a different perspective on ontology, epistemology, axiology, methodology and rhetoric (Creswell, 2009). In this study, the researcher opted for a pragmatism paradigm which provides real-world practice orientated data and focuses on what will work in practice (Creswell, 2009). This paradigm is advantageous as it embraces plurality of methods (often associated with mixed-methods or multiple-methods) and may employ both formal and informal rhetoric (Creswell, 2009; Kassahun *et al.*, 2016). Table 3.1 presents different worldview elements concerning the pragmatism paradigm used in this study.

**Table 3.1: Elements that influence the choice of a worldview (Creswell, 2009)**

| Worldview Element | The pragmatism perspective in thi study |
|---|---|
| **Ontology**<br>**(nature of reality)** | The researcher believes that reality lies in people who suffer from T2DM who practice self-management; the Rwandan people and people who share the same characteristics as those from LICs and LMICs. |
| **Epistemology (study of knowledge)** | The conceptual framework of *self-management* was used to generate knowledge of *self-management* barriers. It was also necessary to resort to more than one method to answer the initial research question, hence, the use of qualitative and quantitative methods. |
| **Axiology**<br>**(role of values)** | Rwandan people needed an instrument to identify their barriers and not an instrument based on other countries' barriers |
| **Methodology (process of research)** | Qualitative data were collected via interviews by researcher and with research assistants who understood the field of diabetes.<br>Quantitative data were collected via questionnaires. Researcher also used the integrative review as a method to identify barriers in countries with similar settings (LIC and LIMCs) |
| **Rhetoric**<br>**(the language of research)** | Both formal and informal language was used. For example, the formal language was used to describe the construct of *self-management* dimensions through the integrative review and validation methodology. An informal writing style was used to describe the findings in the language of participants and in terms of the context in which the study was conducted. |

## 3.3 The context of the research

### 3.3.1 Brief historical background and health system in Rwanda

Rwanda is a low-income and ranks second most highly populated country in Africa (Krakauer *et al.*, 2018). It is geographically located in East Africa. As of 2020, its population was projected to be 12,663,116 for a total area of 26,338 2 $km^2$ (nisr, 2012). The country counts 4 provinces and the City of Kigali which in turn are divided into smaller units including districts, sectors, cells and finally villages. The Rwandans share a single language i.e Kinyarwanda and cultural heritage.

The genocide against the Tutsis in 1994 claimed more than 1 million lives and affected the health system in both structural infrastructure and human resources. Many health professionals died and

others left the country (Binagwaho *et al.*, 2014). After the genocide, Rwanda has made important progress in restoring the health system by increasing health infrastructure and the number of various qualified health professionals (Rwanda Ministry of Health, 2014). In 2013, the number of all public health professionals was 12,012, among them, the majority (9,448) were nurses and midwives (Rwanda Ministry of Health, 2014). Currently, there are 0.06 physicians and 0.41 nurses per 1000 people. The county includes 41 district hospitals with an estimate of 400 health centres (Rwanda Ministry of Health, 2014). There are also three large referral hospitals in Kigali and one referral hospital in each administrative province.

The healthcare system is composed of public and private health care. The lowest level in public health care is known as primary level and includes health centres. The midst level i.e secondary level includes district hospitals and the highest level or tertiary includes referral hospitals. The country now utilises a community-based health insurance system which is affordable and allows even the poorest to access care. There are also other private and public health insurances.

### 3.3.2 Research setting

The integrative literature riview was done and included LICs and LMICs. Low-income economies are based on the Gross National Income (GNI) per capita, of $1,025 or less (World Bank, 2018) (ANNEXURE 1) and lower middle-income countries are defined based on a GNI per capita between $1,026 and $4,035 (World Bank 2018) (ANNEXURE 1). The prevalence of diabetes is growing most rapidly in low- and middle-income countries and 46 % of diabetes-related deaths are attributed to LICs and LMICs (World Health organization, 2016). Low incomes and low middle income share same characteristics that can affect self-management of T2DM such as inequality, poor health care and education, high unemployment, heavy reliance on agriculture, and rapid population growth. According to World Bank (2018) there are 27 LICs and 53 LMICs (ANNEXURE 1).

The qualitative study and the validation studies were done in Rwanda where T2DM patients live in both rural and urban area and they are heterogenous in terms of age and socio-economic status. In Rwanda, T2DM is mainly managed in public health facilities but there is a number of patients attending private sector. In the public sector, the NCDs (including T2DM) policy recommends decentralisation of care, from district hospital level to health centre level. However, during data

collection of this study diabetes and other communicable diseases were still managed in district hospitals, in a nurse-led clinic or outpatient department. There were also patients who were managed in referral hospitals by medical doctors. Decentralisation to the health centre level was still in the process. Patients usually visit the clinic once per month unless they observe emergency symptoms that need immediate attention. They can then consult without waiting for an appointment. They visit to collect medication, check blood glucose and to receive health education.

The researcher met participants in ten hospitals from five provinces: Kigali (Kibagabaga and Kigali Teaching Hospital, CHUK), South (Remera Ruhondo, Butare Teaching Hospital-CHUB), North (Ruhengeli and Ruli), East (Kirehe and Nyamata) and West (Gisenyi and Muhororo). During the survey to establish the construct validity, Kirehe District hospital was repalaced by Gahini district hospital that had more patients with T2DM (Figure 3.1)

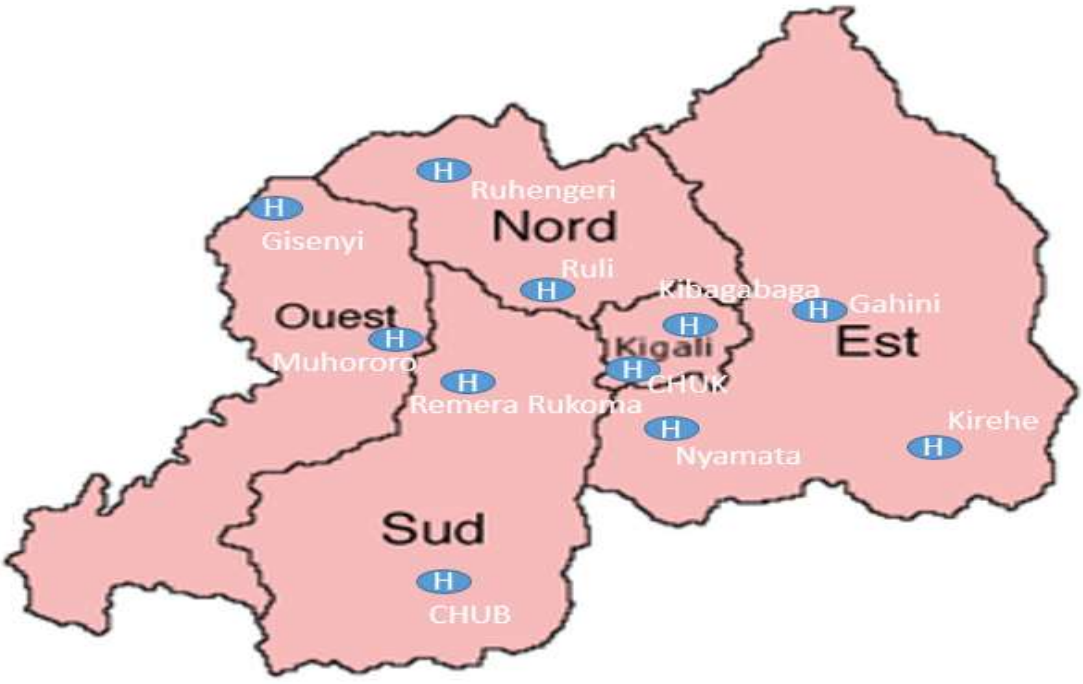


**Figure 3.1 Map of administrative provinces of Rwanda indicating the research setting**

**Source: Ministry of local government (hospital symbols manually added based on hospital location from Labrecque *et al.* (2013)'study)**
**http://www.clgf.org.uk/default/assets/File/Country_profiles/Rwanda**

According to Creswell (2009), in purposive sampling, the researcher selects participants or sites that can best allow her to clearly understand the phenomena or get an answer to the research question. It is in this regard that the researcher chose LICs and LMICs that would share some characterisitics with Rwanda. In addition to that, referral and district hospitals in Rwanda were selected as discussed above; two in each of the five administrative provinces (one in rural and another in urban) to capture all variations in terms of self-management barriers.

### 3.4 Study design: Overview of exploratory sequential design

The current study used a mixed method exploratory sequential design. According to Creswell, (2009), a mixed method exploratory sequential design is when a researcher collects qualitative data and uses results to form variables, instruments, interventions to collect quantitative data. This design is particularly useful when the researcher is developing a new instrument (Creswell, 2009). In this design, 3 phases can be employed. In phase 1, qualitative data is collected and analysed. In phase 2, the themes that emerge are used to design a quantitative instrument. Finally, in phase 3, the instruments is validated using a sample drawn from the population under study (Creswell, 2009).

This design normally results in three stages of analyses. The first analysis consists of qualitative analysis, the second one consists of quantitative analysis and the last stage is the integration of the qualitative and quantitative (Creswell, 2009). Integration can happen at multiple levels of a study, for example at the design level, methods-level or interpretation and can happen in a variety of ways- connecting, building, merging, or embedding (Creswell and Plano Clark 2011). In this study, the first linking of data happened at the design-level with the use of a sequential design, where the results from the first phase of the research were used to build the second phase and the instrument from the second phase was used to gather the quantitative data for psychometric properties.

### 3.5 Summary of phases and methods used in this study

Figure 3.1 displays the exploratory sequential design of this study in three phases.
In the first phase, the researcher conducted an integrative literature review on self-management of T2DM in LICs and LMICs and a qualitative descriptive research among patients with T2DM in Rwanda. Both the integrative review and the qualitative study looked at the barriers of self-

management. The main purpose was to conceptualise the construct of self-management and barriers. An extensive literature review of existing instruments was also conducted. The data from the integrative review and qualitative research emerging from individual interviews were thematically analysed.

In phase two, the researchers used themes that emerged from phase one to design items of for quantitative instrument to assess self-management barriers. In Creswell (2009), the steps to follow in designing an instrument are not specified and the researchers employed the three steps of Boateng, Neilands and Frongillo (2018) and Zamanzadeh *et al.* (2014) which are (a) determining the content domain, (b) generating initial pool of many items and (c) construction of items including the final items refinement, scoring system and instrument naming.

In the phase three, the new instrument went through the validation process. First, 10 experts were recruited to validate the content (content validity). The content validity index (CVI) or level of agreement was calculated to determine the relevance and clarity of the items. Four patients were recruited to assess the face validity, furthermore, 18 nurses and two medical doctors were recruited to determine the clinical utility (how easy it was to use the instrument) of the instrument. They used the instrument to score the barriers experienced by T2DM patients and were given a questionnaire to rate the time, format and clarity of the instrument. Finally, a cross sectional study recruited 650 T2DM patients from ten hospitals to establish the construct validity.

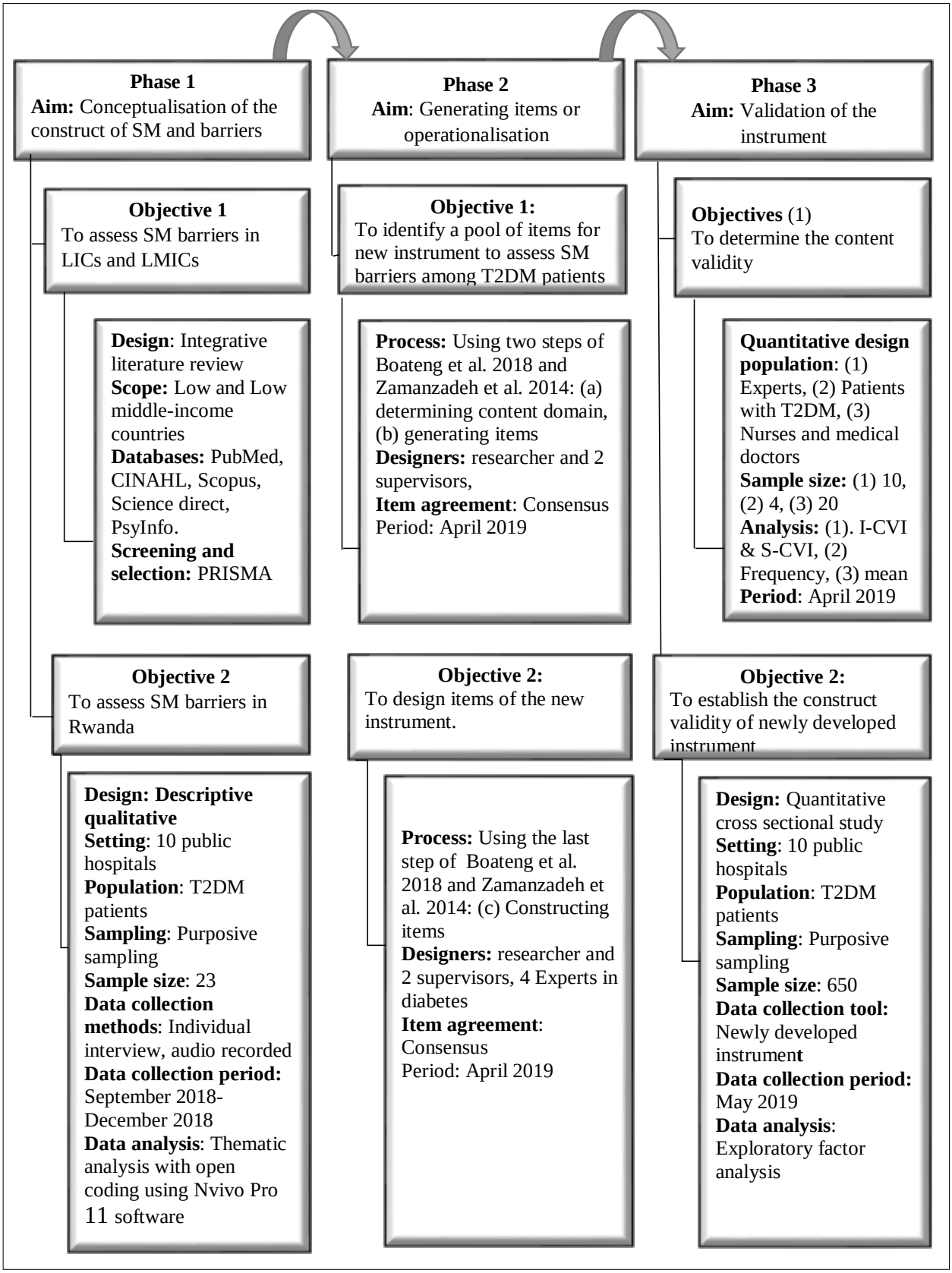


**Figure 3.2: Summary of the methods used**

### 3.6 Ethical considerations

Ethical clearance was granted by the Human Research Ethical Committee (Medical) Approval no. M180432 (ANNEXURE 2) and Institution Review Board University of Rwanda, College of Medicine and Health Sciences No:156/CMHS IRB/2018 (ANNEXURE 3). Permission to conduct study was requested and granted by the hospital management (ANNEXURE 4). The researcher adhered to the scientific guidelines of the research process and the research methodologies to insure reliable data. In all phases, all participants were provided with a specific information sheet and informed consent prior to participation depending on each objective (from ANNEXURE 5 to ANNEXURE 15). Since interviews were audio-recorded, a separate consent form was offered to obtain consent for audio-recording (ANNEXURE 7) Anonymity was ensured by not requiring names from participants but using codes or personal identifiers. To ensure confidentiality, the collected information was only accessible to the researcher and the supervisors.

### 3.7 Conclusions

This chapter presents the philosophic worldview, the study design and the study setting of this research. The chapter ends with a figure that summarises all methods used in different phases of the research. The detailed methods for each objective will be extensively described in the respective chapters. The next chapter will present the details of the integrative review.

# CHAPTER 4: INTEGRATIVE LITERATURE REVIEW

## 4.1 Introduction

Phase one is discussed in two chapters – chapter 4 describes the integrative review and in chapter 5 the qualitative study is described. In this chapter the design of integrative review phases is described, and results of the integrative review that explored the barriers to self-management among T2DM in LICs and LMICs are discussed.

## 4.2 The design of integrative review

An integrative review is a type of review that allows the researcher to combine experimental and non-experimental studies for better analysis and understanding of the studied phenomenon. In this study, the researcher wished to understand the barriers to self-management in people with T2DM in a LIC per se and not which intervention was needed to overcome the barriers

Specifically, it involves the synthesis of analysed data into a new model or view about the phenomenon under study. There are different ways of conducting an integrative review (Ganong, 1987; Whittemore and Knafl, 2005; Tavares de Souza, Silva and Carvalho, 2010). The commonly used phases include (i) research problem identification; (ii) searching the literature; (iii) data evaluation; (iv) data analysis and (v) interpretation of the analysed data and presentation of the report. The integrative review done for this study included studies published between January 2018 and July 2018, and were guided by the Framework of Tavares de Souza, Silva and Carvalho (2010). The results of this review informed the next phase of the study which was the development of an instrument to assess self-management barriers in T2DM.

## 4.3 Phases of integrative review

The framework of Tavares de Souza, Silva and Carvalho (2010) used in this study consists of six phases, namely (i) preparing the guiding question, (ii) searching or sampling the literature, (iii) data collection, (iv) critical analysis of the studies included and (v) presentation of the results, (vi) discussion of results and conclusion.

### 4.3.1 Phase one: Preparing the guiding question

According to Tavares de Souza, Silva and Carvalho (2010) this phase consists of deciding which studies are to be included. The studies that the researcher was interested in, were those that included barriers to self- management of T2DM. Since the outcomes of the integrative literature review was to understand the phenomena of barriers to self-management, the guiding question was: *What are the self-management barriers among patients diagnosed with T2DM in LICs and LMICs?* Arising from this question, T2DM patients constituted the population for the integrative review and the outcomes to be measured were self-management barriers.

### 4.3.2 Phase two: Searching the literature

Tavares de Souza, Silva and Carvalho (2010) state that in this phase, the search of studies can be done through electronic databases, manual journals, the references described in the selected studies, contact with researchers and the use of unpublished material. In addition, the inclusion criteria relavant to the guiding question, considering the participants, the intervention and the results of interest should be determined.

In this integrative review, the research team agreed on the search process, determined the key terms, databases to be searched and inclusion criteria. Five electronic databases, namely SCOPUS, Science Direct, EBSCO host via CINAHL and PubMed were searched. Reference lists of tracked articles were used to track other relevant articles in Google Scholar. A combination of the three broad key terms was used to conduct the search: "type 2 diabetes", barriers and "self-management". Key terms were exchanged, for example the word self-management was substituted with self-care and barriers with factors, challenges and obstacles. Different self-management dimensions such as diet, SMBG, physical activity, foot care and medication were also used interchangeably with self-management. All the identified databases were searched, using the combination of one key term with another using Boolean logics "AND" and "OR". The following are examples of the combinations that were made.

i. Combining all search key terms: "type 2 diabetes" AND (barriers OR factors OR obstacles) AND ("self-management" OR diet OR "physical activity" OR foot care OR "self-monitoring of blood glucose" OR "drug adherence" OR "medication adherence")
ii. "type 2 diabetes" AND barriers AND "self-management"

iii. "type 2 diabetes" AND factors AND self-management
iv. "type 2 diabetes" AND barriers AND self-care
v. "type 2 diabetes" AND factors AND self-care
vi. "type 2 diabetes" AND obstacles AND self-care
vii. "type 2 diabetes" AND obstacles AND "self-management"
viii. "type 2 diabetes" AND barriers AND "self-management" AND "low income" AND "low middle income"

**Inclusion criteria**

Published in the English language, qualitative, quantitative and mix-methods scientific articles and researches were sampled from articles published between January 2008 and July 2018 were considered. Self-management had to refer to at least one of the following areas: physical activity, medication adherence, SMBG, foot care and diet. In addition, all articles had to be in relation to LICs and LMICs as classified by the World Bank 'classification, fiscal year 2018' (World Bank, 2018).

**Selection process**

The first search yielded 10,277 articles that were saved in Mendeley Reference Manager and 2,609 articles were removed as duplicates. About 7,668 titles were screened by the researcher to determine their relevance to the study. When the titles were not clear enough to exclude the study, the abstracts were also read. As the study was limited to low- and low-middle-income countries (World Bank, 2018), the methodology in some of the articles was also read if, in the abstract, the setting of the study was not obvious i.e. could not be determined. After applying the inclusion criteria to all articles, only 25 five articles were selected for inclusion. The first screening was done by the researcher. Two supervisors checked the process and the articles selected (see the PRISMA diagram Figure 4.1).

**PRISMA diagram**

Figure 4.1 below shows that the search from all databases yielded 10,154 articles plus 123 articles from references of articles, totalling a number of 10,277 articles. The articles were exported in Mendeley, duplicates were removed (2,609) and 7,668 articles remained. Selection criteria discussed as previously discussed were applied to select eligible articles. Twenty-seven (27) articles were identified; two articles from South Africa were eliminated because during the data collection process, the country was recognised as a MIC, resulting in the selection of twenty-five (25) articles.

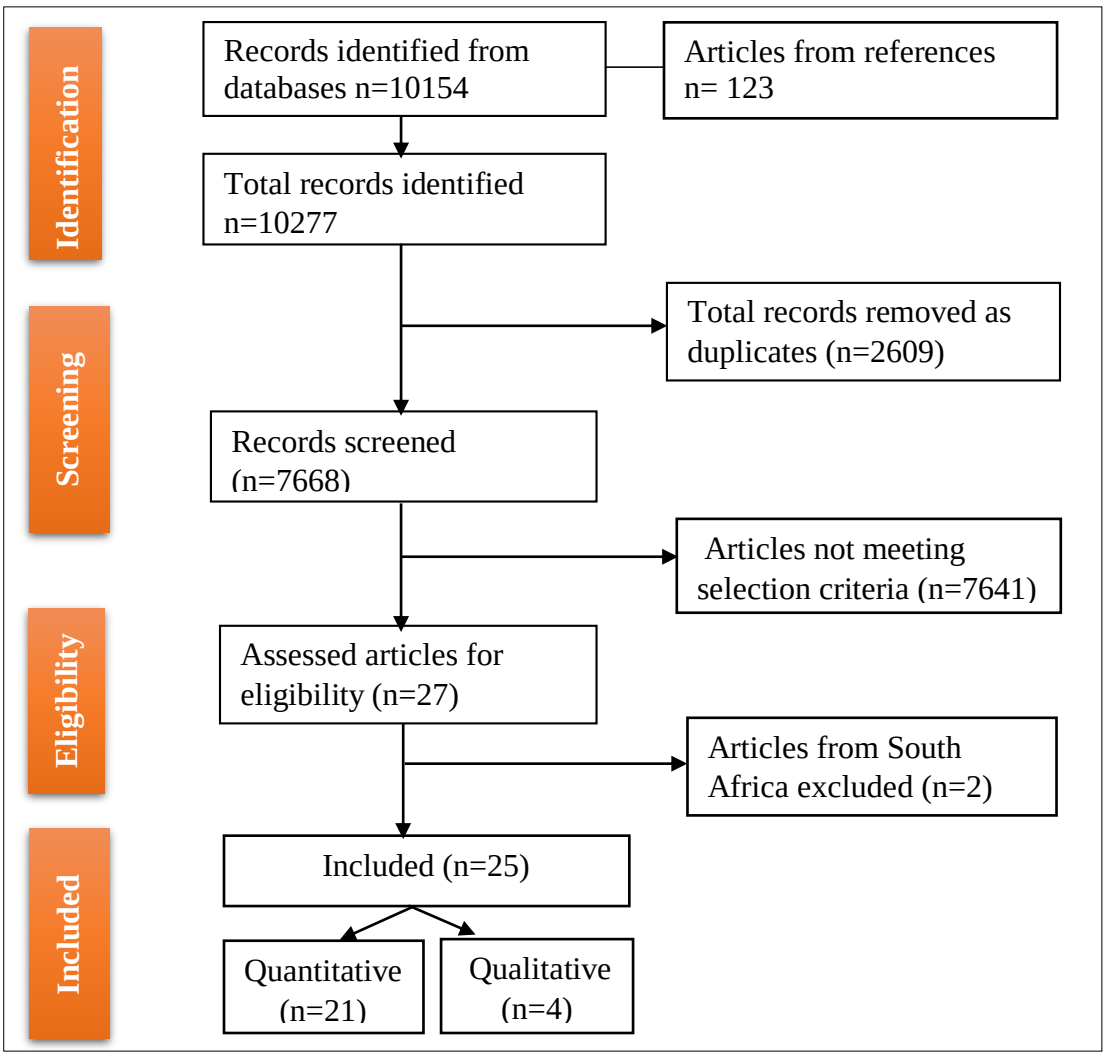


**Figure 4.1: PRISMA diagram of study selection, evaluation and inclusion**

### 4.3.3 Phase three: Data collection

In this phase, it is necessary to use a previously prepared instrument to ensure collection of relevant data and remain focused and consistent. The instrument can include for example, the population, elements like sample size and variables (Tavares de Souza, Silva and Carvalho, 2010). In this study the instrument was developed by the researcher and two supervisors and included the elements: author, year of publication, purpose of the study (ANNEXURE 16).

### 4.3.4 Phase four: Critical analysis of the studies in which were included

This phase consists of weighing the rigour and characteristics of each study. According to Tavares de Souza, Silva and Carvalho (2010), in this phase the researcher assesses or weighs the rigour and the characteristics of each study using evidence classification systems. For that purpose, Mann criteria – Grade I to Grade III – were used to assess the quality of quantitative studies (Maree and Schmollgruber, 2014). The quality of the qualitative studies was evaluated by the researcher and two supervisors using the rating system developed by Cesario, Morin and Santa-Donato (1996) that applies five categories (ANNEXURE 17). The Six levels of Tavares de Souza, Silva and Carvalho ( 2010) were also applied for further assessment.

### 4.3.5 Phase five: Presentation of the integrative review results

According to Tavares de Souza, Silva and Carvalho (2010), this phase is presented after the discussion phase. One of the methods to analyse data proposed by Tavares de Souza, Silva and Carvalho (2010) is the qualitative method by Whittemore and Knafl (2005). The method consists of (i) data reduction, (ii) data display, (iii) data comparison, (iv) drawing conclusions and verification.

#### 4.3.5.1 Data reduction

Data reduction consists of placing data into subgroups according to a previously established classification, the aim of which is to facilitate the analysis (ANNEXURE 18).

#### 4.3.5.2 Data display

Data display refers to converting the extracted data from individual sources into a display that assembles the data from multiple primary sources around particular variables or subgroups. This can be done in the form of matrices, graphs and charts. In this review general characteristics of the studies were identified, data was reduced into research design categories (quantitative, qualitative), level of country income, components of self-management and displayed on a matrix for easy visualisation of patterns and similarities (ANNEXURE 18).

#### 4.3.5.2.1 General characteristics of the studies

In all the 25 studies included, the total sample was equal to N=5630 T2DM patients; female n=3256 and male n=2535. The minimum age was 18 years and the maximum age was 83 years. Most of the included studies (n = 22) had more female participants than males. Fourteen studies reported the mean ages of study participants, with mean ages ranging from 49.7-60.3 years. Two studies reported age categories of participants between 32-83 and 34-81. In the remaining studies (n=9), age was reported from18 years and older.

#### 4.3.5.2.2 Countries and level of income

The search included countries from lower- and low- middle-income countries. Table 4.1 below shows that n=13(52%) articles were from LICS and n=12 (48%) was from LMICs.

**Table 4.1: Distribution of articles according to the level of income of countries (n=25)**

| Level of income | Frequency | Countries |
|---|---|---|
| Low middle income | **12** | Bangladesh (1), Egypt (1), Ghana (2), Indonesia (1), Kenya (2), Nigeria (5) |
| Lower income | **13** | Ethiopia (3), Nepal (1), Rwanda (1), Senegal (2), South Korea (1), Tanzania (3), Uganda (2) |

#### 4.3.5.2.3 Level of evidence

Regarding the level of evidence, quantitative studies were either descriptive or surveys with a cross-sectional design with no comparison group and calculated sample size. Based on Mann's grading criteria (Christmals *et al.*, 2018) for quantitative studies (ANNEXURE 17), all studies were classified into grade IIIB. These are studies which are not observational or randomised and that do not include a comparison group but do include clear definitions of outcome variables. The quality of the qualitative work seemed better since 100% of the studies met the criteria according to which the quality of the study would be regarded as good. Using the level of evidence according to Tavares de Souza, Silva and Carvalho (2010), all studies ranked at level 4 which includes evidence of descriptive (non-experimental) studies or with a qualitative approach.

**Table 4.2: Quality of studies**

| **Quantitative studies** | **n** | **%** |
|---|---|---|
| IIIB | 21 | 100 |
| **Qualitative studies** | | |
| QI (Good) | 4 | 100 |
| **Level of evidence according to (**Tavares de Souza, Silva and Carvalho, 2010) | | |
| L4 | 25 | 100 |

#### 4.3.5.2.4 Components of self-management

Of the n=25 articles, four of them (Arulmozhi and Mahalakshmy, 2014; Rwegerera, 2014; Bagonza, Rutebemberwa and Bazeyo, 2015; Jackson *et al.*, 2015) reported specifically on medication adherence. One article was concerned with diet (Foley and BeLue, 2017) and one with foot care (Chiwanga and Njelekela, 2015).

The remaining n=19 articles included two or more components of self-management, namely diet, physical activity, foot care, glycaemic control and medication adherence.

### 4.3.5.3 Data comparison

Data comparison involves an iterative process of examining data displays of primary source data in order to identify patterns, themes, or relationships. Table 4.3 summarises the themes and sub-themes that emerged from barriers of self-management as extracted from the n=25 studies. Self-management barriers emerged into seven themes. A barrier can affect all components of self-management or can be a barrier to one or two components. For example, knowledge barrier.

**Table 4.3: Themes and sub-themes of self-management barriers among type 2 diabetes mellitus in low income countries and low- middle-income countries**

| No. | Themes | n | Examples of sub-themes |
|---|---|---|---|
| 1 | Socio-demographic characteristics | 16 | Financial constraints |
| | | 8 | Other socio-demographics (age, occupation, education level, male gender, age, family size) |
| 2 | Lack of support | 4 | Lack of family support |
| | | 7 | Lack of support from health care system |
| | | 6 | Lack of health care provider support |
| 3 | Limited knowledge | 15 | |
| 4 | Mental health factors | 5 | Negative feelings decreasing adherence to self-management activities |
| | | 4 | Personal attitudes |
| 5 | Cultural characteristics | 1 | Religious beliefs |
| | | 2 | Gender roles |
| | | 3 | Dietary practices in the society |
| | | 3 | Concomitant use of traditional drugs with T2DM medication |
| | | 1 | Inactivity of the population |
| | | 4 | Patients 'perception and misconceptions |
| | | 1 | Self-stigma |
| 6 | T2DM diabetes, complications, comorbidities and medications | 3 | Duration of the disease |
| | | 3 | Issues related to medications |
| | | 5 | Complications |
| | | 2 | Comorbidities |
| 7 | Environmental factors | 2 | Unavailability of vegetables and health food in some areas |

#### 4.3.5.3.1 Theme 1: Socio-demographic characteristics

- **Financial constraints**

Financial constraints were barriers to one or more self-management activities in many articles. Higher socio-economic status was also linked to the total aggregate score of self-management activities (Gopichandran *et al.*, 2012). It was noticed that patients lack money to buy prescribed drugs (Adisa Alutudu and Fekeye, TO., 2009; Mosha and Rashidi, 2009; Baumann *et al.*, 2010; Adisa, Fakeye and Fasanmade, 2011; Rwegerera, 2014; Adisa and Fakeye, 2014; Arulmozhi and Mahalakshmy, 2014; Basu *et al.*, 2015; Heijmans *et al.*, 2015; Belue *et al.*, 2016; Abdullah and Sameen, 2017; Mogre, Johnson, *et al.*, 2017), healthy diet Belue *et al.*, 2016; Foley and BeLue, 2017; Baumann *et al.*, 2010; Abdulrehman *et al.*, 2016; Basu *et al.*, 2015; Arulmozhi and

Mahalakshmy, 2014) and devices to monitor blood glucose (Baumann *et al.*, 2010; Mosha and Rashidi, 2009; Abdulrehman *et al.*, 2016; Gopichandran *et al.*, 2012). Furthermore, belonging to higher economic status was found to be associated with physical activity (Parajuli *et al.*, 2014) and SMBG (Gopichandran *et al.*, 2012).

- **Other socio-demographic characteristics**

Demographic characteristics like marital status, gender, education, occupation, age and size of the family were found to be related to self-management.

**Marital** status: patients who are widowed seemed to adhere more to medication than married, single persons and divorcees (Adisa, Fakeye and Fasanmade, 2011). Divorcees were more non-adherent to physical activity than married and widowed patients (Parajuli *et al.*, 2014). Being married significantly favoured physical activity, (Gopichandran *et al.*, 2012).

**Occupation:** patients who are professionals and those who are traders appear to remember to take their medication more often than the unemployed respondents (Adisa Alutudu and Fekeye, TO., 2009). There was also a significant association between patients' occupational status and opinions on costs of medication as reasons for preventing optimal adherence to medication (Adisa Alutudu and Fekeye, TO., 2009) (Adisa, Fakeye and Fasanmade, 2011). Busy work schedule (Adisa Alutudu and Fekeye, TO., 2009) and nature of job incompatible with dosage regimen (Heissam, Abuamer and El-Dahshan, 2015; Adisa and Fakeye, 2014), also affect medication adherence. The occupation-related delays for dinner affect diet, eating plan (Basu *et al.*, 2015) and lead to medication use without regard to time of meal (Heissam, Abuamer and El-Dahshan, 2015; Adisa and Fakeye, 2014). Business professions like those related to commercial activities were significant independent predictors of good practice (SBGM, exercise, foot care, smoking, diet) (Saleh *et al.*, 2012). Patients considered physical exercise as part of work or household chores, and did not perform other exercise was done (Basu *et al.*, 2015).

**Education level:** it was noted the education level affects all activities of self-management (Kassahun, Eshetie and Gesesew, 2016)(Ayele *et al.*, 2012). Patients who are educated appear to remember to take their medication more often than the uneducated (Adisa Alutudu, M.B., Fekeye, TO. 2009; Kassahun *et al.*, 2016; Jackson *et al.*, 2015).

Education has been found to influence knowledge of patients on how to perform foot care (Mogre, Abanga, *et al.*, 2017). Education was also found to influence the uptake of physical activity (Mogre, Abanga, *et al.*, 2017).

**Male gender:** showed a statistically significant opinion on physician's mode of approach during consultation as a contributory factor for medication non-adherence (Adisa, Fakeye and Fasanmade, 2011). Male diabetic patients seemed to have greater tendencies to forget to take medications than their female counterparts (Adisa Alutudu and Fekeye, TO., 2009). Male patients were more likely to not adhere to medication, but they were more adherent to physical activity (Gopichandran *et al.*, 2012), diet (Parajuli *et al.*, 2014) and controlling SMBG (Mogre, Abanga, *et al.*, 2017).

**Age:** was also related to medication adherence (Arulmozhi and Mahalakshmy, 2014). For example, low adherence of healthy diet was associated with increased age (Parajuli *et al.*, 2014)

**Family size:** was related to self-management activity of diet (Foley and BeLue, 2017), physical activity (Parajuli *et al.*, 2014) and medication (Parajuli *et al.*, 2014). In terms of diet, in a large family, giving up the diabetic diet sometimes occurs so that family members can have enough food. Regarding medication, it was noted that patients living in a nuclear family adhere more to medication than those staying with an extended family (Parajuli *et al.*, 2014).

#### 4.3.5.3.2 Theme 2: Lack of support

- **Lack of social and family support**

The category of social and family support included any lack of support such as financial, social and emotional from another person; either from a friend, family or community to perform self-management activities. It was noted that family can play both supportive and unsupportive roles. (Belue *et al.*, 2013); Arulmozhi and Mahalakshmy, 2014). Family relationships, support or understanding were found to affect adherence to diet (Belue *et al.*, 2013); Abdulrehman et al. 2016). Family support may be tangible aids and appraisal or understanding that patients received from their families. When members of the family do not understand what T2DM is, difficulties arise in following a heathy diet; for example, patients will wait for family to have dinner together (Arulmozhi and Mahalakshmy, 2014). Family environment is more important and may affect any self-management activities (Belue *et al.*, 2013).

For example, conflicts or misunderstanding in a family (Belue *et al.*, 2013) lead to failure in adhering to medication by patients (Waari, Mutai and Gikunju, 2018).

- **Lack of support from the health care system**

Different barriers related to health care facilities and health care providers were found to affect one or more self-management activities. Among health care facility barriers/factors, there was a problem with accessibility to medication. Patients may not get prescribed drugs in the health care facility or at the nearest pharmacy (Adisa Alutudu, M.B., Fekeye, TO. 2009; (Adisa and Fakeye, 2014); Waari, Mutai and Gikunju, 2018; Bagonza, Rutebemberwa and Bazeyo, 2015; Jackson *et al.*, 2015; Basu *et al.*, 2015), and this means that drugs are replenished. People who live a long way from hospital do not adhere to diet instructions like people staying close to the hospital (Parajuli *et al.*, 2014). Another barrier is the limited printed educational material (Baumann *et al.*, 2010) regarding self-management guidelines available to the patients.

- **Lack of support from health care providers**

Healthcare providers' relationships with patients predicts adherence to medication (Baumann *et al.*, 2010; Jackson *et al.*, 2015; Heissam, Abuamer and El-Dahshan, 2015). Foot care was also associated with advice and examination from a physician (Mosha and Rashidi, 2009). Those who received advice were likely to perform foot care (Mosha and Rashidi, 2009)9. Dissatisfaction with clinicians was associated with poor medication adherence (Waari, Mutai and Gikunju, 2018). Having had diabetic health education influenced the level of adherence to medication (Bagonza, Rutebemberwa and Bazeyo, 2015). Patients with less information did not respect T2DM self-management activity of diet. There was also a lack of information regarding the prescription regimen vis-à-vis duration of taking medication, as well as purpose and benefit of the medications.

Patients with less information did not understand the importance of T2DM self-management activity related to diet (Ayele *et al.*, 2012). Self-management of medication was also affected by lack of information regarding the prescription regimen vis-à-vis the duration of taking the medication, its purpose and benefits (Adisa and Fakeye, 2014).

#### 4.3.5.3.3 Theme 3: Limited knowledge and inadequate health literacy

Limited knowledge and low level of education were barriers to self-management (n=15) of diet, (Foley and BeLue, 2017; Baumann *et al.*, 2010; Saleh *et al.*, 2012; Saleh *et al.*, 2012; Parajuli *et*

*al.*, 2014; Abdulrehman *et al.*, 2016; Kugbey, Asante and Adulai, 2017; Ayele *et al.*, 2012), SMBG (Baumann *et al.*, 2010; Saleh *et al.*, 2012; Abdulrehman *et al.*, 2016; Kugbey, Asante and Adulai, 2017 ; Ayele *et al.*, 2012 ; Nsereko *et al.*, 2013), physical activity ( Baumann *et al.*, 2010; Saleh *et al.*, 2012; Abdulrehman et al. 2016; Kugbey et al. 2017; Ayele *et al.*, 2012; Nsereko et al. 2013), smoking, (Saleh *et al.*, 2012), foot care (Baumann *et al.*, 2010; Saleh *et al.*, 2012; Chiwanga and Njelekela, 2015; Abdulrehman *et al.*, 2016; Ayele *et al.*, 2012), complication awareness and to medication adherence (Baumann *et al.*, 2010; Adisa and Fakeye, 2014; Kassahun *et al.*, 2016; Abdulrehman *et al.*, 2016; Kugbey, Asante and Adulai, 2017; Ayele *et al.*, 2012; Jackson *et al.*, 2015; Basu *et al.*, 2015).

This indicates that patients with less frequent information were less likely to take up self-management activities (Heissam, Abuamer and El-Dahshan, 2015; Chiwanga and Njelekela, 2015; Mosha and Rashidi, 2009); Rwegerera 2014; Abdulrehman *et al.*, 2016; Ayele *et al.*, 2012 ). For example, the practice of upward or downward self-adjustment of medication dosages among patients require patients to have adequate knowledge.

Lack of knowledge also leads to lack of perceived importance of adhering to self-management activities. Lack of access to accurate information was found to be a barrier to medication adherence (Adisa Alutudu, M.B., Fekeye, TO. 2009; Mogre, Johnson, *et al.*, 2017). Furthermore, lack of knowledge of family members does not facilitate adherence by patients to a healthy diet (Foley and BeLue, 2017).

#### 4.3.5.3.4 Theme 4: Mental health factors/problems

- **Negative feelings decreasing adherence to self-management activities**

Psychosocial factors associated with having T2DM were found to be barriers to a healthy diet, foot care (Baumann *et al.*, 2010), medication adherence (Baumann *et al.*, 2010; Jackson et al. 2015), physical activity (Baumann *et al.*, 2010), and SMBG (Baumann *et al.*, 2010; Mogre, Johnson, *et al.*, 2017). Studies indicated that patients who reported negative feelings and who were depressed may have decreased their adherence to self-management (Nsereko *et al.*, 2013; Jackson *et al.*, 2015; Gopichandran *et al.*, 2012). Sexual dysfunction, inability to support the family financially make patients feel useless, worried and too overwhelmed to undertake self-management activities (Belue *et al.*, 2013).

It was found that the group without depressive symptoms had higher scores on medication adherence and the self-management activities of diet and physical activity (Belue *et al.*, 2013).

- **Personal attitudes**

Patients may adopt negative attitudes regarding self-management. Patients may not adhere to medication due to the burden of daily intake of medication(s) and lack of motivation, forgetting, visiting multiple clinics for consultation and purchasing medication without prescription (Adisa and Fakeye, 2014). Some patients are not convinced of the need for prescribed medications and others believe that medications need to be taken together for an optimal outcome ( Basu *et al.*, 2015; Adisa Alutudu, M.B., Fekeye, TO. 2009; Heissam, Abuamer and El-Dahshan, 2015; Adisa and Fakeye, 2014). Patients may have attitudes such as self-contentment which lead them to discontinue their medication (Heissam, Abuamer and El-Dahshan, 2015; Adisa and Fakeye, 2014**),** cease taking their drugs because of absence of symptoms, temptation to eat undesirable food items, erroneous beliefs that dietary adherence is useless in the control of DM. Others may finish drugs before their scheduled appointment and hence omit doses until the next appointment (Basu *et al.*, 2015)(Adisa Alutudu, M.B., Fekeye, TO. 2009; Heissam, Abuamer and El-Dahshan, 2015; Adisa and Fakeye, 2014). There are other patients who are careless about the time of taking drugs (Heissam, Abuamer and El-Dahshan, 2015).

#### 4.3.5.3.5 Theme 5: Cultural characteristics

Culture (Belue *et al.*, 2013; Foley and BeLue, 2017; Baumann *et al.*, 2010; Heissam, Abuamer and El-Dahshan, 2015; Adisa and Fakeye, 2014; Abdulrehman *et al.*, 2016) was identified as a barrier to self-management activities in terms of diet, medication adherence and physical activity.

- **Dietary practices**

Dietary practices involve aspects such as difficulty in changing existing eating habits (habit of eating rice for example in a particular society, eating food that makes a person happy), feeling of isolation when eating separately from the communal family plate and a feeling of abandoning one's culture by adhering to a new and healthy diet (Belue *et al.*, 2013; Foley and BeLue, 2017). Other cultural aspects are ritual obligations expected at weddings or other social events; when patients attend these events, they eat available food which they describe as unhealthy ceremonies (Abdulrehman *et al.*, 2016).

- **Gender roles**

Gender issues are also cultural factors that affect adherence to a healthy diet. The gender role in buying and cooking food was reported. For example, in some cultures men are not involved in cooking and women may cook an unhealthy diet (Belue *et al.*, 2013) for them. It was found that in some cultures women are not financially independent; they rely on their husbands or children to earn money to buy food for a healthy diet and are not involved when it comes to taking decisions on health (Belue *et al.*, 2013).

- **Religious beliefs**

For some Muslims, fasting during the holy month of Ramadan may interfere with diet and medication as appeared in one article (Abdulrehman *et al.*, 2016). Patients may skip medications when they do not eat.

- **Concomitant use of traditional drugs with T2DM medication**

The cultural aspect with regard to medication is related to the concomitant use of traditional drugs with T2DM medication (Belue *et al.*, 2013; Heissam et al. 2015; Adisa and Fakeye, 2014; Abdulrehman *et al.*, 2016).

- **Inactivity of the population**

In terms of physical activity, it was noted that in some cultures, people are not interested in sport or physical activity (inactivity of the population) (Belue *et al.*, 2013).

- **Patients' perceptions and misconceptions about T2DM**

Patients' perceptions and misconceptions about T2DM were also found to affect SMBG (Belue et al. 2013; Nsereko *et al.*, 2013) physical activity, (Ayele *et al.*, 2012; Nsereko *et al.*, 2013;), diet (Ayele et al. 2012 ; Nsereko *et al.*, 2013;. 2013), drugs (Heissam, Abuamer and El-Dahshan, 2015; Nsereko *et al.*, 2013; and foot care (Nsereko *et al.*, 2013).

- **Self-stigma**

Patients reported fear of being labelled with T2DM (Adisa Alutudu and Fekeye, TO., 2009), hence their inability to carry medication with them or to travel (Adisa Alutudu, M.B., Fekeye, TO. 2009; Heissam et al. 2015; Adisa and Fakeye, 2014).

#### 4.3.5.3.6 Theme 6: Type 2 diabetes, complications, comorbidities and medications

- **T2DM complications and consequences**

T2DM complications like blindness may cause stress that can inhibit self-management activities (Belue *et al.*, 2013). Past hospitalisation with DM was associated with poor medication adherence (Waari, Mutai and Gikunju, 2018). Clinical conditions like knee joint pain, dyspnoea and fatigue were reported as the most frequent barriers to exercise adherence, (Basu *et al.*, 2015). Memory and cognitive impairment also affect self-management activities (Heissam, Abuamer and El-Dahshan, 2015) (Adisa and Fakeye, 2014).

- **Duration of the disease**

One study revealed that those who had lived with T2DM for five years or less had slightly higher scores in general diet, specific diet and physical exercises while those who lived with T2DM mellitus for 6 years and more scored better in foot-care (Mosha and Rashidi, 2009). Poor medication adherence was associated with the duration of the disease 2 –10 years (Waari, Mutai and Gikunju, 2018). A duration of less than one year since diagnosis was found to be associated with low medication adherence (Arulmozhi and Mahalakshmy, 2014).

- **Barriers related to medications**

Side effects, unpleasant tastes, unhappiness with daily ingestion of medications and fear of injections when patients do not want to shift from oral drugs were found to affect medication adherence (Adisa Alutudu, M.B., Fekeye, TO. 2009; Heissam, Abuamer and El-Dahshan, 2015). Modalities of keeping insulin when going out was also raised as an issue (Baumann *et al.*, 2010).

- **T2DM coexisting with another diseases/comorbidity**

Patients with additional chronic diseases may fear taking too many drugs due to the complexity of the regimen, (Jackson *et al.*, 2015). However, one study reported that patients with other medical conditions who were taking other drugs in addition to T2DM were more likely to adhere to anti-diabetic medications (Rwegerera, 2014).

#### 4.3.5.3.7 Theme 7: Environmental factors

Seasonality of fruits and vegetables (Adisa Alutudu and Fekeye, TO., 2009) affect the patient's diet.

### 4.3.6 Phase six: Discussion

#### 4.3.6.1 Introduction

The purpose of this review was to critically analyse the literature related to self-management barriers among T2DM patients in LICs and LMICs and to identify self-management barriers experienced by T2DM patients in five domains: (1) diet, (2) exercise, (3) medication, (4) SMBG and (5) foot care. The study was guided by the research question: what are the self-management barriers among patients diagnosed with T2DM in low-income countries and low- middle-income countries. The discussion has two parts; the first part consists of a critical analysis of the identified articles. The second part synthesises and classifies the analysed data into a new model describing the barriers of self-management among T2DM patient for better understanding. The discussion ends with a conclusion. Limitations and recommendations will be presented in chapter 9.

#### 4.3.6.2 Critical analyses of identified literature on self-management barriers

In this review the barriers to self-management of patients with T2DM were identified in 25 articles involving a sample of 5,630 T2DM patients, 3,356 females and 2,535 males with a minimum age of 18 years and a maximum age of 83 years. Regarding the quality of the studies, no observational or experimental studies were identified, indicating the need for conducting research with high levels of evidence in LMICs and LICs. The results of the study designs were closer to the results of Mhpe *et al.* (2019) where only one study with a case-control study was observed.

The sample in this integrative review was lower than that of the systematic review conducted Mhpe *et al.* (2019) evaluating the level of adherence to five self-care behaviours recommended for people with T2DM: diet, exercise, medication taking, SMBG and foot care in which they had a total sample of 7,620. The differences are due to the inclusion criteria and the purpose of the study. Their review included articles from 1990 while integrative review in this study included articles from 2008. The integrative review in this study focused on the barriers to self-management while their review focused on adherence to self-management activities.

Few articles (n=6) looked at the dimension of foot care. The remaining n=19 articles included two or more components of self-management, namely diet, physical activity, foot care, glycaemic control and medication adherence.

Foot care is important as amputation is a common complication of T2DM and further studies in this regard should be conducted. All studies which were included in this review used instruments that do not specifically measure the barriers to self-management. They measured how patients perform self-management activities and assessed barriers as factors associated with self-management. It is essential to develop specific instruments for LICs and LMICs to assess barriers to self-management in order to provide better support.

#### 4.3.6.3 Application and discussion of the barriers to self-management of T2DM patients in low- and low- middle-income countries

According toTavares de Souza, Silva and Carvalho (2010), the discussion of the integrative review consists of a comparison of the interpreted and analysed data with the theoretical references and synthesis of analysed data to form a new model or view about the phenomenon under study (Whittemore and Knafl, 2005). The new model emanating from the integrative review makes the review different from a simple scoping review. Figure 4.2 below depicts the model describing the barriers to self-management of T2DM patients in low- and low- middle-income countries.

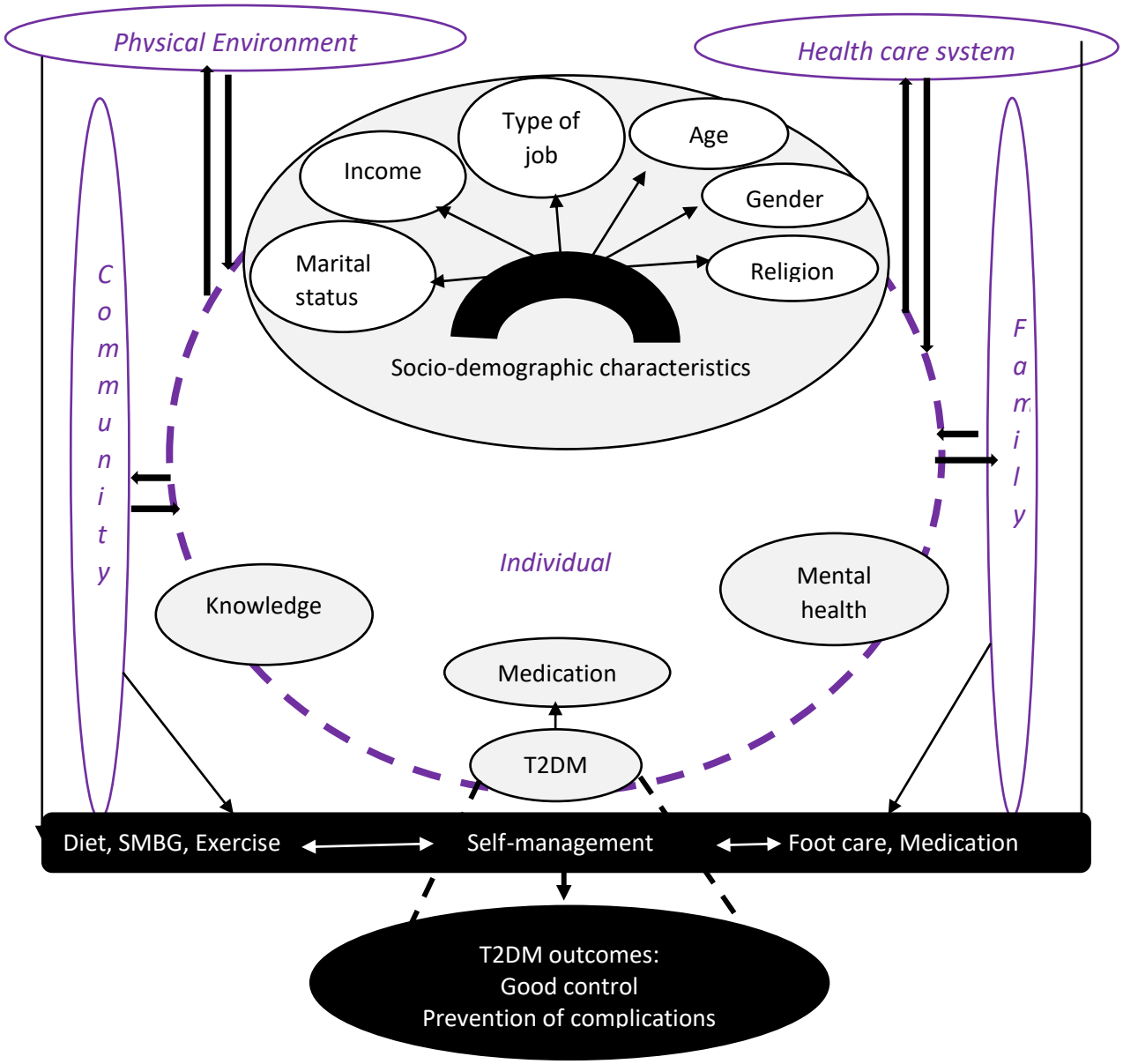


**Figure 4.2: Barriers to self-management of T2DM patients in low- and low- middle-income countries**

As displayed in figure 4.2, barriers to self-management of T2DM patients in low- and low-middle income countries may be described based on 5 components: individual, family, community, environmental and health care system.

**Individual component**

**a. Barriers related to individual characteristics**

- Social demographic characteristics
  - Age
  - Type of job
  - Income
  - Gender
  - Marital status
  - Religion
- Negative attitude or lack of motivation or self-efficacy
- Low level of individual knowledge
- Mental health status leading to negative feelings, anxiety and depression

**b. Barriers emanating from type 2 diabetes**

- Different complications of T2DM
- Duration of the disease
- Existence of another disease parallel to T2DM
- Medication taken by the patient
- T2DM antecedents in the family

**Family component**

- Poor relationship between spouses and family members with lack of emotional support
- Low family income
- Family size
- Low levels of family knowledge about T2DM
- Lack of emotional support

**Community component**

- Culture implying how people eat, exercise, organise events
- Illness perception and misconception implying how people consider the disease
- Self-stigma leading to patients practising self-management activities in isolation and affecting them psychologically

**Health care component**

- Communication between patient and health care providers
- Availability of clear instructions
- Access to care
- Health system organisation

**Physical environment component**

- Availability of healthy food in different areas and in different seasons

In figure 4.2, self-management is delineated on different dimensions of diet, SMBG, exercise, foot care, and medication. It is influenced by all the components and denotes that good adherence to these activities can improve T2DM outcomes and prevent T2DM complications. Barriers emanating from the individual component are dispatched to the midpoint and visualised on a broken line suggesting a continuous interaction with other components. In other words, succeeding in self-management will depend on individuals themselves, the family, the community, the environment and the health care system. The individual component in this figure also includes other factors in line with the disease patients live with, such as complications related to T2DM and drugs being taken.

**Individual component**

This review demonstrated that poverty is the most outstanding barrier in T2DM self- management; its effects are not only felt in the area of access to health care but also when it comes to hinder effective T2DM self-management (Gopichandran *et al.*, 2012). It was revealed that most T2DM patients fail to adhere to the prescribed medication simply because diabetes medication cost is too high. This finding was consistent in the different studies of this review ( Belue *et al.*, 2013; Adisa Alutudu, M.B., Fekeye, TO. 2009; Adisa, Fakeye and Fasanmade, 2011; Baumann *et al.*, 2010; Heissam, Abuamer and El-Dahshan, 2015; Adisa and Fakeye, 2014; Mosha and Rashidi, 2009; Rwegerera 2014); In some areas there is no insurance and health care costs are paid for in cash by patients from their personal pockets (Waari, Mutai and Gikunju, 2018). In addition to the costly lifelong antidiabetic medication, some patients may be taking other drugs for some diseases linked to diabetes, which are also too expensive; thus causing an extra financial burden for the patient. Therefore, two approaches to this problem could be adopted.

The first approach relates to drug prescription where generic drugs which are less costly and affordable could be given priority as they have same effects as branded drugs, often too expensive and sometimes scarce (Jackson *et al.*, 2015). The second approach has to do with the governments which need to regularly provide and replenish public hospital pharmacies with appropriate T2DM medication because private pharmacies would charge too much money for same medication.

Inadequate income caused limited access to blood glucose monitoring equipment hence irregular blood glucose testing and monitoring (Abdulrehman *et al.*, 2016). Blood glucose results are an indicator of good self-management. In the absence of its control, it is difficult to measure the outcome of self-management which may lead to further complications (Foley and BeLue, 2017). Where diet is concerned, the financial issue becomes critical as a lack of healthy food choices can lead to missed meals or, despite the patient's will to avoid them, consumption of a diet consisting mainly of carbohydrates because they are less expensive than other food groups (Baumann *et al.*, 2010).

Findings assessing the association between physical activity and income are mixed. In their results Parajuli *et al.* (2014) revealed that belonging to a higher economic status was associated with physical activity adherence, stipulating that poor people did not adhere to the requirement for physical activity. However, Mosha and Rashidi (2009) stated that patients from low income groups mostly perform manual activities and consider their daily work good enough as a physical exercise rather than engaging in exercise session separately. This is not surprising because activities such as swimming, gym in designated venues or jogging do not form part of the cultural norms in the developing world (Baumann *et al.*, 2010). People belonging to a higher economic class may also have performed exercise due to other factors such knowledge which was found to influence all activities of self-management.

Several factors contributed to low levels of practising foot care in the T2DM population and one of them was poverty, affecting patients' ability to purchase appropriate footwear, as demonstrated by (Mogre, Abanga, *et al.*, 2017).

In this review, insufficient knowledge and low education level were interchangeable barriers in performing self-management activities. This is so in that it is well known that people often acquire knowledge through education (Kassahun *et al.*, 2016).

This is corroborated by a number of studies in this review ( Mogre, Johnson, *et al.*, 2017; Chiwanga and Njelekela, 2015; Kugbey, Asante and Adulai, 2017; Saleh *et al.*, 2012; Foley and BeLue, 2017; Adisa and Fakeye, 2014) and were consistent with other studies from the developed world like the United Arab Emirates (UAE) (Al-maskari *et al.*, 2013) and Bangladesh (Kassahun *et al.*, 2016). More educated patients may be able to interact with healthcare providers (Mogre, Abanga, *et al.*, 2017) and seem to better understand what they are requested to do for efficient self-management than those with less education. This is so simply because they can read and access relevant literature about T2DM and then get to know the importance of what is required of them. This is a concern since in developing countries there is a large number of patients whose literacy levels are low (Mogre, Abanga, *et al.*, 2017). To this end, Putra Yasa *et al.* (2018) showed that lack of knowledge is a major obstacle for low-income patients with T2DM.

Knowledge deprivation is a hindrance for the patients to know which foods are allowed and how big meals should be. They are less aware of the benefits of exercise in lowering blood glucose levels; they do not know that their feet need to be observed, how it should be done; they do not understand blood glucose level targets and they do not understand the course of treatment plan(s) (Putra Yasa *et al.*, 2018).

Conversely, a study included in this review found that education level had nothing to do with medication adherence (Waari, Mutai and Gikunju, 2018). Chiwanga and Njelekela (2015) opined that knowledge in low-income countries like Africa, does not always lead to change of behaviour about foot care but that other obstacles and barriers exist which may result in poor foot care. Those may include lack of foot care services, insufficient programmes keeping healthcare professionals informed of appropriate treatment and lack of surveillance mechanisms.

Barriers and challenges to self-management in LICs and LMICs are indeed profuse. Among individual barriers identified in this review, there are barriers that are related to individual characteristics like age, sex, occupation and marital status.

Literature has revealed that with increasing age, adherence to physical activity, diet (Parajuli *et al.*, 2014) and medication adherence decreases (Arulmozhi and Mahalakshmy, 2014), and this may be justified by several reasons.

For example, many of the old people may easily forget what they are told and their capacity to learn and distinguish what has to be done goes down and leads to poor compliance to instructions. They are unable to perform exercises and to follow instructions on glucose monitoring and foot care.

Moreover, as patients become older, they become less productive and cannot work to generate money for purchasing healthy food or medication. Increased age can lead to decreased physical and social functioning influencing self-management. However, in many low-income countries, this may seem strange as many people were accustomed to the idea that old people were cared for by their relatives. Due to socio-demographic changes in LICs and LMICs, this reality is no longer always feasible and together with this, centres for the care and assistance of the elderly are scarce.

Gender was found to influence the success of self-management. It has been found that female diabetic patients seemed to adhere and stick more on medications than males (Adisa Alutudu and Fekeye, TO., 2009). In another study, it became clear that gender was a cultural issue where attribution of certain responsibilities was gender-based (Belue *et al.*, 2013). For instance, a study done in Senegal revealed that men normally do not take part either in cooking or buying food items and eat what has been prepared by the spouses. On the other hand, it was observed that though women are the ones to prepare food, they often do not have control or power to decide on the amount of money to spend on it (Belue *et al.*, 2013).

Additionally, women may lack self-confidence in performing the self-management activity of SMBG and may choose to satisfy their spouses and children's needs instead of their own (Waari, Mutai and Gikunju, 2018). These results show why family education is more important than individual one since it brings about harmony and family cohesion when it comes to agreeing on expenses to incur for T2DM-appropriate meals (Foley and BeLue, 2017). These results were in contradiction to a study included in this review stating that there is no correlation between gender and adherence to self-management, also found in other studies (Mhpe *et al.*, 2019). However, due to the relative unproportioned gender ratio in the studies, they may have been unable to demonstrate this association (Waari, Mutai and Gikunju, 2018) and it is therefore imperative for health care providers to take into consideration all aspects of gender in T2DM self-management.

Marital status and occupation were other individual characteristics that seemed to hinder self-management in this review (Jackson *et al.*, 2015). A study by Parajuli *et al.*(2014), showed a

statistically significant difference between marital status an adherence level of medication. Widowed participants complied more with dietary advice than participants who were married or separated. This may have been because widowed persons are freer of responsibilities and have more concerns about their health. However, married respondents were more adherent to physical activity that those who were divorced or separated. This may be because married respondents are better supported by their spouses and families than those who are divorced or separated.

Studies indicated the relationship between occupation, income and the level of self-management (Mosha and Rashidi, 2009). People with high pay enjoyed health much more than those with low pay ( Mosha and Rashidi, 2009) . Depending on the nature of work, some patients may be caught up and get too busy and end up forgetting medication timings while others may feel ashamed to be seen taking medication by their workmates (Adisa Alutudu and Fekeye, TO., 2009). Low levels of adherence to foot care was influenced by factors such as inconvenience for work, for example where it is impossible to bear footwear like farmers in different developing countries (Mogre, Abanga, *et al.*, 2017). Health care providers should understand a patient's profession for giving specific education and guidance.

Religion as a barrier only appeared in one article and was about the fasting period for Muslims that takes place during the holy month of Ramadan. This interfered with diet and medication (Abdulrehman *et al.*, 2016). Patients skipped medications because they did not eat. It is vital to understand a patient's beliefs and religious membership to be able to provide better support and guidance.

Factors related to the disease and treatment such as the number and the types of T2DM medications, presence of comorbidities and complications may become barriers in performing self-management activities (Waari, Mutai and Gikunju, 2018). The duration of the disease may become an obstacle to self-management. When the patient has had the disease for long time, adherence level can decrease and many complications may rise ((Parajuli *et al.*, 2014; Waari, Mutai and Gikunju, 2018; Mosha and Rashidi, 2009).

The explanation for a decrease in adherence with increasing duration of the disease, may lie in the patients' frustration with the treatment and the dietary regime they are required to follow.

It could also be associated with progressive Beta-cell failure in T2DM which results in progressive increase in the number and dosage of medications required to achieve optimal glycaemic control (Parajuli *et al.*, 2014). If the duration has been short, patients seem to have interacted less with health care providers (Parajuli *et al.*, 2014) and adherence may decrease. However, the findings of the studies included in this review were conflicting on this issue. A study by Chiwanga and Njelekela (2015) showed that patients who have had T2DM for long time were more likely to have had several education sessions which may have favoured their knowledge and adherence to foot care scores. A study by Jackson *et al.* (2015) differed vastly from other studies and concluded that the duration of T2DM had nothing much to do with non-adherence.

The complications of T2DM can be associated with poor self-management or the duration of the disease and when they are profuse, they can, in turn hinder T2DM patients from performing self-management activities. The prognosis of the disease affects the income of T2DM patients as they are not able to work but also, the physical symptoms and complications such as poor vision and learning difficulties lead to low performance levels of exercising, understanding diet and medication instructions, self-injection, checking blood glucose and observing to foot care.
Patients with hard labour may feel exhausted and lack opportunities to attend social events and assume other responsibilities (Abdulrehman *et al.*, 2016). This is aggravated by chronic co-morbidities such as hypertension and which will require additional lifelong self-management like taking medication, checking blood pressure and others. The fear of hypoglycaemia or fear of aggravating comorbidities can limit physical activity as reported by Mogre, Johnson, *et al.* (2017). This was confirmed in another study conducted in high income countries (Jordan and Jordan, 2010).

The burden of the disease together with poverty, change the patient's emotional status leading to a depressed mood (Baumann *et al.*, 2010; Mogre, Johnson, *et al.*, 2017). Patients do not see their futures clearly and are pre-occupied with the complications of T2DM (Belue *et al.*, 2013). In addition, patients may choose to isolate themselves, feel ashamed of the disease and may omit taking medication in public for fear of being labelled with T2DM (Adisa Alutudu and Fekeye, TO., 2009). This is consistent with other studies that assessed the comorbidity of DM with depression (Mukeshimana and Mchunu, 2016).

Management of T2DM is not easy and patients may display different negative attitudes that can hinder self-management. Some may choose to stop medication (Baumann *et al.*, 2010) when they feel better, viewing T2DM as an acute disease. The chronicity of the disease should be emphasised when educating patients. Unbeknown to health care providers some patients become frustrated with daily ingestion of medication and do not take it. Long term diet adherence may also be difficult and patients may fail in their efforts to refrain from eating unhealthy food (Saleh *et al.*, 2012).

**Family component**

In this review, it became clear that the family is important in the management of T2DM and poor family support has been linked to various self-management barriers (Parajuli *et al.*, 2014). Family support may be valued in terms of money, emotional support, psychological support and everyday decision-making support. Without family support, diet management becomes difficult in terms of access to healthy food but also in terms of having one's own plate at home. Buying glucose monitoring devices and accessing health care becomes difficult. Patients who reported lack of family support had difficulties adhering to medication (Waari, Mutai and Gikunju, 2018; Arulmozhi and Mahalakshmy, 2014). This is not surprising as in some societies decisions regarding health are taken by the family (Foley and Belue, 2016).

Living conditions within families have been reported to affect T2DM self-management. When there are family conflicts and a tense atmosphere, patients manifest anxiety which affects metabolic control of blood glucose according to Baumann *et al.* (2010) and Waari, Mutai and Gikunju (2018) who found that family members and friends play an important role thata enables the patient to cope with daily emotional distress. Considering the importance of the family in self-management of T2DM it is recommended that the family be involved in patient education and counselling. As it is done in the case of HIV and Tuberculosis treatment, it would be more beneficial to enrol patients into T2DM care when they are accompanied by a supporter.

The family size is another barrier that appeared in the results of this review. The family size is crucial; family members may help each other but it also influences the availability of resources needed for the wellbeing of the whole family.

Access to food and available finance for purchasing glucose monitoring devices and medications were found to be problematic in big families (Mosha and Rashidi, 2009).

In contrast, result in a study where patients who belonged to nuclear families followed dietary advice for the full duration of T2DM (Kasturia *et al.*, 2018).

The family type also matters in self-management regarding physical activity. Those living in nuclear family did not adhere to physical activity but those who lived in an extended family were more adherent to physical exercise (Parajuli *et al.*, 2014). This finding was inconsistent with a study conducted by Brownson *et al.* (2000) who stated that the more the support and responsibility of each other by nuclear family, the more the adherence to physical activity.

The influence of positive history of T2DM in the family was found to be a protective aspect. When a patient had a relative or family member with T2DM, it was believed that the patient benefited by having prior knowledge and exposure to the experiences of the family member in carrying out self-management activities (Saleh *et al.*, 2012; Kassahun *et al.*, 2016) and this reality has not been confirmed in previous studies (Saleh *et al.*, 2012; Kesha *et al.*, 2007).

**Community/society level**

The culture of people in their society and community is a strong part of their lives. It influences their views, values and loyalties. In this review a number of cultural customs were identified that affected the acceptability of recommended physical activity, diet and medication guidelines (Baumann *et al.*, 2010).

The suggested eating plan for people living with T2DM did not always consider culturally acceptable ways of planning, cooking, and eating food (Baumann *et al.*, 2010). The preferences in eating in some cultures, the joy of eating together with the family, ceremonial foods are some of the issues that patients reported as cultural barriers ( Abdulrehman *et al.*, 2016; Baumann *et al.*, 2010). In some cultures it was revealed that men do not cook and they do not decide on their diet (Foley and Belue, 2016). In those cases, women may cook unhealthy food due to lack of knowledge or due to their preferences. In other culture, it was found that women do not take health decisions because they may depend on their husbands or on their children and they could not choose what to cook (Foley and Belue, 2016).

The concomitant use of herbal or traditional drugs with modern drugs make patients discontinue medication (Foley and BeLue, 2017; Abdulrehman *et al.*, 2016; Adisa and Fakeye, 2014).

This is concordant with the study by Arulmozhi and Mahalakshmy ( 2014) who found that in some societies in countries like Africa, traditional medicine is believed to be effective and dates far back before the arrival of colonisers. Unlike in western culture, traditional healers are respected, reputed and influential in their communities. Traditional medicine is also used due to limited resources in some societies and some religions like Islamic Marabouts use traditional medicine (Foley and BeLue, 2017).

In some societies, a culture of physical activity is uncommon while the opposite is true for inactivity amongst the population (Foley and BeLue, 2017). In addition, people in some cultures consider their routine home or labour activities to be part of physical activity. Activities such as swimming, gym in designated venues or jogging are not cultural norms in the developing world (Baumann *et al.*, 2010). Advances in technology, for example computers, motor cars, have also led to a more sedentary lifestyle and an increase in diseases associated with inactivity.

The prevalence of misconceptions limiting the acquisition of knowledge regarding self-management constitutes another cultural barrier (Abdulrehman *et al.*, 2016) and is congruent with findings by Fezeu *et al.* (2010) where participants believed that T2DM was transmitted by insect bites or through sexual intercourse. The beliefs about the disease itself in different cultures is an issue; some may feel embarrassed because of the disease and may not do T2DM self-management activities properly ; others have adopted the mind-set that the illness is incurable and tend to avoid practising self-management (Kugbey, Asante and Adulai, 2017; Heissam, Abuamer and El-Dahshan, 2015). In addition, the results of the current study were in accordance with early results reported by Donnan and Macdonald (2002) who showed that the majority of patients are aware of the severity of T2DM and advantages of adherence to treatment with significant effect. These are critical issues implying the crucial need for involving a psychologist or a sociologist in the treatment of T2DM. Health care providers should also understand the culture and the beliefs of patients.

Self-stigma was not common in this review and only one study showed that stigma attached to T2DM in the population studied was high and therefore patients with T2DM would not reveal their diabetic status (Gopichandran *et al.*, 2012).

This implied that patients would fear taking medication or checking their blood glucose when they were in public places to avoid being stigmatised. Mass education to prevent stigmatisation of DM patients is of considerable importance.

**Health care system level**

The study revealed that a domineering mentality is still prevalent amongst health care professionals (Baumann *et al.*, 2010). Patients reported dissatisfaction with clinicians, poor communication, lack of information and guidance regarding prescription regimens vis-a-vis duration of taking medication, the purpose and benefit of the medications and the diet (Adisa and Fakeye, 2014). Over time, this leads to patients to changing clinics making follow-up difficult. However, the rapport built between T2DM patients with health care providers are essential to maintain bond that in turn enhances self-management. Health care providers' relationships predict adherence to medication as they shape awareness of the disease and increase knowledge and trust ( Baumann *et al.*, 2010; Heissam, Abuamer and El-Dahshan, 2015; Jackson *et al.*, 2015). Practising foot care was also associated with advice from and examination by a physician (Mosha and Rashidi, 2009). Those who received advice were likely to perform foot care (Mosha and Rashidi, 2009). Health providers should improve their attitudes and adopt a patient centred care model.

The barriers experienced by T2DM patients in terms of health facilities in LICs and LMICs are twofold; firstly, they are related to poor relationships and ineffective communication and secondly, they are faced with problems in the accessibility of care. Health facilities may be far from their homes. Non-replenishment of stocks, unavailability of various guidelines, lack of specialised units and insufficient numbers of health care providers are specific issues in LICs and LMICs (Adisa Alutudu, M.B., Fekeye, TO. 2009; Adisa and Fakeye, 2014; Waari, Mutai and Gikunju, 2018). Also problematic is the limited printed educational materials (Baumann *et al.*, 2010) regarding self-management guidelines that are available to the patients. Increasing health care accessibility and adequate numbers of well-trained health workers should be a priority in LICs and LMICs as it has been shown that living near a health facility may help patients to benefit from advice and help from health providers (Parajuli *et al.*, 2014).

**Environmental level**

Financial constraints may be barriers to purchasing healthy food as discussed earlier but seasonality of fruits and vegetables is also an issue that was shown in this review (Adisa Alutudu and Fekeye, TO., 2009) and that affects the patients' diet.

## 4.4 Conclusions

Self-management of T2DM is a global challenge and patients from both high- and low-income countries may face challenges like those identified in this review. However, this integrative review revealed that a shortfall in the supply of medical equipment such as glucometers, T2DM medication and fruit and vegetables is greater in LICs and LMICs due to financial constraints. There are also other individual characteristics such as the level of education which has consequences for health. In addition, cultural and social contexts vary across developed and developing countries and therefore, information on self-management, barrier levels and interventions taking place in developed countries are not all applicable in the rest of the world.

# CHAPTER 5: PERCEPTIONS OF BARRIERS TO SELF-MANAGEMENT AMONG PATIENTS WITH TYPE 2 DIABETES IN RWANDA

## 5.1 Introduction

Chapter 5 describes a study conducted in Rwanda public hospitals with the objective of exploring self-management barriers among T2DM patients. It briefly describes the research design and methods used, present and discuss the results.

## 5.2 Research methods and design

### 5.2.1 The study design

The study employed a qualitative descriptive design to describe self-management barriers among patients diagnosed with T2DM in Rwanda. This design is appropriate for an in-depth description of a life experience or event (Sandelowski, 2000).

### 5.2.2 Study setting

The researcher met T2DM patients in the outpatient departments of two selected public hospitals in each province and the city of Kigali; one hospital being in the urban area of the province and the other in the rural area. The idea was to ensure a variety of settings in order to obtain a comprehensive account of the barriers experienced by patients across the country.

### 5.2.3 Study population

The study population was composed of T2DM patients attending the outpatient departments of selected hospitals.

**Inclusion criteria**

T2DM patients, both male and female, aged from 18 years and older, whom the diagnosed of DM was confirmed for one year and willing to be interviewed were recruited.

**Exclusion criteria**

Patients who were disorientated or actively psychotic who could not be interviewed.

### 5.2.4 Sampling, sampling strategy and sample size of participants

A purposive sampling with maximum variation was used to select T2DM patients who were mentally oriented, able to be interviewed and willing to participate. The nature of variation expected was demographic variation such as age, gender and urban-rural setting. Phenomenal variation such as variation in the time T2DM patients had lived with T2DM was also used.

Two or three participants in every hospital were recruited for in-depth interviews of 40-60 minutes duration. A total of 23 interviews from ten hospitals were conducted; the number of interviews determined by saturation. In qualitative research saturation is reached when collected or analysed data is sufficient and no new information is observed in the data (Saunders *et al.*, 2018). In this study, data saturation was reached by the 23$^{rd}$ interview when the researcher declared redundancy in the data because no new information to add to the previous two interviews was forthcoming. In addition, the variation in terms of age, gender, setting and time of living with T2DM was sufficient.

### 5.2.5 Data collection instrument and technique

Face-to-face in-depth individual interviews using a demographic questionnaire (ANNEXURE 19) and interview guide (ANNEXURE 19) were used to collect data. These instruments were developed by the researcher to ensure the consistency of topics discussed. Among the topics discussed were diabetes, the components of self-management and the barriers. The English language was used to develop the interview which was then translated into the local language (Kinyarwanda). The interview guide was then pre-tested with two T2DM patients before data collection was commenced. The aim of the pilot study was to estimate the length of interviews, to become familiar with the questions in the guide and to ensure standardisation of the topics discussed. The pilot was conducted by the researcher herself.

### 5.2.6 Data collection procedures/process

Data were collected between September 2019 and December 2019. Assisted by the nurse in charge, the researcher approached patients who were waiting in the hall, then introduced herself, explained the purpose of the study and how long an interview would take. Patients who were willing to participate entered into a private discussion with the researcher about the selection criteria. Information sheet as well as a consent form to be signed were disturbed to those who gave their consent to participate in the study. The interviews took place in the office availed by the health facility. Since both English and Kinyarwanda are official languages, interview guides in both languages were available (ANNEXURE 19). All participants suggested to have interviews conducted in local language, i.e. Kinyarwanda. The research digitally recorded the interviews following the permission granted by the respondents and then had them transcribed verbatim by two students who were trained and who were doing their Master's Degree in Nursing. The interviewer took notes during the interviews. Each individual interview lasted for approximately 40 to 60 minutes. The researcher collected data from one hospital to the next, based on pre-set variation.

### 5.2.7 Data analysis

Thematic analysis with open coding was used to analyse the data resulting from in-depth interviews. To start with, the researcher would read the transcript while listening to the corresponding audio for the purpose of accuracy, and then had it translated into English by a professional translator. Both versions of the transcript were sent to the research committee of University of Rwanda to confirm validity and consistency of translation prior to importing data into in NVivo 11 for coding. The researcher then read and reread each transcript and used an open coding technique. A coding template was created by the researcher and two supervisors of this study also developed their own template. The two templates where then compared to come up with a final template that was used throughout the analysis process. After open coding as guided by Maguire and Delahunt (2017), similar categories were produced using an iterative process. The research team agreed on list of final themes, described them and ensured that themes are linked to data by assigning a direct quote. The notes taken by the interviewer were used during the open coding process for inductive identification of iterative themes.

### 5.2.8 Trustworthiness

In qualitative studies, there are different approaches to ensure the study quality i.e. trustiworthiness. These include credibility, dependability, transferability and confirmability, as proposed by Anney, Dar and Salaam (2014).

#### 5.2.8.1 Credibility

Credibility is defined as "the confidence that can be placed in the truth of the research findings"(Anney, Dar and Salaam, 2014; p 276). Credibility shows "whether or not the research findings represent plausible information drawn from the participants' original data and is a correct interpretation of the participants' original views" (Anney, Dar and Salaam, 2014; p 276). The researcher established rigour of research by adopting different credibility strategies. The interview guide was piloted in order for the researcher to become familiar with the questions. The researcher spent sufficient time in the field to engage with participants. The open-ended questions were used to get a deep understanding of participants' experiences. The interview phase was as iterative as possible as the researcher used probes to encourage detailed answers. The researcher also ensured that only participants who met the inclusion criteria were selected. During data collection, member checking was done. This was insured by a summary of information gathered at the end of each interview, then by requesting the participants to confirm whether everything narrated was covered in the interview to determine its accuracy.

#### 5.2.8.2 Transferability

Transferability refers to "the degree to which the results of qualitative research can be transferred to other contexts with other respondents" (Anney, Dar and Salaam, 2014; p. 279). To ensure transferability, in this study a detailed explanation of methods and results were reported for the purpose of enabling other researchers to decide if the context matches theirs and if findings could be transferred to similar settings. The purposive sampling aided to recruit participants that the researcher believed to have sufficient knowledge on the topic of the study.

#### 5.2.8.3 Dependability

Bitsch (2005), defined dependability as "the stability of findings over time" (p. 86). Dependability involves evaluation of the findings, the interpretation and recommendations made by the study. This requires not only a continuous review of the findings of the study but also an examination of interpretations as well as recommendations made, by someone outside the research to insure that they are matching the collected data (Anney, Dar and Salaam, 2014). In this study, the research process was documented in sufficient details for replication using an audit trail to account for all the research decisions and activities involving data collection, recording and analysis.

#### 5.2.8.4 Confirmability

Confirmability "refers to the degree to which the results of an inquiry could be confirmed or corroborated by other researchers" (Anney, Dar and Salaam, 2014; p. 279).The researcher took reflective notes of her feeling and thoughts, she clearly stated her own position to avoid any deviation from what participants said during the analysis of data. In the same way, the audit trail was used and enabled the researcher to show the evidence from the data, thus approving that the findings are not merely based on anticipated assumptions of the researcher. The accuracy of translation of interviews was ensured by using bilingual experts who understood both Kinyarwanda and English.

### 5.2.9 Data storage

Before being destroyed, the transcripts and recorded interviews will be kept in a password-protected computer for five years. The destruction process shall be overseen by the researcher.

## 5.3 Results

### 5.3.1 Sample size description

Table 5.1 shows that about 2 to 3 participants were selected from 10 public hospitals across four provinces of Rwanda.

**Table 5.1: Number of participants at each hospital**

| Hospital | Province | Number of patients | Hospital | Province | Number of patients |
|---|---|---|---|---|---|
| CHUK | Kigali City | 2 | Kirehe | East | 2 |
| Kibagabaga | Kigali City | 3 | Gisenyi | West | 2 |
| Remera Rukoma | South | 3 | Muhororo | West | 2 |
| CHUB | South | 2 | Ruhengeli | North | 2 |
| Nyamata | East | 3 | Ruli | North | 2 |

All twenty-three (23) participants were T2DM patients. Fourteen (14) were female and nine (9) were male. The age of participants was ranging between 34-74 years, mean age of M (±SD) 52 ±12.6. The demographic characteristics of 23 participants are summarised in table 5.2.

**Table 5.2: Demographic characteristics of participants n=23**

| Characteristics | Percentage (n) | Characteristics | Percentage (n) |
|---|---|---|---|
| **Age, years, M (SD)** | 52 (±12.6) | **Profession** | |
| **Gender** | | Farmer | 8.2(2) |
| Female | 60.8(14) | Retired | 13(3) |
| Male | 39.2(9) | Business | 17.6(4) |
| | | | |
| **Marital status** | | East | 17.3(4) |
| Married | 73.9(17) | West | 26.4(6) |
| Widow | 13(3) | South | 17.3(4) |
| Single parent | 8.6(2) | North | |
| Separated | 4.3(1) | | |
| **Level of education** | | Private servant | 8.2(2) |
| None | 13(3) | Public servant | 13(3) |
| Primary | 39.1(9) | Unemployed | 13(3) |
| Secondary | 39.1(9) | **Province** | 17.3(4) |
| Tertiary | 8.2(2) | Kigali City | 21.7(5) |
| **Smoking** | | **Alcohol use** | |
| Yes | 0(0) | Yes | 86.96(20) |
| No | 100 (23) | No | 13.043) |

### 5.3.2 Barriers to self-management among T2DM in Rwanda

Barriers to self-management emerged into seven interrelated themes, namely (1) individual characteristics, (2) implications of those delivering health care services, (3) access to health care facility and operation, (4) complexity of managing diabetes (5) psychosocial factors (6) community and environment aspects and (7) family dynamics (table 5.3).

**Table 5.3: Self-management barriers among participants n=23**

| Themes/sub-themes | Sources(NVivo) | References (NVivo) |
|---|---|---|
| **1. Individual characteristics** | | |
| Financial constraints | 22 | 84 |
| Advanced age | 6 | 7 |
| Level of education | 2 | 4 |
| Marriage status of individuals | 1 | 1 |
| **2. Implications of those delivering health care services** | | |
| Lack of guidance on how to perform self-management activities | 18 | 44 |
| Difficulty to understand written information by HP | 7 | 8 |
| Lack of individual care | 6 | 7 |
| Lack of patient participation in decision making | 5 | 5 |
| Lack of continuity of care | 4 | 6 |
| Poor communication or using bad or bitter words | 1 | 1 |
| **3. Access to health care facility and operation** | | |
| Non-replenishment of stocks | 9 | 17 |
| Long queues | 9 | 10 |
| Long travel to health care facility | 3 | 6 |
| Health care policies | 1 | 1 |
| **4. Complexity of managing diabetes** | | |
| Diabetes repercussions, complications and comorbidity | 17 | 46 |
| Medication realities | 5 | 5 |
| Lack of awareness about self-management and T2DM | 15 | 22 |
| **5. Psychosocial problems** | | |
| Negative emotions | 17 | 37 |
| Personal attitudes of T2DM patients | 16 | 23 |
| Illness perceptions | 4 | 9 |
| Behavioural or personal beliefs | 2 | 4 |
| **6. Community and environment aspects** | | |
| Cultural realities among T2DM patients | 10 | 11 |
| Stigma of T2DM patients | 5 | 9 |
| Lack of supporting programmes | 5 | 5 |
| Unavailability of fresh food | 4 | 5 |
| Requirement of the work | 6 | 8 |
| **7. Family dynamics** | | |
| Lack of family support | 8 | 12 |
| Gender roles | 8 | 8 |
| Other responsibilities and priorities of the family | 1 | 3 |

#### 5.3.2.1 Theme 1: Individual characteristics

There were some modifiable and non-modifiable individual characteristics expressed by participants as being barriers to self-management. Characteristics included financial constraints, age, level of education and marital status.

- **Financial constraints**

Almost all participants that said financial constraints isa barrier to undertaking self-management activities. Some stated that their income was very low and they were unable to get what they needed for self-management.

> *"...diabetes takes a lot of money! Sometimes we fail to satisfy our needs for* self-*management".* P2DMH52

Almost all participants agreed that it was not easy to get money to buy different devices needed for self-control of their blood glucose, such as glucometer and reagent strips. One participant explained in detail by saying:

> "*There are challenges in controlling blood sugar level… we are told to come for check up every 30 days, i.e. at least in a month. But we know well, that blood sugar level is something which regularly keeps changing and thus requiring even unplanned check-ups anytime you feel something wrong in the body! When you suspect something, you should control but unfortunately, we do not have appropriate equipment for that! Waiting for 30 days to come here… don't you think it is a problem!".* P2DMH21

For example, one participant said that he had never had the results of fasting blood glucose. He stated that he doesn't have money to buy a glucometer to use at home.

> *"The fasting blood glucose was done long ago; I cannot even remember when...when my glucometer was functioning. I would often have fasting blood glucose but because it is now broken…and can't buy another one it is a problem…here it takes time to get blood test and we eat before…".* P2DM92

Many participants said that they cannot afford either a glucometer or reagent strip but there were others who said they could only afford a glucometer.

> *…" the blood glucose monitors (glucometers) are available but getting these small things… I do not know what you call them… "reagent strips? Are they?", it is a problem. They are too expensive! "...* P2DMH11

Not having a glucometer at home is a burden to those using injectables as they cannot react to changes in blood glucose levels.

*"For those taking insulin injectable…after injection, all the sugar in the body is consumed and when there is no glucometer to control, the patient only come to know that there is a problem when they start crawling like a baby! I think that availability of glucometers and reagent strips would help a great deal".* P2DMH102

Participants expressed the view that income affects their diet. For some participants this is a permanent barrier but for others it may happen quite often or occasionally as stated by these participants:

*I often see here old ladies who are nearly dying of malnutrition! it is really so sad. When I see them I feel like crying! How can you tell an old mum to be selective about what she eats while she has nothing at all to choose out of?* P2DMH11

"*…we try but again everything depends on your financial abilities to afford appropriate diet…… For example, we are advised not to eat red meat, but how can we afford white meat like chicken, rabbit and fish which are expensive? Therefore, as we fail to get this, we end up eating red meat…* P2DMH21

The participants also mentioned that they did not regularly respect their diet.

*you may respect the recommendations for a week but thereafter you fail!"*. P2DMH23

Participants in rural areas had problems maintaining a balanced diet but those in town also were concerned.

*People in rural place know very well about this but they so rarely manage to take balanced diet! People in rural places do not often eat things like fruits…maybe they can eat vegetables because they grow everywhere even in the bushes but all that they recommend …. I am telling, only just few people can afford it!* P2DMH21

*"Are you talking about appropriate diet…ahhaa…? too expensive too. For one to get appropriate diet, s/he needs to have enough financial means. You know that people like me living in city do not grow anything around their houses, we have to buy food from the market. If you need a special diet and you have a family…it is a serious problem".* P2DMH11Female47eng reedited

Income affected medication adherence as well.

"*I take drugs well and the only challenge is when I finish drugs and I do not have money to get more. This may sometimes happen but it does not take long"*. P2DM41

"*…we may sometimes fail to get drugs when we do not have money…"*P2DMH41

Participants expressed the opinion that the government should subsidise some of the diabetic needs and that health insurance should help them to pay for blood glucose devices as they were unable to afford them.

*"…at least if reagent strips could be covered through health insurance schemes…I also think the hospitals and Government should subsidize some of the things we need, like glucometers to test".* P2DMH61

Some participants even suggested that they should receive free medication, similar to people living with HIV.

> *"Let me tell you something; if at least drugs for diabetes were free of charge like for HIV/AIDS, I would say they do something to help us but…"* P2DM41

> "*The way the country look at HIV/AIDS should be the same for diabetes. You know very well that treatment for diabetes is expensive. Let's me be clearer about this: I need to have 3,500 RWF every month to pay this additional fee to what my medical aid pays. For you, maybe you think it is not a lot of money but it is for me".* P2DM32

During this study, a participant mentioned difficulties to access diabetes care due to financial categorisation (Ubudehe category).

> *"I think something has to change about poverty categorisation in Rwanda. If for instance you are in category 3, you can't come to hospital and tell the doctor what you need because they won't help you saying you are wealthy... honestly, a diabetic patient can't be in the 3rd. poverty category".* P2DM55

- **Advanced age**

Opining on this barrier, a participant of an advanced age stated that it was difficult to engage in self-management activities such as being too old to get to hospital to collect medication, get their blood glucose checked, get instructions and others were not able to work to earn money because of old age. It was also difficult to do physical exercise because of the age.

> *"we may sometimes fail to get drugs or forget to take them… I am old…there is a time I am weak and cannot reach the hospital".* P2DMH41

> *I do exercise what I feel I can do and this is because of my age! It is not easy for us. When you are old exercise is not something easy…"* P2DMH22

- **Level of education**

Participants said that because of their levels of education, they could not read what the health care providers were writing down for them.

*"I am not good at writing because I went up to primary 4 but…. This is the only problem as I can't read all that they write to me".* P2DMH41

*"About understanding the prescription or any other papers from the doctor... others read for me… It is written in foreign languages, so I never read".*P2DM91

- **Marital status**

In this study a participant who was separated from her husband explained that she was the only breadwinner in the family and being the only person who earned an income was stressful.

*"…as a female head of a household… the challenges are so numerous…I sometimes get stressed and collapse in a coma. Poverty and meeting my children's needs are the biggest challenges …conditions are nowadays very hard to everyone but for me you understand…I am alone".* PD2MH82

Another participant who was a widower also mentioned the same problems.

*"Remember there are also some other household expenses to be incurred! I am a widower and I have 10 children that I have to take care of... there are also some other things we spend money on. Sometimes I do prioritize my family and forget my diabetes".*P2DMH43

#### 5.3.2.2 Theme 2: Implications of those delivering health care services

In this study almost all participants expressed problems related to health care providers. This theme will be presented as five sub-themes consisting of; difficulty in understanding information written by health providers, lack of guidance on how to perform self-management activities, lack of individual care, lack of patient participation in decision-making, meeting different doctors and poor communication or using bad or bitter words

- **Lack of information and guidance on how to perform self-management activities**

Many participants reported that they were not well guided by health providers on how to perform self-management activities.

*"We do not have enough time to talk to them our own problem…they rush and you cannot have time to ask what you did not get well… They will always ask you same information about drugs …if you still have medication! This is not good because we can't be open when we find that they are not ready to listen to us. We prefer to keep quite".* P2DMH41
*"I do not know about my recent Glycated hemoglobin…they just do blood or urine tests and do not tell us for what purpose. Maybe they took it but I am not aware"*P2DMH41

*"Sometimes doctors are busy and they do not find time to listen to us! They just prescribe medications!".* P2DMH71

"*We do not know what we can exactly eat. They will tell you eat this and this but no one will tell you the amount. And the information is sometimes conflicting. Some people will take for example potatoes, rice etc. others will say you should not. We need dieticians who could guide us*". P2DMH72

Lack of information was expressed in different opinions of participants and consisted of lack of information for all dimensions of self-management and specifically on certain dimensions like foot care where almost all participants stated that they never received information about foot care. One participant said:

*"Information is something important…though we may sometimes not have full access…"* P2DMH23

*"...balanced diet? I just eat whatever I have as long as it makes me feel ok no one told me about that".* PD2MH82

*"I am afraid I know nothing about this foot care. Specific hygiene of the feet? Like what?*". P2DMH22

- **Difficulty in understanding information written by health providers**

Some participants explained that it was hard to read or understand what health care providers write such as instructions and prescriptions unless they were helped by other persons.

"*…to be honest with you, I actually do not understand anything they write… I need someone to help you understand*". PD2MH82

"*…we just get drugs and go... additionally, doctors have such a special handwriting that we fail to read…if only could they at least tell us the name of the drugs and how we have to take them. Honestly we do not know the names or the types of drugs that we take*." PD2HM81

- **Lack of individual care**

Some participants said that health providers adopted a global approach when caring for patients and did not focus on individual care or understanding individual challenges.

*The problem is that this is done in general while they could talk to individual patients to learn more about us especially that we have different problems. For example, some come with problems related to medication… we would appreciate if they could attend to each of us separately!".* P2DM101

"*...that is worsen by the fact that information is given to everyone. Imagine… they give food related information to poor and rich together…the nurse gave the same education about diet! They should understand that we have different challenges".* P2DMH72

- **Lack of patient participation in decision-making**

Participants expressed their trust in the doctors but that they were not active in their self-management

> *"When I come here, I get drugs without... But I can't say I am very sure I am given drugs for diabetes! We simply trust doctors and know that what they are doing is good for us. However, as I said above, they never tell us what effects the drugs we get are going to have!".* PD2HM81

Some would even take prescribed drugs even if they realised that their blood sugar was very low or very high.

> *"I cannot decide myself when at home… I just abide by what the doctor tells me because I trust them as educated people… if for example, I notice the blood glucose is too low or high I still take the medication and later I will go to hospital".* PD2HM81

- **Lack of continuity of care**

A participant reported that patients met different doctors when they visited the hospital and this compromised the continuity of care.

> *"The problem is that we meet different faces of doctors when we come here and they tell us different stories...we do not have one doctor to follow up our cases or we are not told this is specialist doctor for diabetes to go to…. this is the problem we have!"* P2DMH32

Continuity of care was also hampered by what participants expressed as lack of specialist care, that is, they were not treateded by specialists and felt that there were times when they were not well treated. Participants recommended specialised doctors and services be made available as is evident in this extract.

> *"What we need is to be treated by medical specialists. I fell somewhere I am not well treated…. If we have opportunities to openly talk to specialists, this would make a lot of difference".* P2DMH22

- **Poor communication or using bad or bitter words**

A participant stated that the communication between patients and health providers was not as good as they would have wished and they felt unwelcome when visiting the hospital.

> *"sometimes also the doctors do not use good language, we feel not welcome".* P2DMH11

> *"…there is a need for the health providers to know which language to use with the diabetes patients because they use bitter words. They should know that everyone has his/her own problems that are to be dealt with carefully…You may feel like not coming on appointment day because of the language they use.* P2DMH22

#### 5.3.2.3 Theme 3: Access to health care and facility operation

This theme consists of all barriers related to the health care facility. It includes five sub-themes, namely non-replenishment of hospital pharmacy stocks, long queues, long travel to health care facility, health care policies and lack of specialised services for diabetes

- **Non replenishment of hospital pharmacy stocks**

Participants agreed that those who had a health insurance or medical aid, paid less money for medication. However, the community insurance used by most participants only partnered with the hospital pharmacy which was often out of stock of the necessary medication. Patients were then sent out to buy medication at a private pharmacy which was expensive. Some patients may have gone back home without medication for a few days while waiting for the hospital pharmacy stock to be replenished.

> *"Drugs are covered by health insurance…but when we don't get them here, most of us can't buy in private pharmacies! …we are often brought to hospital in coma and then the hospital ends up admitting us…"* P2DM91

> *"When you get drugs here, you only pay 10% of the total price and the health insurance covers the rest, but you pay 100% in private pharmacies… those who have relatives may go and beg them so that they can assist…"*P2DMH61

> "…*there is a problem of getting drugs here. The provider sometime fails to have drugs in the store and most patients go back home without getting them. For example, there are some patients who were here with me today who told me they have not received any medication for 2 months. They were also told there was no hope for them to get any today and you know well that there are too expensive in private pharmacies".* P2DMH21

- **Long queues**

Many participants stated that they spent protracted time in the health facilities before being attended to because of long queues. Most of the time they had left home without having anything to eat as there was the expectation that they may have had to have blood glucose tests. The long wait in queues meant that they became hungry, would eat, and consequently blood glucose results would be high.

> *"Coming here and sitting down for hours waiting to get service make some of us very stressed… remember that after sitting for hours here may make the blood glucose levels either too high or too low…Always! We spend long hours here up to five...or six…I think we need advocacy on this!".* P2DMH42

*"Maybe you saw a young man who was here with us, he has diabetes but it took too long before he could get attended to! He had been waiting so long and the level of blood sugar had gone down. His wish was to be tested before eating anything but as they delayed, he decided to have a sweet because he was feeling bad, as a result, when they do the test they find the sugar level high, which actually is not the right results!".*P2DMH21

Participants stated that they waited not only for consultations but also for prescriptions to be filled at the pharmacy, laboratory tests and cashier services.

*"The pharmacies have poor performance. A patient spends hours there before they can get drugs…one often spends about two hours there. Actually this is very hard for us* P2DMH23

*"Another thing is long queues here! You may come for a laboratory test and you end up spending long hours, even until later than noon and because you haven't had breakfast, you may get hypoglycaemia! This is very possible!"* P2DMH72

The participants opined that the long queues may have been caused by the low number of the health providers in comparison with the large number of patients, carelessness of health providers and the technology used in the filing system and for payment. Slowness of the internet also featured in patients's remarks.

*"…they should increase the number of staff they are few…we spend long hours waiting… there are also technology-related issues… I am even told that there are some data being entered in computers today…it is a problem…".* P2DM92

- **Long travel to health care facility**

The long distance from home to the health facility was an issue as some patients become exhausted and collapse is always a fear.

"*The only challenge is the distance between my home and hospital and sometimes when the level goes up I fail to arrive here on time and sometimes I end up getting admitted then…".* P2DMH73

"*Some of the problems include long travels from our homes to hospital…one may even collapse into a coma on the way".* PD2HM81

- **Health care policies**

At the time that this study was conducted, T2DM patients were taken care of in the district hospitals and patients were requested to bring a transfer paper to access care every month. These discouraged patients and some missed appointments as related by one participant.

*"Every month I need a transfer to come here…so funny…This something hard for us. It is both time and money consuming and people may get discouraged….and miss appointment!".* P2DMH22

#### 5.3.2.4 Theme 4: Complexity of managing diabetes

T2DM is a chronic disease requiring complex management. It has various complications and comorbidities such as hypertension. Different barriers can be associated with the complexities and in this theme they were summarised into three sub-themes: diabetes repercussions, complications and comorbidity, and medication realities.

- **Diabetes repercussions, complications and comorbidity**

Participants were aware that T2DM has many repercussions and complications that would affect their self-management. They may be unable to work and consequently have little money to buy healthy food, medication or blood glucose monitoring devices.

> *"…the biggest challenge is body fatigue which is a hindrance for us to make money and then when it comes to spend money to come to hospital and buy drugs, this becomes a challenge because you haven't got money".* PD2MH82

Diabetes complications and comorbidities may result in failure by patients to engage in physical activity.

> *"I have been advised to do sports but I can't run because when I try, my heart starts beating so fast…I also have constant fatigue…and also when you get a wound it is hard for it to heal".* P2DMH72

An example was cited referring to patient has blurred vision and cannot read and as a result, does not understand instructions or give her/himself an injection.

> *"I cannot read! I think you have noticed… I live with a niece my elder sister's child to whom I show the paper when I arrive back home and she tells me the date of the next appointment. When she is not there it is a problem…"*P2DMH41

> *"I cannot withdraw the insulin from the small bottle to the syringe because of the blurring vision … my husband and other small boy of my sister help me when they are at home…when they are not there I have to wait for them to be back…".* P2DMH52

Frequent hunger was also reported as a repercussion of T2DM and difficult to control.

> *"I personally go so hungry very often…it makes me want to eat so frequently that I have to eat something in the morning, something else around ten and so on…I may have to eat 5-6 times in a day and I find this as a serious effect on my weight".* P2DMH22 Female 36

Another repercussion mentioned was the attitude of employers toward people with T2DM.

> *"When I learnt that I have diabetes, I immediately lost my job…. nowadays, I simply get casual jobs and that is all…they maybe did so because they were realizing that what they were expecting from me could no longer be there! (sighing), and I think I was then physically weaker than now…that job requires to be physically and mentally strong...".* P2DM92

- **Medication realities**

These realities consist of the side effects of taken drugs and how insulin at hand is kept.

> *"I have a problem with metformin. This drug reduces appetite because I always feel like vomiting".* P2DMH102
> *"I am telling you these injectable have had such serious complications that I even have difficulties to have a position to lie in when I am in bed…I just asked them if they could change my medication from injectable to tablets but they said no (crying)". P2DMH52*

> *"When I have to travel, I do not take any injectable... they need to be kept in a cold place how can you transport it, it is not easy…".* P2DMH43

> *"When you take medication in the morning you feel dizzy and forgetful... you oversleep and have difficulties getting up… you can fail to attend to your usual business activities…I only take them at evening".* P2DMH62

- **Lack of awareness about self-management and type 2 diabetes mellitus**

Participants expressed loinsufficient knowledge regarding T2DM

> *"I know nothing about T2DM. They always say there is type 1 and type 2 but I don't know the difference. I am just given drugs and that is all".* PD2HM81

> *"I do not know anything at all about T2DM causes...how is different from type 1?".* P2DMH41

Some participants expressed lack of knowledge regarding diabetes and self-management. Some were not even aware of self-management activities that they had to perform:

> "I *don't think there is anything you can do about diabetes... I simply pray God so that I can go on getting on well with other people*" P2DMH51

When they were asked to name some activities done for self-management some responded by saying that they were unware of any.

> *"nothing else I can do...just nothing I only come here to get medication".* P2DMH21

Some participants considered physical activity as equating with home activities.

*No... apart from some manual activities like digging in the fields. No other physical exercises… I just work in my banana field weeding with a hoe. That is what I have been doing recently.* P2DMH41

A number of particpants were not aware of dietary self-management as evidenced by the remark below:

*"No, I cannot say they have enough knowledge about amount of diet I should take, I simply use common sense to think about average amounts required*". P2DMH21

#### 5.3.2.5 Theme 5: Psychosocial factors

T2DM is chronic disease creating difficulties in dealing with daily life challenges. Patients explained some of the psychosocial problems and behaviours they encountered. The theme was characterised by four sub-themes categorised as negative emotions, personal attitudes of T2DM patients, behavioural or personal beliefs, and illness perceptions.

- **Negative emotions**

Negative emotions were expressed by many participants as a barrier to self-management. Participants were worried about the diagnosis of T2DM and that this could affect activities of self-management. Some participants were worried about the complications of T2DM or those related to the drugs being taken.

*I always think about adverse effects of drugs I take like causing kidney problems and/or hypertension…this would make me so worried. During such a period, I would stop medication for a period of 3 days or more and this would make me feel bad again and then I would decide to resume (Crying…….)* P2DMH41

*"This disease will almost make you go mad and lose hope in life…!"* P2DMH61

*"I am telling you that the patient may even commit suicide or fail self-management it is a severe disease".* P2DMH61

Another complication that caused patients to worry was the the inability to have sexual intercourse, making them feel useless.

"*...it is such a bad disease…you just live with your spouse as if you were not married because sexually you are not active! It is just a disease you live with for years…. You just look at your spouse but you fail to assume your conjugal responsibility! and you feel like you want to stop everything...*" P2DMH51

Some participants were also worried about the fate of the family and the children. They felt unable to support their family and considered themselves as being irrelevant to the family.

*"I felt desperate and fed up with my life… This happened to me and I nearly stopped medication… seen that I was the only one to satisfy my children's needs like school fees…and looking at the way my health conditions were worsening, I would always wonder what would happen to them and this would make me feel so hopeless… when I talk of diabetes, I feel bad and wish I was even no longer alive (crying…)* P2DMH52

*"There is no hope for T2DM patients to leave the family in good conditions when they die. Let's take my own example: you know well that the husband is normally the one to support his family, as days go by and as I get weaker and weaker…I am afraid my family will face a lot of difficulties when I die. I can see the family situation is progressively going lower and lower. It stresses me! (shaking head)".* PD2HM81

- **Personal attitudes of T2DM patients**

They are different individual attitudes that can hinder T2DM patients from undertaking self-management activities. Patients may forget to take medication, lack time to do exercise and fear injections.

*"Let me tell you, I have so many things to do I cannot have time for sport!?* P2DMH32

*"I fear injections I cannot check my blood glucose! even when I am here for the control, I can't dare look at the doctor when using a needle to control".* P2DMH21

"*sometimes in the morning I am in such a hurry that I forget to take them".* P2DMH62

Ignorance is another attitude that may hinder T2DM patients from undertaking self-management activities. In addition, patients may not change what they had been accustomed to doing before being diagnosed with diabetes.

*"Maybe because of ignorance, we never ask type of diabetes or causes. We simply know that diabetes is diabetes, a disease that a patient gets when their levels of blood glucose are high. My levels never go down and sometimes I reach 500 and at that level, I collapse in a coma".* P2DMH61

*" Sometime I feel like I should again drink some alcohol as I used to do- nature is something hard to control …I have strong desire for alcohol. To be honest, I don't think I can stop having alcohol all my life*!"
"! P2DMH21
"*… but to be honest it is not easy to be on special diet*". P2DMH23

- **Illness perceptions**

Participants had different perceptions about the causes of T2DM and these could constitute barriers to self-management. Some participants associated DM to witchcraft or a disease affecting old people.

*"Some people in remote places still confuse diabetes with witchcraft! And this is something that needs to be addressed as some people can stop medication…"* P2DM92

"*…would get up and take drugs immediately and thereafter I would feel dizzy and nearly collapsing…because of ignorance, I didn't know this was caused by drugs but I would instead attribute it to bad spirits I thought they were haunting me".* P2DMH61

*"I feel ashamed because I am always told that diabetes is for very old ladies and men or just unhealthy people…"* P2DMH62

There is also a perception that T2DM is a severe disease and that nothing can be done to treat it. This can result in reduced efforts to undertake self-management activities. This response was received by a participant when was asked which self-management activities a T2DM patient can undertake:

*"I don't think there is anything you can do about T2DM, it is a bad and severe disease. I simply pray God so that I can go on getting on well with other people".* P2DMH51

- **Behavioural or personal beliefs**

Patients living with T2DM may have their own considerations about self-management. They share information among themselves and may be influenced by that information.

*"I heard that diabetes medication may cause kidney problems and hypertension because diabetes medication expands over a long period of time, and so as a consequence the patient may contract some other diseases…and this causes worries…you may even stop them!"* P2DMH71

Other beliefs relate to opinions on which diet is better to manage diabetes. Patients hear rumours and reported experiences that they consider to be the truth.

*"Let me tell you one thing: when I take juice, juicy wine from banana or sorghum, I feel bad but when I take beer in small quantity, I feel well. I cannot even take tea or porridge from sorghum or maize because they cause stomach ache".* P2DMH41

"*Sometime back, a friend of mine advised me to take banana juice after boiling it and leave it for some time to get cold. I did prepare it, put it in a small jerry can and left it to cool down for two days and had some!... It nearly killed me and I almost spent 2 weeks in bad conditions. That friend of mine told me that that this may be caused by amoeba. I think I have it!".* P2DMH41

#### 5.3.2.6 Theme 6: Community and environment aspects

This theme was characterised by four sub-themes: cultural realities, stigma, the lack of supporting programmes and unavailability of fresh food in some areas.

- **Cultural realities among T2DM patients**

The culture of people determines who they are and includes habits (what they prefer to eat) and routines (expectations when attending ceremonies such as weddings). Most of the time, food prepared for ceremonies is inappropriate for DM patients.

> *"The problem with ceremonies is that they serve food that one cannot eat it because of diabetes and it is hard to ask for special food which is appropriate for your disease, you just eat".* P2DMH32

Many participants reported concomitant use of herbal or traditional drugs with diabetes medication.

> *"I sometime used herbal liquid medication …there is a time I had to stop other medication for a month. I took that medication when the level of insulin had reached 416 and it decreased. This was brought to me by someone and I would use it through anus in the morning and in the evening. I still keep some grain from these herbs".* P2DMH22

The use of nutritional supplements was also reported by some participants. They used what is locally known as "Abagorozi medicine"; supplements that are mainly used by members of the Seventh Day Adventist Church.

> *"... there are some healers called abagorozi. We are told that they treat diabetes until it is cured but I am not sure if it true! They give some supplements which are good".* PD2HM81

- **Stigma**

Stigma was mentioned by many participants. One the one hand, the stigma was attributed by members of the community. Participants stated that people in the village did not understand diabetes patients demonstrated stigmatising behaviour by talking about patients behind their backs. As a result, patients become discouraged and feel abandoned.

> *"(with delays) … people would instead discourage you…! Sometime they look at a diabetes patient as a dead person! useless and if you don't make yourself strong enough and try your self-management, you may get stressed and die".* P2DMH42

> *For example, you may hear people saying that the diabetes patients are useless since they eat while they can't do anything and this causes some stigma. When you hear that, your blood glucose goes up and this makes you feel embarrassed*.P2DM92

*"This is something I witnessed the day before yesterday. We had a meeting in our village and we were asked to raise our hand if you were a head of household and had a given disease. Some would do and people would start questioning about that and even like laughing at them, especially when they look healthy….! Therefore, I decided not to say anything about my health conditions …….one day I had to die because I could even hide my own children that I am taking diabetes drugs."*PD2MH82

On the other hand, participants expressed self-stigma where they feared reporting themselves to get support, fearing that they would be stigmatised. Some participants revealed that they felt ashamed and could not reveal their status.

*"I don't get any other support especially that I do not open up to show them that I have such a problem...I feel ashamed because I am always told that diabetes is for very old ladies and men or just unhealthy people... I didn't tell the children"* P2DMH62

*"This is a so bad disease but I do not see why I should be raising my voice in public revealing it to anybody! You feel useless!".*PD2MH82

- **Lack of supporting programmes**

Participants said that they lacked local supporting programmes or clubs that would help them to assist to each other.

*"My wish is that there is a need to form the patients' groups or cooperatives where they can meet and discuss their problems and solutions…this could be an opportunity to raise awareness for those who do not know much about diabetes especially in rural areas… we lack suck opportunities".* P2DM92

*This is something which does not exist…if we could form an association…the association of people with same problems …that an association brings together people and then they can discuss the problems they have. Remember what I was saying about people who fail to get transport money to come here, if we have an association, we could each contribute some money and this would help such people*. P2DMH22

The absence of such programmes left participants feeling that their voices were not heard by health care providers.

*"However, we eventually realised that our voice could not be heard maybe because the cooperative was not powerful enough to influence the decisions that are taken about this issue".* P2DMH23

- **Unavailability of fresh food**

Participants mentioned that healthy foods such as fruits and vegetables were inaccessible in some areas and in dry seasons.

*"…you may have money to get vegetables, but depending on where you stay, you may need to pay more money for transport than for buying the commodity and as a result, some patients may even fail to eat vegetables"*. P2DMH23

"*We plant vegetables ourselves but during dry seasons, the harvest becomes insufficient for household consumption... during dry season, getting vegetables is a challenge* P2DMH41

- **Requirement of the work**

The physical requirements of some jobs were revelead as a barrier to self-management activities. Some participants who were famers stated that they were always in the field working hard to satisfy the needs of their family and did not have time to rest or to care about themselves. As explained by this participant:

"*This is what I most often spend my life in, working so hard even though I know it is not good for my self-management and my health! This is done for a better future of my children!".* P2DMH41

Depending on the type of job, some participants said that it was not easy to stick on diet. One participant who was a driver said:

"*I sometimes fail to eat on time…. because of the nature of my work I may even spend the whole day without eating*

Some farmers expressed barriers in terms of practising foot care as one mentioned:

"w*e are advised to put shoes…. just wear shoes and avoid any wound…. but remember I am a farmer. I can't always put shoes"!* P2DMH73

Some participants stated that nature of their job impacted on their intention to engage in physical activity evidenced by one of the participants who said:

*"….to do sports for me is a problem because of the distance between my home and the workplace. I sometimes plan to run but I often arrive back home from work late in evening".* P2DMH23

### 5.3.2.7 Theme 7: Family dynamics

The barriers to self-management related to family dynamics were grouped into three sub-themes: lack of family support, gender roles and other responsibilities and priorities of the family.

- **Lack of family support**

In this study, this issuewas expressed by many participants. Participants considered family as being necessary in the management of T2DM. However, they stated that while they had received support at the beginning of their illness the family tired of providing support as the patient was perceived as being a heavy burden on them.

> *"Those who have relatives they can assist at the beginning but you know… with time relatives start showing that they are fed up because the patients have had enough of such a long and incurable disease…"* P2DMH61

> *"Not at all! They used to but I think they are now fed up because this disease has been there for a long time!".* P2DM92

Participants also informed that their family members were busy with their own work. In addition, some patients live alone; their children are married and do not come to check on them.

> "*For some children are away and no one to help because they are away from me, they do not do anything".* PD2HM81

> "*Forget about family members. Everyone is busy doing their own business*" P2DMH32

T2DM requires patients to change and adopt a new lifestyle implying that family members may also be affected in terms of nutrition. This may happen if the patient forces other family members to eat what s/he eats while they wish was to continue eating as they always have done. In such a case family support would be lacking.

> *"…patient may be told to stop carbohydrates, oil, etc... then, when you go back home or in the society and you start saying I can't eat such food, the people you live with, will have difficulties doing as you want!".*PD2HM81

Family conflicts and marriage issues were also mentioned by participants as a cause for lack of support. Spouses would not support each other or would misuse the resources at their disposal and the partner suffering from diabetes would not get what s/he needed for self-management.

> *"I don't get on well with my husband; I do not know what he spends money on! If he is married to another woman, I don't know anything about it! this is the situation I have always lived and have always not wanted anybody to know for fear to denounce my husband! He has lot of debts… I would make a lot of money and do saving and at any time I can see people coming and claiming their money. I cannot take care of my DM (shaking the head)".* P2DMH41

- **Gender roles and bias**

In Rwandan culture household activities are mostly undertaken by women and this may have repercussions for both men and women living with T2DM. If for example, a husband has diabetes, he has to rely on his wife to cook and the food she cooks may be unhealthy.

> *"There is no special shopping at home! They shop and cook same food. I eat with them the same food because there is nothing else I can do".* P2DMH21

> *"If I tell them appropriate diet recommended by the doctor I am afraid they may show me that they are already fed up with me! I prefer silence! I do not cook…You just eat what you are given otherwise they may get fed up!*PD2HM81

On the other hand, women found themselves doing most of the jobs at home leaving little time to take care of themselves.

> *"Sometimes I miss appointment; I am busy at home trying to make sure my children can get something to eat but can't go beyond 3 days".* P2DMH41

> *"As mother I may not get help from my husband…. I do everything…. work, education of our kids…a lot of stuff…I do not find time for myself…I am scared I will get complications of diabetes".* P2DMH41

Women reported that when they get sick they are not taken care of by their husbands.

> *"He may not feel like doing it but he finds himself in situation where he can't don otherwise! When he doesn't do anything, children or other people who come to our home blame him for not assisting me…For example, you may find children asking him if he can't himself see that I am seriously sick.* P2DM53

Women lack financial and emotional support from their partners.

> *I have had a lot of difficulties satisfying my household needs comprising so many children and some other foster children… Actually I do live such hard life; I have to work alone very hard to survive… I do not know what my husband spends money on! If he is married to another woman, I don't know anything about it! From time to time, we would see people coming to us claiming their money that he spent on what I don't know…and this has some effects on me…I would even feel like paralysed on some parts of my body because of the way I look at life. P2DM43*

Some women said that their husbands even stopped having sexual relations with them but when men got sick women tried to be there for them.

*"When I make friends with other females, they immediately start attracting my husband and this has prompted me to stop any relationship with females because it makes me feel bad… you can realize he has no feeling to engage in sexual intercourse with me…maybe because I do inject myself everyday (crying)…I am telling you, women face a number of challenges. When the husband is the one suffering, the wife takes care of him but it is not the other way round!".* P2DM53

- **Other responsibilities and priorities of the family**

Participants expressed that they did not have the means to afford special diets, other food items, medication and blood glucose devices because there were other demands by the family. Based on other responsibilities and priorities, patients ate what the family ate or chose not to buy blood glucose monitoring devices.

*"I do not have special diet at home… It is expensive and this would be hard for the people I live with".* P2DMH23

*"I do not have an option. My children are all that I have. I can't buy nice food when they are hungry! or buy those machines!".*P2DMH41

*"Remember there are also some other household expenses to be incurred! I am a widower and I have 10 children that I have to take care of... There are also some other things we spend money on. Sometimes I do prioritize my family and forget my diabetes".*P2DMH43

## 5.4 Discussion

### 5.4.1 Introduction

The discussion of this chapter will revolve around individual characteristics, implications of those delivering care, access to care and health care facility operation, complexity of managing diabetes, psychosocial factors, community and environment aspects and family dynamics as per the results of this study.

### 5.4.2 Individual characteristics

In this study, for the majority of patients, financial constraints appeared to be the major factor impacting on self-management. Participants faced financial stress and had to sacrifice healthcare, specifically, when it came to buying a glucometer and healthy food, aspects that were previously documented in other researches (Mogre, Johnson, *et al.*, 2017; Basu *et al.*, 2015; Arulmozhi and Mahalakshmy, 2014), healthy diet (Belue *et al.*, 2013; Foley and BeLue, 2017; Baumann *et al.*, 2010; Abdulrehman *et al.*, 2016; Basu *et al.*, 2015). People with diabetes are more financially constrained than others. They are not only requested to pay medical care but are also indepted to transportation fee which could be a burden to some, depending on the individual level of income. This issue results in irregular check up of blood glucose in delopping world and to be specific, in this study, participants stated that they can only check their blood glucose once per month, an activity that is daily perfomed in developed world. Participants in this study suggested that the government should treat them similarly to people living with HIV by offering them free medication or by assisting them with health insurance to buy blood glucose devices. Health care providers should help patients with T2DM to manage these important barriers by asking them about the existence of financial barriers and implementing strategies to mitigate their impact.

Age was a barrier to engagement in physical activity and some elderly patients living alone may have difficulty in reaching the health facility or performing daily living activities, also a barrier found in other studies. The findings in this study were consistent with those from a cross- sectional study to evaluate the factors related to non-adherence to exercise in T2DM patients, Nepal (Parajuli *et al.*, 2014). In the Rwandan context people believe that elderly people should be taken

care of by their families, although the society is changing. Health care providers should take this issue into consideration and advocate for the elderly.

Participants who were widowed expressed difficulties in managing their families alone. They may be faced with financial constraints limiting them from buying food for a healthy diet and glucose monitoring devices. A study to assess how patients stick on self-care in India (Gopichandran *et al.*, 2012) found that married participants living with a spouse adhered more to self-care than widowed participants and concluded that married particpants were probably receiving financial support from their spouses. However, a study by Arulmozhi and Mahalakshmy (2014) revealed that adherence by patients who were widowed seemed to be better than those who were married.

Patients with a low level of education expressed difficulties in reading printed material and lacked understanding of self-management and diabetes. This was also reported in Ghana (Mogre, Johnson, *et al.*, 2017) where people with low literacy did not adhere to self-care activities. Health care providers should provide accurate, individualised health education. Education strategies for the patients with low literacy levels should be implemented by the Government. As described in an article by Nkosi-Mafutha, de Sward and Mogotlane, (2020) in South Aftrica, patient health education should be contextual and provided in local lanugages in pamphlets and posters.

### 5.4.3 Implications of those delivering health care services.

The majority of participants experienced a lack guidance from health care providers with regard to performing self-management activities. Participants expressed the opinion that health providers were busy, did not take time to listen to them, they were rushed and patients did not have time to ask about what they did not understand. Participants had expectations; they wished to get information about the disease, about the amount and type of diet they should be following, the type of exercise that should be undertaken, how to take medication and which side effects should be anticipated, how to examine and take care of their feet and how to maintain normal blood glucose levels. However, they did not get guidance and failed to manage their diabetes. For many participants, health providers were their source of information but they also sought information from other patients or friends and this resulted in conflicting information. Accurate information is important in supporting patients in the correct ways of self-management and alleviating their ignorance in how to deal with their diabetes.

These findings were consistent with the findings in studies by Mendenhall and Norris, (2015) and Adisa and Fakeye, 2014)) which found that health providers do not provide enough support and clear explanations.

In addition to the lack of guidance, participants reported that they were not able to read the information written by health providers because it was written in a foreign language using medical terminology. A patient would carry a prescription without knowing what medication or dosage was to be taken. A patient could be being sent to the laboratory, ignorant of the type and purpose of the sample to be tested.

Health education was not tailored to individual needs and problems; participants expressed their desire for individual attention as they presented with diverse problems. Participants also felt inactive in their own management because of the directive approach taken by health care providers with little or minimum patient involvement. This highlighted the significance of purpose of this study which aimed at developing an instrument an instrument to determine the barriers experienced by each patient.

Continuity of care was hampered by what participants called "meeting different faces of doctors" at each visit. In referral hospitals consultations are done by medical doctors while in district hospitals units called non communicable disease units (NCD) led by trained nurses receive all ambulatory NCDs cases such as diabetes and hypertension. The complicated cases are transferred to medical doctors in the out-patient department. Most of the patients did not differentiate between medical doctors and nurses. It is important to provide patients with explanations about the care they receive and who is in charge. All measures of care should be documented so that even if a patient is seen by a different health provider at each visit, the continuity of care is ensured. Another issue that came to the fore was poor communication or use of bad or bitter language by health providers. Poor communication was also reported in a cross-sectional study in South-western Nigeria with the aim of assessing reasons of not complying with medication (Adisa and Fakeye, 2014).

### 5.4.4 Access to the health care facility and health care facility operation

Non-replenishment of stocks in the hospital pharmacy and long queues in health facilities were the most outstanding barriers in this theme.

Rwanda utilises a community-based health insurance system which allows even the poorest to access care (Rwanda Ministry of Health, 2014). However, this particular health insurer does not partner with private pharmacies and when diabetic medications were not available in the hospital pharmacy, patients reported that they were unable to afford the price of medications in private pharmacies. The participants, mainly those taking oral medication, reported that they may be without medication for more than a month. For those who used insulin, the problem was not common but did exist from time to time. In such cases they may have collapsed and been taken to hospital for admission. Affordability and accessibility of medication is a serious barrier for T2DM patients. Unfortunately, participants admitted that they did not even tell the doctors that they had not taken medication. The results of this study agree with the findings of a cross-sectional research by Basu *et al*. (2015) in the Indian government hospital, Capital of Delhi. The study revealed that lack of irregular replenishment of medication stocks was common, leading to poor adherence of medication. Thus, it is vital for health providers working in public hospitals to take note of the serious impact of non-replenishment of medication and to put anticipatory measures in place.

Long queues in the hospitals were reported by many participants as an obstacle to self-management. It was also reported that there were high numbers of patients in public hospitals as they wished obtain less expensive medication but the time spent awaiting a consultation, going to the laboratory for tests, waiting for the the prescription to be filled at the pharmacy and then making a payment to cashier, could take up to eight hours. The long wait has serious implications; most of the patients expressed that they were only able to check their blood glucose once they come to hospital because they did not have a glucometer at home. Because of this, on the day of the appointment they fast as much as possible in anticipation of fasting blood glucose tests. While waiting for attention, they may collapse, others decide to eat something and as a result, they will never know what their true fasting blood glucose level at the time was. Some may even leave the hospital without having received attention, or decide to spend a night within the hospital premises or in friends' houses close to the hospital. In their qualitative study among diabetic women, South Africa, Mendenhall and Norris (2015) found similar results; waiting time was the most common complaint, and for that reason, some women would prefer to visit non-public institutions or traditional practitioners. However, in this study, participants chose public institutions as these partnered with the participants' health insurance making affordable, hence they had nowhere else to go.

The long distance that patients had to travel because of the geographical accessibility of health care facilities was another barrier cited by some participants who stated that it took time and money for transport to reach the health facility. An experiences from three different countries, Uganda, South Africa and Sweden confirmed that geographical accessibility was an issue in Uganda but not in South Africa and Sweden (De Man *et al.*, 2019). This was unsurprising since Uganda and Rwanda are both low-income countries. In this study, however, the number of participants who expressed that geographical inaccessibility were not as many as the Ugandan participants.

The structure of the health care system and policies regarding the transfer of patients from one level of care to another, was also a barrier. One participant claimed that she needed a transfer from the health center each time she needed to visit the hospital for a consultation, a policy she considered time and money consuming. The Rwanda Non Communicable Diseases policy of 2015 directs that monitoring and long term follow up of uncomplicated NCD patients including diabetes are done at the health center level, although at the time that this study was conducted, most patients were visiting district hospitals and a transfer was a requirement (Rwanda Ministry of Health, 2015). There is a need for close collaboration among all stakeholders for NCDs policy implementation.

Lack of information and clear guidelines presented another barrier. The results of this study were similar to those reported in studies in Uganda by De Man et al., (2019) and (Baumann *et al.*, 2010), highlighting non availability of accurate and printed guidelines. T2DM is a multifaceted lifelong disease necessitating constant care and self-management plays a fundamental role. Hence, to be successful, the patients need to be equipped with clear information. Clear guidelines give a deeper understanding of DM mechanisms and care to patients and health care personnel and ultimately elucidate the overall goal of treatments (American Diabetes Association, 2020). Therefore, health care personnel must avail clear and updated guidelines to patients and ensure they understand them.

### 5.4.5 Complexity of managing diabetes

Diabetes is a life-long disease with a variety of complications and associated comorbidities such as hypertension.

Many participants said that they refrained from activities for example, because of other diseases such as hypertension or that they did not adhere to medication due to the complexity of the drug regime.

T2DM patients may have permanent physical and cognitive problems such as fatigue, discomfort, and loss of memory. These may impact on the ability to work and may result in a reduction of income. This in turn reduces the capability to buy indicated food, equipment for blood glucose monitoring and medication. These findings are in accordance with a previous study carried out among T2DM clinic patients in M'bour, Senegal (Belue *et al.*, 2013) when it was revealed that a lack of money led to patients buying unhealthy foods and skipping medication dosages.

Poor self-management is associated with complications of T2DM and the presence of complications in this community should call attention of health providers to the need for regular assessment of the adherence to self-management activities and barriers that patients are experiencing. Aside from complications, other aspects that have been proved to be challenging, for example, side effects of medications, storage and transport of insulin when travelling and pain associated with administration of a daily injection, make it imperative to focus on the individual when monitoring.

Negative mood was the outstanding barrier in this theme. Diabetes is a chronic disease imposing life style changes and with complications that disrupt patients' everyday activities and routines. Coping with T2DM is difficult as was expressed by many participants. Patients acknowledged that they lived with complications for example, hypertension and kidney disease, while others lived with the fear of expecting complications sometime in the future. The disease weakened them; they were unproductive and felt useless to their families. These concerns were always on their mind and may have prompted them to discontinue medication and other self-management activities; even raising the prospect of committing suicide. Many patients were sexually inactive and were worried about being unable to satisfy their partners. They often felt desperate and frustrated with life which led to depression. The results of this study are concur with other research (Mukeshimana and Mchunu, 2016; Baumann *et al.*, 2010; Mogre, Johnson, *et al.*, 2017), that highlighted the fact that depression is common among T2DM patients.

In this study, illness perceptions denote individual's representation about the cause of diabetes, symptoms, complications and treatment effects. Literature has shown that illness perceptions can affect adherence to recommended self-management activities (Tang and Teacher, 2019). Participants in this study expressed the belief that diabetes could be associated with witchcraft and discontinued medication, rather resorting to help from traditional healers. Some symptoms of T2DM such as dizziness were associated with bad spirits and participants could collapse without understanding that the symptoms they experienced were due to uncontrolled blood glucose. T2DM in itself was considered to be a disease which afflicted old and unhealthy people and therefore making people feeling ashamed to seek health care and help in the family or community. Participants also expressed the idea that diabetes is a severe disease and that nothing could be done to stop it, thus failed to adhere to self-management activities. The results of this study were similar to those found the study by Kugbey, Asante and Adulai (2017 in Ghana and a study by Tang and Teacher (2019) in China which concluded the illness representation of DM and perceptions remain the important determinants in self-management.

In the light of above discussion, it is essential to understand patient perceptions because poorly controlled blood glucose may be more likely if associated with the beliefs that diabetes is an unpredictable severe disease that cannot be controlled (Tang and Teacher, 2019). Participants also had misconceptions or beliefs that different diets that could help control diabetes or the way one could cook or prepare food. Some believed that boiling a sugary juice may extract some sugar. Diet and culture are related as was confirmed in the study by Belue *et al.* (2013), who found that health education on health diet is is critical.

T2DM is a chronic disease requiring active participation by the patient in self-management. However, many people may find it difficult to incorporate the various activities of self-management into their daily lives. Some patients participating in this study explained that self-management demanded a great effort and some had attitudes such as ignorance that affected them. The results of this study were not far from those found in the cross-sectional research carried out in Australia (Kueh *et al.*, 2015). Attitudes are hard to change and health providers should engage in continuous health education and support to effect change in patients' attitudes.

Some participants in this study expressed lack of awareness and understanding of what DM s is, what self-management activities to conduct and how to conduct them. Research by Kueh *et al.* (2015) has demonstrated that knowledge of DM is the foundation when want to choose an appropriate self-management activity and consequently, people with low levels of knowledge demonstrated low levels of self-management practices. For that reason, DM knowledge patient 'attitudes are obviously linked to self-management.

### 5.4.6 Community and environment aspects

Among community and environment barriers, the most frequently expressed by many participants were those emanating from culture. Literature has shown that culture can predict health behaviours, like DM self-management (Belue *et al.*, 2013). In this study participants admitted that they visited traditional healers and would discontinue other medication and use herbal medication instead. Although diabetes is known as a chronic disease, those who used traditional medicine believed that it could heal diabetes completely. In addition, traditional medicine was used by those who lacked resources to access to medication or those who believed that diabetes has something in common with witchcraft.

It seems that there are many traditional healers in the community where this study was done. Even those who said they did not use traditional medication, reported having heard of or knowing of one or more traditional healers for diabetes. Traditional medicine in Rwanda has a long history and its knowledge is handed-over from generation to generation. Apart from traditional healers there is another religious group known as Abagorozi, that provides certain types of food supplements and patients would discontinue other medications to take their remedies. In 2017, the Rwanda Ministry of Health implemented a policy regulating traditional medicine. However, its practice is still not well controlled and there is a gap in the research in understanding the effectiveness of traditional medicine in Rwanda (Rwanda Ministry of Health, 2017).

Stigma was another barrier expressed by a number of participants. In this community there are two type of stigma. The first is self-stigma where participants were ashamed of their disease and would conceal their status even to their own children. There was for example, a participant who by-passed her nearest hospital for the purpose of hiding her status. This has implications for self-management as patients may fear taking drugs in public and may not receive support from the

community. The second type is social stigma, that is, stigmatisation by the community when the population considers diabetic patients as being useless and unhealthy people in the society. A participant for example, told of losing his job after being diagnosed with T2DM on the pretext that he could not accomplish his duties. The findings of this study are parallel with earlier studies (Mendenhall and Norris, 2015; Mendenhall and Norris, 2015) . In a study by De Man *et al.* (2019), however, stigma in Uganda was less common due to the fact that people are well rooted in their communities.

Similar to the study by De Man *et al.* (2019) in Uganda, participants in this study expressed the lack of community initiatives or programmes relevant to self- management. Participants felt that they lacked mutual support among themselves as the existence of community intitiatives would help them to share resources, T2DM information, knowledge and experiences. Supporting each other as individuals with T2DM would help them to give voice to their problems and challenges, thereby making them known. Philis-Tsimikas and Gallo (2015) state that community-based diabetes programmes are advantageous. They make both information and support accessible to the entire local population, taking into consideration their culture, level of education, beliefs and the level of income. Therefore, it is imperative to promote these programmes to enhance interactions between the health care institutions and community.

The unavailability of healthy food and vegetables in certain communtities was obvious. In addition to that, seasonal fruits are available only at certain times in the year and in dry seasons there may be a scarcity of fruits and vegatables. These circumstances were observed as barriers for some participants. This barrier was also mentioned in Belue *et al.* (2013)'s study in Senegal.

### 5.4.7 Family dynamics

Patients deprived from family and society support are not able to carry out self-management activities, maintain the glycaemic level in normal ranges or prevent DM complications (Ravi, Kumar and Gopichandran, 2018). In this study, participants expressed a lack of family support in their self-management. The poor support was in terms of financial means to buy medication, healthy food, glucometers and in terms of encouraging patients to adhere to a new lifestyle. For example, the family would persist with the same diet as was enjoyed before the diagnosis of T2DM and would not encourage sport.

Children of elderly persons lived far from their parent who may have lived alone and experienced difficulty in finding appropriate foods, or accessing a health care facility or checking blood glucose levels.

In Rwanda, a family is defined as a blood relative but in ancient Rwanda, a member of a family was beyond that. Friendships were maintained by a practice known as "Kunywana" where close friends used "to cut and drink blood" (Doná, 2001). In the Rwandan context, as in most African countries, family ties are important. However, the 1994 Tutsi Genocide and rapid development have reconfigured family relationships (Doná, 2001). Families are not supporting each other, they lack unity and cohesion, people are only considering their individual needs and are more concentrating on the nuclear family rather than the extended family (Doná, 2001). Therefore, the support available from families should be reviewed for each individual patient with diabetes (Ravi, Kumar and Gopichandran, 2018).

Conflicts in marriage create an unhappy environment and stress and when spouses do not understand each other, they cannot support each other as was found in this study. Gender roles in the family also constitued an issue where, for example, men did not cook or decide what to cook. As far as women were concerned, they lacked financial support as men were heads of the family and did not support their wives. It has been noted that a stress-free environment with less conflict among family members decreases anxiety and improved metabolic control has been associated with greater support (Belue *et al.*, 2013). Families also expressed that they have other responsibilities, for example, many children. With the scarcity of financial means, patients prioritise the needs of the family over their own needs. Though, this choice can progressively affect their health and result in even higher costs for health care expenses. The results are similar to the study by Baumann *et al.* (2010)

## 5.5 Conclusions

This study aimed at exploring self-management barriers among T2DM in Rwanda. The findings revealed that participants lacked financial means and as a consequence the ability to buy healthy food, glucose monitoring devices and medications was limited. Lack of guidance from health care providers was not uncommon and participants were not satisfied with the care they received.

Other issues raised by participants included inaccessibility to services and a health care system operation in which non-replenishment of stock and long queues were common. T2DM is a complex disease and there are some barriers that can be associated with that complexity such as complications and co-morbidity. As a lifelong disease, participants expressed that they may present with a negative mood or worry about their future. Barriers emanating from the family, community and environment were also acknowledged by participants and included for example, lack of support, the use of traditional medication, stigmatisation, gender issues and other issues associated with the requirements of the job. The findings have contributed to the lack of knowledge on barriers to self-management in Rwanda and to the development of an instrument to assess barriers to self-management among T2DM that will be discussed in the next chapter.

# CHAPTER 6: DEVELOPMENT OF AN INSTRUMENT TO ASSESS SELF-MANAGEMENT BARRIERS OF PATIENTS WITH TYPE 2 DIABETES MELLITUS

## 6.1 Introduction

Phase one conceptualised the construct of self-management barriers through a review of the literature and the qualitative study conducted in Rwanda. Given the sequential design of this study, the results of phase one were used to build up the second phase with the aim of generating the items for the new instrument. This chapter will describe the process undertaken to draw items from the results of the integrative review as well as from the individual interviews with patients with T2DM. In addition, the process of refining the items that were first generated will be described.

## 6.2 Instrument development process

The process followed 3 steps, (a) determining the content domain, (b) generating items and (c) instrument construction (Boateng, Neilands and Frongillo (2018; Zamanzadeh *et al.*, 2014)

### 6.2.1 Determining content domain

This step had started early with phase one and it normally consists of precise and proper definition of a construct by setting its boundaries and definitions (Boateng, Neilands and Frongillo (2018; Zamanzadeh *et al.*, 2014). This can be done using both deductive and inductive methods. In Boateng, Neilands and Frongillo (2018), deductive means using the literature or referring to existing instruments and inductive refers to the use of the qualitative research results and being open to identifying what emerges from the data. In this study both the deductive and inductive approaches were used to describe the content domain. The integrative review (chapter 4) and existing instruments (chapter 2) were reviewed as a deductive approach and the results of a qualitative research (interviews with people living with T2DM) (chapter 5) were used as the inductive approach.

The construct of self-management was initially defined and was limited to the activities of diet, medication, physical exercise, SMBG and foot care. In phase two, self-management barriers were grouped under the concepts of the conceptual framework of Zeng *et al.* (2014) (Figure 6.1) to arrange the content under specific domains. However, the initial conceptual framework was adapted to add the concepts that emerged from integrative review and the interviews.

The concepts which were added are highlighted in green (Figure 6.1), thus the new concepts used to group the self-management barriers were (1) individual characteristics, (2) behavioural change, (3) psychological characteristics, (4) lack of family, friend support, (5) health facility related barriers, (6) complexity of managing diabetes, (7) knowledge, linguistic and ignorance, (8) cultural characteristics and (9) environmental barriers.

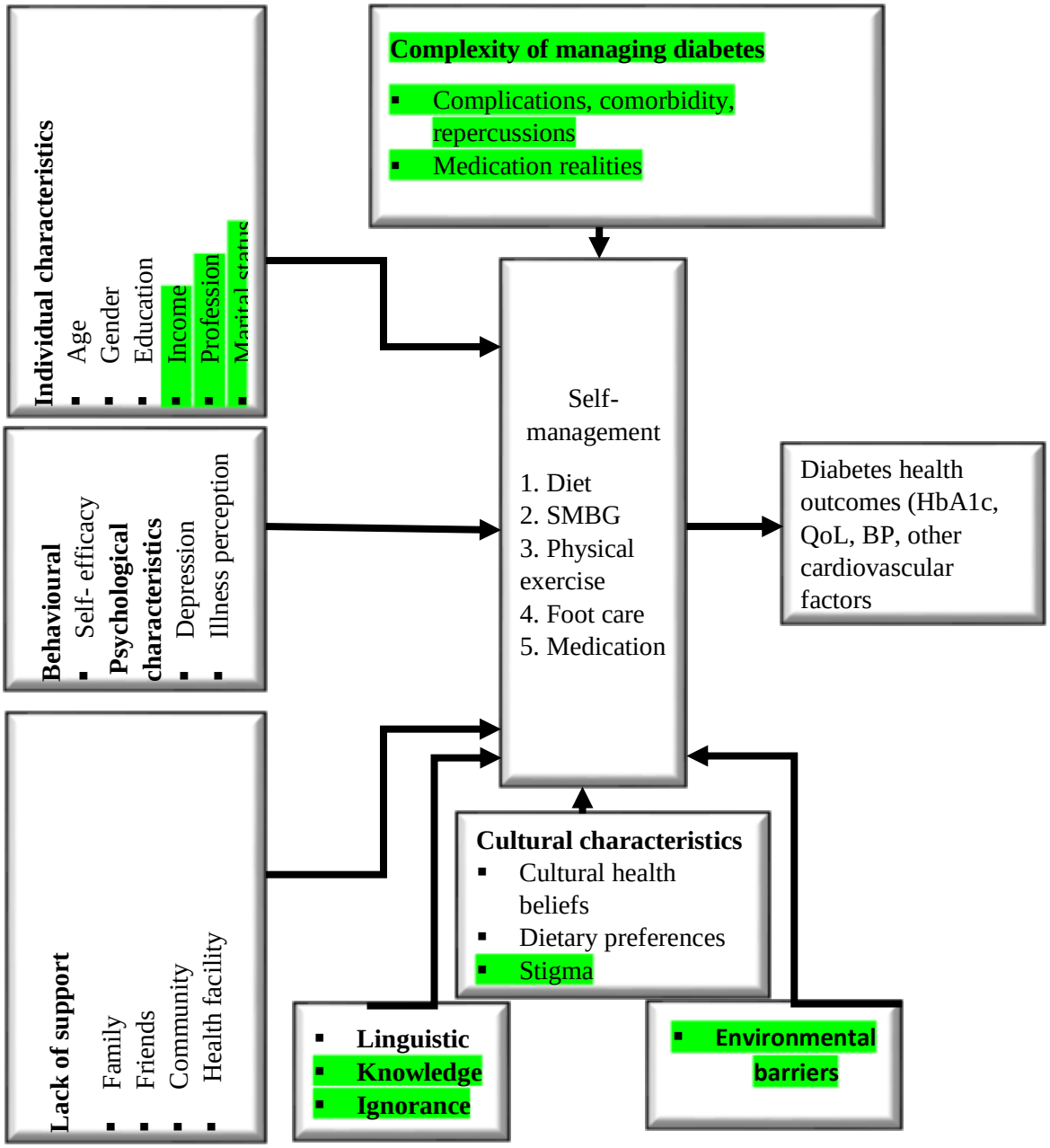


**Figure 6.1: Adapted conceptual framework for Type 2 diabetes self-management**

As a means of being more practical in the exercise of grouping items into domains, a table of specification or a blue print was designed to align the items with their related concepts. The table of specification is merely an attempt to line items up with a set of concepts (Newman, Lim and Pineda, 2013)

Table 6.2 is an illustration of what was done and the table should be read as follows: the researcher placed the concepts of the framework displayed above (Figure 6.1) in the first column headed *Category or Concepts*, and the example given portrays barriers related to individual characteristics. The second column headed *Sub-category* indicates what is underlined in the individual's characteristics for example low income. The third column is split into six columns; the first of the six representing common barriers and other five representing barriers falling in specific dimensions of self-management namely, diet, SMBG, physical activity, foot care and medication.

**Table 6.1: Blue print or table of specification**

| Category /concepts of barriers | Sub-categories or concepts | Barriers emerging in different dimensions of self-management | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | COMMON/GENERAL BARRIERS TO ALL DIMENSIONS | | DIET | | SMBG | | PHYSICAL ACTIVITY | | FOOT CARE | | MEDICATION ADHERENCE | |
| | | Content from literature | Content from interviews | Content from literature | Content from interviews | Content from literature | Content from interviews | Content from literature | Content from interviews | Content from literature | Content from literature | Content from literature | Content from literature |
| Example: Individual Characteristics | Example: Low income of the patient | Items generation | Items revision (new items, rephrase, delete the first items) | Items generation | Items revision (new items, rephrase, delete the first items) | Items generation | Item revision (new items, rephrase, delete the first items) | Items generation | Item revision (new items, rephrase delete the first items) | Items generation | Items revision (new item, rephrase delete the first items) | Items generation | Items revision (new item, rephrase delete the first items) |
| | | **Item(s) sample:** | | **Item(s) sample:** | | **Item(s) sample:** | | **Item(s) sample:** | | **Item(s) sample:** | | **Item(s) sample:** | |
| | | **Feedback** | | **Feedback** | | **Feedback** | | **Feedback** | | **Feedback** | | **Feedback** | |

### 6.2.2 Generating item pool

To generate the first items (table 6.1), the results of the integrative review and the literature on existing instruments were used (blue arrow). Thereafter, the results of interviews were used to revise the pool of items (red arrow). The revision of items was done in three ways: (1) rephrasing the items for grammar or fitting them into the local context, (2) deleting the items if they did not fit into the context and (3) generating a new item if necessary. The first draft was generated by the team of researchers (researcher and her two supervisors) and the purpose was to identify as many items as possible. The literature suggests that at this step, it is imperative to have an exhaustive list of items to facilitate the next steps. The researchers would propose two to three options for one item to choose the best one in the analysis step. Thus, 105 items were generated after the first attempt (table 6.2).

**Table 6.2: Pool of items generated at first attempt**

| No | Items | Sources of content | | |
|---|---|---|---|---|
| **1. Individual characteristics (education , age, income, profession)** | | **Review** | **Existing tools** | **Interviews** |
| 1 | I do not understand instructions they write to me regarding self-management. Or Instructions regarding self-management are written in foreign languages with medical terminology | √ | √ | √ |
| 2 | My low level of education doesn't facilitate me to learn about healthy diet | √ | | √ |
| 3 | My low level of education doesn't facilitate me performing physical activity | √ | | √ |
| 4 | My level of education is not high to learn foot care | | | |
| 5 | I am old, performing self-management activities is a challenge | √ | | √ |
| 6 | I do not do a lot about physical exercise, I do what I can depending on my age | √ | | √ |
| 7 | Self-management activities require money, sometimes I fail to satisfy my needs | √ | | √ |
| 8 | I don't have enough money to buy healthy prescribed diet OR My financial constraints don't allow me to buy healthy food OR I end up eating unhealthy food very often as it is all I can afford | √ | | √ |
| 9 | I cannot buy special food items for myself like when I have not enough money, I first think about my family | | | √ |
| 10 | Because of limited income, I fail to buy a glucometer/test strips OR I only control blood glucose when I come here to hospital | √ | | √ |
| 11 | My financial problems don't facilitate me performing physical activities | | √ | |
| 12 | My financial constraints don't allow me to buy prescribed medication OR Sometimes, I fail to get money to buy drugs | √ | | √ |

| | | | | |
|---|---|---|---|---|
| 13 | My nature of job is incompatible with medication dosage regimen | √ | | √ |
| 14 | My working condition may lead to escape a meal OR My working condition does not facilitate me to stick on diet OR I fail to eat on time because of the nature of my work OR I may spend the whole day without eating until the evening when I have dinner and this interferes much with medication OR I am in such a hurry that I forget to take food in the morning. | √ | | √ |
| 15 | My working condition does not facilitate me to control blood glucose | √ | | √ |
| 16 | Beyond work or household chores it is hard to find time to do physical exercise | √ | | √ |
| 17 | I earn my living by digging in the fields it is a problem to take care of my feet. | | | √ |
| **2.** | **Psychological characteristics /Depressed mood or negative emotion** | | | |
| 18 | I feel like doing nothing regarding self-management because of diabetes | √ | | √ |
| 19 | I feel like I am useless to my family, there is no need to adhere to self-management | | | √ |
| 20 | I am psychologically unstable, I keep thinking that this disease is not curable and that affects my self-management. | | | √ |
| 21 | It is being long time taking diet, I am really tired | √ | | √ |
| 22 | I am not psychologically stable and this keeps me thinking about diabetes and it affects my blood glucose | √ | | √ |
| 23 | I have such fatigue that I get desperate to perform physical activity | √ | | √ |
| 24 | I just think I am there waiting for death, I don't find importance to regularly take medication. | √ | | √ |
| 25 | Sometimes I get a depressed mood, during such a period, I would stop medication for sometimes then I would decide to resume. | | | √ |
| 26 | I have such fatigue that I get desperate to perform foot care | √ | | √ |
| **3.** | **Behavioural and illness perception** | | | |
| 27 | It is difficult to me to stop what I have been eating/ drinking I take some alcohol as I used to do | √ | | |
| 28 | I do not like physical exercise and this inhibits me to be active | √ | | |
| 29 | I have been taking medication for long time I am fed up | √ | √ | |
| 30 | I do not think that taking SMBG will change anything to diabetes | √ | | |
| 31 | I do not think exercise will change anything to diabetes | √ | | |
| 32 | I do not think medication will change anything to diabetes | √ | | |
| 33 | I have a feeling that the medication prescribed to me is not effective | | | |
| 34 | I fear injections I cannot check blood glucose at home | | | √ |
| 35 | I miss medication by forgetting or when I am busy | √ | | √ |
| 36 | I am not a person who cares about times of taking medication | √ | | |
| 37 | When symptoms decrease I stop medication | √ | | √ |
| **4.** | **Complexities of managing diabetes** | | | |
| 38 | My eyes do not work properly. I fail to read what doctors wrote as instruction for self-management | √ | | √ |
| 39 | I spend time doing nothing that can generate income because of fatigue and complication of diabetes | | | √ |
| 40 | I am worried because of comorbidity: kidney, hypertension | | | √ |
| 41 | Physical problems/diseases inhibit me from taking exercise Or I have other diseases related to diabetes they do not allow me to do much sports | √ | √ | √ |
| 42 | I always feel too tired for physical activity because of diabetes | √ | | √ |

| | | | | |
|---|---|---|---|---|
| 43 | Taking many drugs other than diabetes drugs inhibits me adhering to medication OR I take many drugs other than diabetes medication and this inhibits from adhering to medication | √ | | √ |
| 44 | I miss medication when travelling because I do not have means to transport my drugs | √ | | |
| 45 | The medication I am taking has many side effects | √ | | √ |
| **5.** | **Social support/lack of family, friends, community support** | | | |
| 46 | My family is busy in their own business; they are no longer helping me OR I am left alone and I do everything by myself in self-management | | √ | √ |
| 47 | I may fail to come to health facility for appointment my family does not help me to keep children | | | √ |
| 48 | My husband/spouse treat me badly making self-management harder | | | √ |
| 49 | My dependence to family /children inhibits me from having a healthy diet | | √ | |
| 50 | I don't participate in cooking and this inhibits me from having healthy diet | √ | | √ |
| 51 | I sometimes miss medication appointment; I am busy at home trying to make sure my children can get something to eat. | | | √ |
| 52 | I would manage my diabetes much better if I had participated in diabetes group support | | | |
| **6.** | **Health providers and health facility related barriers** | | | |
| 53 | Nurses/doctors use bitter words I fear to ask more information about self-management | | | √ |
| 54 | Sometimes doctors are busy and they do not find time to listen to me | | | √ |
| 55 | Sometimes doctors are busy and they do not find time to listen to me, they just prescribe medications | | √ | √ |
| 56 | Patients are many we do not have enough time to talk to doctors/nurses our own problems regarding self-management | | | √ |
| 57 | I do not get individual information on my personal challenges, the information is given in general | | | √ |
| 58 | I do not get clear explanation on medication, exams and lab tests prescribed to me | | | √ |
| 59 | I have to wait for long time when I come for appointment OR I get exhausted while waiting and I may go back home without being attended to | | | √ |
| 60 | I meet different faces of doctors/nurse they tell me different information that affect self-management | √ | | √ |
| 61 | I do not get information about self-management. | √ | | √ |
| 62 | Inappropriate guidance of health provider inhibits me from adhering to healthy diet. | √ | | √ |
| 63 | The information I get from doctor/nurse is not clear enough to guiding me in what diet I should take | √ | | √ |
| 64 | I would mention lack of specific/individual information about diet and diabetes | √ | | √ |
| 65 | Lack of education material inhibits me from adhering to healthy diet | √ | | √ |
| 66 | Absence of established guidelines inhibits me from performing SMBG | √ | | |
| 67 | The provided guidance and information about SMBG diet do not fit my knowledge and understanding | √ | | √ |
| 68 | There is also a problem of getting the Glycated Hb every month, which does not happen here | | | √ |
| 69 | There are so many patients here and I had been waiting so long and the level of blood sugar had gone down. | | | √ |
| 70 | Lack of established guidelines inhibits me from performing physical activity | √ | | |
| 71 | Long waiting hours inhibits me from adhering to medication | √ | | |
| 72 | Long distance from home to health facility inhibits me from adhering to medication | √ | | |

| | | | | |
|---|---|---|---|---|
| 73 | I sometime fail to have drugs in the hospital pharmacy and I go back home without getting drugs OR Pharmacy here are not always replenished and I am not able to buy drugs in private pharmacy, it is expensive. | √ | | √ |
| 74 | Poor relationship with health provider inhibits from adhering to medication | √ | | √ |
| 75 | Inadequate information inhibits me from adhering to medication | √ | | √ |
| 76 | Inappropriate/irrational prescription inhibits me from adhering to medication. | √ | | √ |
| 77 | The provided guidance and information about medication do not fit my knowledge and understanding | √ | | √ |
| 78 | Inadequate information inhibits me from performing foot care | √ | | √ |
| 79 | I am just given drugs and that is all, treatment options are not discussed with me | | | |
| 80 | The provided guidance and information about foot care does not fit my knowledge and understanding | √ | | √ |
| **7.** | **Ignorance, knowledge, linguistic barriers** | | | |
| 81 | I fail to learn/perform about various things in relation to self-management due to ignorance | | | √ |
| 82 | I do not think diet will change anything to diabetes treatment | √ | | |
| 83 | I do not take into account diet. I just eat whatever is available | | | √ |
| 84 | The provided guidance and information about self-management do not fit my knowledge and understanding | √ | | √ |
| 85 | I cannot say I have enough knowledge, I simply use common sense to think about average amounts required/appropriate diet | √ | | √ |
| 86 | The provided guidance and information about my diet does not fit my knowledge and understanding | √ | | √ |
| 87 | I really do not know about normal blood glucose and how? | √ | | √ |
| 88 | I do not know how I should go to have normal blood glucose | | | |
| 89 | Physical activity do not fit my knowledge and understanding | √ | | √ |
| 90 | I know nothing about medication I take | | | √ |
| 91 | I know nothing special about hygiene of feet | | | √ |
| **8.** | **Environmental barriers** | | | |
| 92 | It is difficult to find vegetables and other health food in this area and this inhibits me from having good diet | | | √ |
| 93 | My resident ? residence is not facilitating me in physical exercise (security, few facilities of exercises) | √ | | √ |
| **9.** | **Culture (Cultural health beliefs, Dietary preferences, Stigma)** | | | |
| 94 | There is no culture of doing sport in this area and this inhibits me from being active in physical activity | √ | | √ |
| 95 | I am not able to restrain myself from taking ceremony food | √ | | √ |
| 96 | Having a different diet or eating separately from the communal family plate makes me feeling isolated. I eat what they eat | √ | | √ |
| 97 | I concurrently use prescribed drugs with traditional drugs. | √ | | √ |
| 98 | There are patients who stop medication and only use supplements (abagorozi drugs) | | | |
| 99 | Sometime people look at me as dead person/ useless. I get stressed and hopeless in taking self-management | | | √ |
| 100 | I don't get any other support especially that I do not open up to show them that I have such a problem | | | √ |
| 101 | I cannot go to nearest health facility, I fear that other people could know I am diabetic | | | √ |
| 102 | People in village do not understand diabetic patients, you can hear people talking on your back | | | √ |
| 103 | I am stigmatized and get discouraged with self-management | | | √ |
| 104 | The fear of being labelled with having diabetes inhibits me taking medication outside of home OR | √ | √ | |
| 105 | I fear taking medication outside of home/in public because I can be labelled with having diabetes | √ | | |

Table 6.2 indicates the pool of items generated by the team of researchers. The three columns to the right show the sources of content of the items. The symbol "√" was used for that purpose. As it was explained above the items were first generated from the literature and existing instruments, then revised using the results of qualitative research to fit the context.

### 6.2.3 Instrument construction

This is the third step in the process of developing an instrument. It consists of refinement or improvement of written items, choosing an appropriate format and put them in a logic sequence with clear wording.

#### 6.2.3.1 Analysis of the first pool of items

The researcher and her two supervisors went through the105 items as depicted in Table 6.2. The purpose of this analysis was to make sure all domains were represented, observe grammar for correctness, using appropriate words, set a suitable order of items and choose the scoring system The first analysis was also done by four experts working in diabetes clinics (three nurses and one medical doctor) purposively selected based on their experience in diabetes. The experts followed the same purpose as for researchers.

During the process of analysis, it was observed that there were items that would be specific to diet, exercise, SMBG, foot care, and medication. For example, item 92 in the pool (table 6.2) falls under environmental barriers but it specifically affects diet. There were other items that were common to all self-management activities like for example item 1 in the Table 6.2. The item is about the low level of knowledge or less education to understand written instructions. In addition to that, the analysis also focused on reducing the number of items by merging items that looked similar and by choosing the best items among different proposed options. For example, item number eight in the pool had three options and one was chosen, the items from 10 to 105 about stigma were merged and only three items were newly generated. Finally, grammar and sentence construction were reviewed. The final analysis yielded 73 items and were grouped into six domains (Table 6.3) which are (1) common barriers, (2) medication, (3) diet, (4) SMBG, (5) physical exercise, and (6) foot care. The common barriers had six sub-domains which are

knowledge, stigma, health facility, family, complexity of managing diabetes and behaviour and psychology issues.

**Table 6.3: Final items designed for the self-management of Diabetes Mellitus Type 2**

| No | Items | Stronly Disagree (SD) | Disagree (D) | Agree (A) | Strongly Agree(SA) |
|---|---|---|---|---|---|
| | **1. Knowledge** | | | | |
| 1 | I can't pretend and confidently say that I have enough knowledge about diabetes | | | | |
| 2 | I may fail self-management in one way or another either because I am not aware or not very sure of what I have to do | | | | |
| 3 | I lack self-confidence and necessary skills to manage my diabetes | | | | |
| 4 | I may fail to understand written self-management instructions/literature | | | | |
| | **2. Stigma** | | | | |
| 5 | People may have wrong perception of diabetes, show me stigma and discrimination | | | | |
| 6 | I fail to open up to tell others that I have diabetes. | | | | |
| | **3. Health facility** | | | | |
| 7 | I don't have one specific health provider who can regularly and exclusively follow-up on me | | | | |
| 8 | I feel I am not well-guided to set achievable goals for each activity of self-management | | | | |
| 9 | I feel self-management activities have not been clearly explained to me | | | | |
| 10 | Health care providers rush, they do not find time to listen to me | | | | |
| 11 | I live far from hospital and getting here is so challenging | | | | |
| 12 | I have to wait for long time when I come for appointment | | | | |
| 13 | I feel I am given guidance without considering my individual problems | | | | |
| 14 | Instructions and prescriptions are unclear, written in foreign languages with medical terminology | | | | |
| 15 | Nurses/doctors use bitter /unpleasant words I fear to ask for more information about self-management | | | | |
| 16 | I would say that diabetes management decisions are not discussed with me | | | | |
| | **4. Family, friends and community support** | | | | |
| 17 | My family treats me badly and does not help me in self-management making self-management harder | | | | |
| 18 | I do not get support from my friends | | | | |
| 19 | I have a feeling that my family members do not give me enough support | | | | |
| 20 | I feel I get little support from my friends | | | | |
| 21 | There are no community programmes supporting me | | | | |
| 22 | I would manage my diabetes much better if I had participated in diabetes group support | | | | |

| | | | | | |
|---|---|---|---|---|---|
| | **5. Comorbidity and complications** | | | | |
| 23 | I spend time doing nothing that can generate income because of fatigue and complications of diabetes | | | | |
| 24 | I fail to read what doctors wrote as instructions for self-management due to blurred vision | | | | |
| 25 | Having other diseases/complications related to diabetes prevents me from adhering to self-management activities | | | | |
| 26 | I have other treatments besides those for diabetes and it becomes hard for me to be on different treatments at the same time | | | | |
| | **6. Behaviour and psychology** | | | | |
| 27 | Since diabetes is chronic disease I see little benefit in self-management | | | | |
| 28 | I am desperate I keep thinking that this disease is not curable and that affects self-management of diabetes | | | | |
| 29 | I feel like I am useless to my family | | | | |
| 30 | I am not psychologically stable, T2DM has put stress in my life | | | | |
| 31 | I feel hopeless, T2DM has ruined my life | | | | |
| 32 | It is difficult to change my habits in accordance with T2DM condition | | | | |
| | **7. Diet** | | | | |
| 33 | In my area, it is not easy to get vegetables and other food items recommended | | | | |
| 34 | Having a special diet or having different dishes among my family members makes me feel isolated, I sometimes prefer to share what others eat | | | | |
| 35 | It is hard to take appropriate diet when I am away from home | | | | |
| 36 | I don't attach a lot of importance to special diet recommended to diabetes patients, I just eat what I like | | | | |
| 37 | I think the medical staff don't provide me with clear and consistent information about appropriate diet that I need | | | | |
| 38 | I cannot buy special food items for myself like when I do not have enough money, I first think about my family | | | | |
| 39 | It has been a long time taking the diet. I am really tired | | | | |
| 40 | I do not think diet will change anything to diabetes treatment | | | | |
| 41 | It is difficult for me to stop what I have been eating or drinking; I take some alcohol/tobacco as I used to do | | | | |
| 42 | I am in such a hurry that I forget to take food in the morning. | | | | |
| 43 | I end up eating unhealthy food very often as it is all I can afford | | | | |
| | **8. Physical activity** | | | | |
| 44 | The general environment in my community is not conducive for physical exercise (security, appropriate venues and equipment etc.) | | | | |
| 45 | In this community there is no culture of doing physical exercise and you don't find people to motivate you | | | | |
| 46 | I was not given as much information as I needed about physical activity | | | | |
| 47 | Physical problems/diseases related to diabetes inhibit me from taking exercise | | | | |
| 48 | I don't feel interested in physical exercise. That is something I don't easily enjoy. (Split in second round) | | | | |
| 49 | I do not think exercise will change anything to diabetes | | | | |
| 50 | Except engaging in regular home and domestic chores, it is hard for me to have physical exercise (rephrase in clinical utility) | | | | |

| | | | | | |
|---|---|---|---|---|---|
| | **9. Medication** | | | | |
| 51 | When I find that the blood glucose level is fine, I may sometimes stop medication | | | | |
| 52 | I sometimes forget to take drugs | | | | |
| 53 | I take drugs that have been recommended for diabetes but I also take traditional medicine and the latter seems to be efficient. | | | | |
| 54 | I think that food supplements (abagorozi) seem to be as good as diabetes treatment | | | | |
| 55 | I have a feeling that the medication prescribed to me is not effective | | | | |
| 56 | Inappropriate/irrational prescription inhibits me from adhering to medication. | | | | |
| 57 | Sometimes doctors are busy and they do not find time to listen to us, they just prescribe medications | | | | |
| 58 | I often fail to get drugs at the hospital pharmacy and this makes it hard for me to afford drugs in private pharmacies. | | | | |
| 59 | I sometimes miss medication appointment; I am busy at home trying to make sure my children/family can get something to eat. | | | | |
| 60 | I miss medication when travelling because I do not have means to transport my drugs | | | | |
| 61 | Sometimes I get a depressed mood, during such a period, I would stop medication for a time then I would decide to resume. | | | | |
| 62 | Because of the nature of my job, I sometimes fail to take drugs at regular intervals | | | | |
| 63 | I sometimes fail to get money to buy drugs for diabetes | | | | |
| 64 | I feel bad taking drugs everyday | | | | |
| 65 | Patients taking tablets hardly agree to shift to insulin | | | | |
| | **10. SMBG** | | | | |
| 66 | I fear injections I cannot check blood glucose at home | | | | |
| 67 | There is also a problem of getting the Glycated Hb every month, which does not happen here | | | | |
| 68 | Absence of established guidelines inhibits me from performing SMBG | | | | |
| 69 | I do not think that regular self-management of blood glucose (SMBG) will change anything to diabetes | | | | |
| 70 | I am not psychologically stable and this keeps me thinking about diabetes and it affects my blood glucose | | | | |
| 71 | Because of limited income, I fail to buy a glucometer/strip reagents Have two in clinical utility | | | | |
| | **11. Foot care** | | | | |
| 72 | Given the nature of my job, I think it is too hard for me to have hygiene of feet as it is recommended. | | | | |
| 73 | I was not examined by health care providers to know what I am supposed to do | | | | |

### 6.2.3.2 Determine the scoring, format and type instrument

A Likert scale with 4 scoring points from strongly disagree (1) to strongly agree (4) was selected on which higher values correspond to barriers of self-management. The Likert scale is good when one wants to measure attitudes, beliefs or behaviours and was found to fit the assessment of barriers.

The three nurses and one doctor who participated in reviewing the items, suggested that based on their experiences, the scale should avoid a neutral option as people with T2DM tend to be introverts and may all choose neutral. The same decision was reached by Schmitt *et al.* (2013) in the development of the *Diabetes Self-Management Questionnaire*. The team agreed to keep the four-point score structure. The instrument is a self-report questionnaire that will be used in clinical settings and for research purposes.

#### 6.2.3.3 Naming the instrument

The last step was to name the instrument. The instrument was named Be-Seed2. The name is extracted from **B**arri**E**r to **SE**lf-manag**E**ment of type **2 D**iabetes (Be-Seed2). The researcher chose the name based on the following two assumptions: (1) For a seed to grow, it faces many challenges implying the barriers to self-management and (2) those challenges may be due to the seed which was not good in the first instance, but in addition, the problems may arise from a lack of fertiliser and water. Literature has revealed that there are self-management barriers emanating from individual characteristics such lack of motivation but there are also other barriers emanating from family and community. Therefore, there must be active engagement by the patient in self-management while support from outside is also essential. The first seed may fail but the second one will do better because once the challenges have been identified they can be confronted, allowing the seed to grow.

#### 6.2.3.4 Choosing participants' characteristics.

Based on the literature, the integrative review and the interviews, emerging characteristics were identified to be used together with the items of BE-SEED2. The characteristics were two-fold. The first section related to socio-demographics and the second section to clinical information (Table 6.4).

**Table 6.4: Participants' characteristics**

| | | | |
|---|---|---|---|
| **SECTION 1: IDENTIFICATION INFORMATION** | | | |
| **1.1** Date<br>...../……./……. | **1.4.** Residential district of respondent<br>_____ | **1.7** Sex<br>1= Male___<br>2 = Female___ | **1.10.** Health insurance used:<br>1. None___<br>2. Mutual___<br>3. RSSB___<br>4. Private___ |
| **1.2** Health facility code:_____ | **1.5.** Age:_____ | **1. 8.** Education: 1. None__<br>2. Primary__<br>3.Secondary___ 4. Tertiary____ | 1.11. Ubudehe (income) category:<br>1 __<br>2 _<br>3 _<br>4 _ |
| **1.3** Respondent's ID:_____ | **1.6** Profession:<br>1. Farmer___<br>2. Government employee___<br>3. Private employee__<br>4. Other_____ | **1.9.** Marital status:<br>1. Single___<br>2. Married__<br>3. Widowed___<br>4. Separated__ | |
| **SECTION 2: CLINICAL INFORMATION** | | | |
| **2.1.** Date of diabetes diagnosis:<br>_____<br>_____ | **2.3.** Recent Glycated Hemoglobin: _____ | **2.5.** Height: ___ | **2.7.** Smoking:<br>1. Yes____<br>2. No___ |
| **2.2.** Recent Fasting Blood Glucose:<br>_____ | **2.4**. Recent weight<br>_____ | **2.6.** Comorbidity/complications:<br>1. Hypertension__<br>2. Vision impairment___<br>3. Neuropathies___<br>4. Sexual impairment.<br>Other_____ | **2.8.** Alcohol:<br>1. Yes___<br>2. No___ |
| **2.9**: Type of medication:<br>1. Insulin___<br>2. Hypoglycemic agents: ___ | **2.10:** Diabetes antecedents:<br>1. Yes_____<br>2. No_____ | | |

#### 6.2.3.5 Translation

The instrument was first developed in English and translated into Kinyarwanda by a professional translator who was fluent in both languages. Normally, English is used by educated people and in some institutions and the national language spoken by all Rwandans is Kinyarwanda; hence the need to translate the instrument into the local language (ANNEXURE 21).

### 6.3 Discussion

This chapter aims at designing and refining an instrument to assess self-management barriers experienced by T2DM patients. The instrument was designed following rigorous steps and multiple methods and identified barriers of self-management using a conceptual framework (Zeng *et al.*, 2014)). In addition, the conceptual framework was adapted after conducting an extensive literature review and conducting a qualitative study. Caro-bautista *et al.*(2014) underline the importance of using a conceptual model in addition to other methods and opine that this provides a means of exhausting all possible items relevant to the construct to be measured. The use of a conceptual framework helps to exclude irrelevant items, and to include the most important. In her early research note Ng (2006), recommends that in the process of instrument development, choosing a conceptual framework that will guide the process is vital.

The conceptual framework facilitated a comprehensive selection of items from all levels; for example, at an individual level barriers related to knowledge, income and other demographic characteristics were identified; at family level the items on family support and relationship were identified and at the community level items such as those asking about the availability of supporting programmes or healthy food were designed. Furthermore, comprehensive areas of barriers were identified. As an example, the social area was described in the interaction between health providers and patients, family and friends. Other areas namely, psychological and emotional were covered, and physical or biological areas such as the barriers due to diabetes itself were described.

In addition to the conceptual framework, a table of specification was used for its practicality in allowing the comparison of the results of the integrative review and of the qualitative study without omitting any of the barriers.

In previous studies in which literature and a qualitative study were used, it was not clear how they merged or compared the results to formulate the items (Caro-bautista *et al.*, 2014). It is vital to assist novices in instrument development to comprehend the entire process.

When developing an instrument, it is common practice to recruit experts in the validation of the content of items for relevance and clarity. In this study however, a decision was taken to use experts in diabetes as an early step in study as they work with patients in their daily practice and have a far better understanding of the reality on the ground.

## 6.4 Conclusion

In this chapter the process of generating and constructing the new instrument was described. From an initial pool of 105 items, 73 were constructed in accordance with the adapted concepts of a self-management model. A Likert scale of four points was used to avoid a neutral option. The instrument was a self-report questionnaire that could be used by clinicians and researchers. The instrument was named BE-SEED2 and was translated into the local language to fit the context. This process concluded phase 2. In the next phase, the validation process, methods and the results will be discussed.

# CHAPTER 7: THE CONTENT VALIDITY, FACE VALIDITY AND CLINICAL UTILITY

## 7.1 Introduction

Phase 2 ended with the construction of the new instrument (BE-SEED2) and in Phase 3 it was validated. Chapter 7 presents the methods and the results of the content and face validity of BE-SEED2. The clinical utility methods and results will also be presented. The chapter ends with a discussion and a conclusion. The final step in the validation process, construct validity, will be discussed in chapter 8.

## 7.2 Methods

### 7.2.1 Content validity

The content validity is a subjective judgement by experts and is "defined as the extent to which an instrument has appropriate items for the construct being measured" (Yaghmaie, 2003; p.27). It can be done by five to ten experts in the field (Yaghmaie, 2003). In this study, the construct to be measured consists of barriers to self-management among T2DM patients.

#### 7.2.1.1 Participants and sampling

The researcher purposively selected 10 diabetic experts from the fields of medicine, nursing, nutrition and social work. The participants recruited were clinicians and academics with a minimum of five years of work experience.

#### 7.2.1.2 Data collection instrument and procedure

A questionnaire to evaluate the content validity was devised (ANNEXURE 23). Experts assessed each item using a 4 point Likert scale to selected items that were relevant, clear, simple and without ambiguity as described in Table 7.1. The researcher contacted the experts either telephonically or in a physical meeting to request their participation in the study. An e-mail invitation was forwarded to those who agreed to participate. The instrument, an information letter and a consent form were also attached to the email, for them to comprehend the nature of the study. The content validity was assessed in a one-day meeting that took place in the first week of April 2019.

During the meeting, the researcher explained the purpose of the study, the process used to develop the instrument and the objective of the meeting. Participants indicated their agreement to participate by signing the consent form and were randomly assigned codes to ensure anonymity and confidentiality.

**Table 7.1: Criteria for measuring content validity**

| **Relevance (relevant to the construct)** | **Clarity (precision)** | **Simplicity (easy)** | **Ambiguity (significance, meaning)** |
|---|---|---|---|
| "1 = not relevant" | "1= not clear" | "1 = not simple" | "1 = doubtful" |
| "2 = item needs some revision" | 2 = item needs some revision | "2 = item needs some revision" | "2 = item needs some revision" |
| "3 = relevant but needs minor revision" | "3 = clear but needs minor revision" | "3 = simple but needs minor revision" | "3 = no doubt but needs minor revision" |
| "4 zeng= very relevant" | "4 = very clear" | "4 = very simple" | 2 = meaning is clear" |

Source: Criteria for measuring content validity according to Yaghmaie, 2003

#### 7.2.1.3 Analysis

A Content Validity index (CVI), a measure of expert agreement on each item, was calculated for all individual items (I-CVI) and for the overall scale (instrument), the Scale Content Validity Index (S-CVI) was calculated. For each item, I-CVI was computed as the number of experts giving a rating of 3 or 4, divided by the total number of experts. The literature suggests that when the researcher has five or less experts, the I-CVI should be 1.00 and in cases of six experts and above the I-CVI should not be less than 0.78. In this study the I-CVI was set at 0.8 and above as 10 experts were used (Shrotryia and Dhanda, (2019). The mean I=CVI was calculated followed by a calculation of the Scale of overall Content Validity Index (S-CVI) by computing the average of all I-CVIs. It is recommended that a minimum S-CVI should be 0.8 for reflecting the content validity (Polit and Beck, 2010).

Following this process, the instrument was revised. The items that did not meet the criteria set for content validity were eliminated and BE-SEED2 was then ready for the assessment of face validity.

### 7.2.2 Face validity with target population

The face validity was assessed during the second week of April 2020. As stipulated in Polit and Beck (2010), face validity seeks to know if the instrument measures a certain construct to target population. In this study the target population was T2DM patients.

#### 7.2.2.1 Participants and sampling

Four T2DM patients living with T2DM who had been living with T2DM for a minimum period of one year (two males and females) were purposively recruited. Patients were from both rural and urban areas, able read and write at least the local language. Levels of education extending over primary, secondary and tertiary education were chosen.

#### 7.2.2.2 Data collection instrument and procedure

To determine whether the instrument demonstrated adequate face validity, participants completed a face validity questionnaire developed by the researcher (ANNEXURE 24). The questionnaire had four questions on a Likert scale and one open ended question. The right column of the questionnaire allowed the opportunity for additional comments and suggestions whenever a score below four was given. T2DM patients were physically contacted and invited to a one-day meeting. During the meeting, the researcher took time to explain the instrument itself as well as the purpose of the study. After signing a consent form, participants completed the BE-SEED2 then the face validity questionnaire. Participant codes were used to ensure anonymity.

#### 7.2.2.3 Analysis

The analysis was done by observing the given score and the comments and suggestions on the four questions of Likert scale. These served to revise items where necessary. There were open- ended questions and response of participants were grouped together in under appropriate themes and were also considered when revising the items.

### 7.2.3 Clinical utility

The clinical utility refers to the degree of which an instrument is user-friendly (Sandström and Lundin-Olsson, 2007) and clinically applicable (Eklund and Gunnarsson, 2008).

#### 7.2.3.1 Participants and sampling

A clinical utility study was done to determine BE-SEED2 applicability in the clinical settings during the third week of April 2019. The researcher purposively selected 18 nurses and two medical doctors from four hospitals, two in rural settings and two in urban settings. The clinicians were working in the outpatient departments or the departments of non-communicable disease and were fluent in both English and Kinyarwanda.

#### 7.2.3.2 Data collection instrument and procedure

The instrument to assess clinical utility was devised to assess ease of use, the format and relevance based on a 4-point Likert scale. The time used to complete the instrument was also assessed. In addition, there was an open-ended question to assess the difficulties encountered while administering the questionnaire (ANNEXURE 25). An information sheet was provided and all participants were requested to sign an informed consent. Then, the researcher oriented each participant to the newly developed instrument (the 63 item version which had been reduced due to the CVI scores). before commencing with data collection by explaining what it was, its components and how to use it. Each of them selected two to three participants to assess the T2DM barriers. After using the newly developed instrument, the same nurses and medical doctors were given the questionnaire to assess its clinical utility.

#### 7.2.3.3 Analysis

The scores of health providers were interpreted using the majority on each aspect of easiness, format and time. A score of 80-100% (Mean of 3.2-4) was considered as highly easy and applicable, 70-80% (mean of 2.8-3.2) was considered as moderately easy and applicable, needed minor revision, 69% (mean less than 2.8) and below was considered as having low easiness and applicability and needed major revision.

The open-ended question regarding difficulties, comments and suggestions was qualitatively analysed showing the themes which emerged and their frequency. The feedback was taken into consideration and helped to make minor changes regarding grammar, re-phrasing and format of the newly developed instrument.

## 7.3 Results

### 7.3.1 Results of content validity

#### 7.3.1.1 Social demographic characteristics of experts

**Table 7.2: Social demographic characteristics of experts for the content validity n=10**

| Code | Age | Education level | Working setting | Specialty |
|---|---|---|---|---|
| 1 | 50 | Master | Clinical | Medical doctor, specialist in internal medicine and diabetes |
| 2 | 48 | Master | Clinical-academic | Medical doctor, specialist in internal medicine and work in diabetes clinic |
| 3 | 46 | PhD | Academic | Nursing, specialist in diabetes and hypertension |
| 4 | 33 | Master | Clinical | Medical and surgical nursing, working in diabetes |
| 5 | 32 | Master | Academic | Medical and surgical nursing, teaching diabetes in nursing department |
| 6 | 61 | PhD | Academic | Nursing, specialist in medical surgical nursing, teaching diabetes in nursing |
| 7 | 58 | Bachelor | Clinical | Nutritionist working in diabetes ward in hospital |
| 8 | 45 | PhD | Academic | Researcher in social sciences and instrument development and psychometrics |
| 9 | 38 | Bachelor | Clinical | Nurse working in diabetes department |
| 10 | 37 | Master, PhD candidate | Academic | Nutritionist, teaching in nutrition department |

Table 7.2 indicates that 4 experts between 32-61 years of age were working in a clinical setting and five in an academic setting. One was working in both clinical and academic areas. There were two medical specialists in internal medicine and working in diabetic clinics. Among five invited nurses there were two with PhDs, two with Masters and one with a Bachelor degree all working or teaching in the diabetic field. Two nutritionists and one social worker were also invited.

#### 7.3.1.2 Content Validity Index and Scale Content Validity Index

**Table 7.3: Item Content Validity Index (CVI) and Scale Content Validity Index (S-CVI)**

| | Mean I-CVI per domain | | | | S-CVI |
|---|---|---|---|---|---|
| **Barriers/domains** | **Relevance** | **Clarity** | **Simplicity** | **Ambiguity** | |
| Knowledge | 1 | 1 | 1 | 1 | |
| Stigma | 1 | 0.9 | 0.9 | 0.95 | |
| Health facility | 0.96 | 0.92 | 0.95 | 0.9 | |
| Family, friends, community | 0.98 | 0.95 | 0.96 | 0.93 | 0.92 |
| Comorbidities and complications | 1 | 1 | 1 | 0.93 | |
| Behaviour and psychological coping | 1 | 0.95 | 1 | 0.91 | |
| Diet | 0.98 | 0.95 | 1 | 0.92 | |
| Physical exercise | 1 | 1 | 1 | 1 | |
| Medication | 1 | 0.96 | 1 | 0.9 | |
| SMBG | 0.97 | 1 | 0.97 | 0.97 | |
| Foot care | 1 | 1 | 1 | 1 | |

After computing the Content Validity Index, 10 items were eliminated because their I-CVI was below 0.8. Those items are presented below:

- Instructions and prescriptions are unclear, written in foreign languages with medical terminology
- My family treats me badly and does not help me in self-management making self-management harder
- I feel I get little support from my friends
- I fail to read what doctors wrote as instructions for self-management due to blurred vision
- Since diabetes is chronic disease I see little benefit in self-management
- I do not think diet will change anything to diabetes treatment
- It is difficult for me to stop what I have been eating or drinking; I take some alcohol/tobacco as I used to do
- I am in such a hurry that I forget to take food in the morning.
- Sometimes doctors are busy and they do not find time to listen to us, they just prescribe medications

The I-CVI of the remaining 63 items was high ranging between .8-1. The Mean I-CVI per domain ranged between 0.90-1. The S-CVI was also high and scored at 0.92.

### 7.3.2 Results of face validity

Table 7.4 displays the characteristics of the four participants who assessed face validity. Their mean age was 47±11.6, (2) had completed secondary school (2) were female and (2) were from an urban area.

**Table 7.4: Social demographic characteristics of participants n=4**

| Characteristics | Frequency (%) |
|---|---|
| **Age (mean ±SD)** | 47±11.6 |
| **Gender** | |
| Female | 2(50) |
| Male | 2(50) |
| **Time (years) living with diabetes** | |
| 1-5 years | 2(50) |
| 5 years and more | 2(50) |
| **Education** | |
| Primary | 1(25) |
| Secondary | 2(50) |
| Tertiary | 1(25) |
| **Area** | |
| Urban | 2(50) |
| Rural | 2(50) |

**Table 7.5: Results of four Likert scale questions**

| Item | SD | D | A | SA | Comments |
|---|---|---|---|---|---|
| The instrument included all my barriers in self-management of T2DM | 0 | 0 | 0 | 4 | None |
| I would be happy to complete the instrument as part of routine care | 0 | 0 | 0 | 4 | None |
| I was able to read and understand | 0 | 0 | 2 | 2 | -The translation of diabetes in Kinyarwanda (Gisukali) is not commonly used. Use diabetes 2 and write it in Kinyarwanda "diyabete y'ubwoko bwa kabiri"<br>-Revise the translation of indicated items |
| The time was reasonable | 0 | 0 | 3 | 1 | The items seem to be many though relevant to me and do not know which one you can take away |

The results of face validity indicated in table 7.5 show that all participants strongly agreed that the items were relevant and were willing to use the instrument in the hospital. Participants suggested using the word "diabetes" instead of its Kinyarwanda translation "Gisukali".

They also indicated the items that would need revision of grammar and translation. One participant said that the items were many, though found all items to be relevant.

**Results of open-ended question**

All participants revealed that Glycated Hemoglobin and height are rarely taken and would have missing data and one said:

> *"There are social demographic characteristics that you will not be able to find the response such as height, glycated hemoglobin. Those measurements are not taken in our hospital* "

### 7.3.3 Clinical utility results

**Demographic characteristics of health providers**

As displayed on Table 7.6, among 20 health providers that assessed the clinical utility of BE-SEED2, 90% were nurses and 10% were medical doctors. The majority of the participants had five or more years of experience. Participants were recruited from four hospitals; two located in urban areas (60%) and two in rural areas (40%).

**Table 7.6: Demographic characteristics of health providers (n=20)**

| Characteristics | n (%) |
|---|---|
| **Profession** | |
| Nurses | 18(90) |
| Medical doctors | 2(20) |
| **Experience** | |
| 0-4years | 8 (40) |
| 5years and more | 12 (60) |
| **Hospital** | |
| Gahini | 4 (20) |
| Kibagabaga | 6 (30) |
| CHUB | 6 (30) |
| Ruli | 4 (30) |

**Table 7.7: Results of clinical utility n=20**

| **1. How easy is the instrument** | **SA 1** | **D 2** | **A 3** | **SA 4** | **Mean** |
|---|---|---|---|---|---|
| The instrument was easy to administer | 0 | 2 | 7 | 11 | 3.4 |
| Language and terminology in the instrument were easily understood | 0 | 0 | 4 | 16 | 3.8 |
| Patients were able to understand the concepts used and get what I am asking | 0 | 0 | 3 | 17 | 3.8 |
| **2. The format** | | | | | |
| The format of the instrument allowed for easy recording | 0 | 0 | 5 | 15 | 3.7 |
| **3. Efficiency** | | | | | |
| The instrument identified self-management barriers of T2DM patients | 0 | 0 | 2 | 18 | 3.9 |
| **4. Time (exclude time to get and sign consent form as well as information sheet)** | | | | | |
| How many minutes did you use to administer the instrument for the first patient | | | | | 17.1 Min:10, Max:26 |
| How many minutes did you use to administer the instrument for the second patient | | | | | 16.4 Min:10, Max:24 |
| How many minutes did you use to administer the instrument for the third patient | | | | | 15.3 Min:8, Max:22 |
| How many minutes did you use to administer the instrument for the fourth patient | | | | | 14.8 Min:8, Max:22 |
| How many minutes did you use to administer the instrument for the fifth patient | | | | | 13.7 Min:6, Max:22 |
| How reasonable was the time taken to complete the instrument | **Not reasonable** | **Slightly reasonable** | **Reasonable** | **More reasonable** | **Mean** |
| | 0 | 2 | 16 | 2 | 3.5 |

In terms of clinical utility, the scores of the nurses and medical doctors generally indicated more positive views of the questionnaire's relevance, format, time and easiness. Table 7.7 shows that only two out of 20 professionals were negative regarding the question about how easy it was to administer the instrument and only 2 out of 20 said that completing the instrument took a slightly reasonable time. None of the participants was negative about the format and time efficiency.

On the clinical utility questionnaire there was an open question regarding difficulties, observations and suggestions, table 7.8 shows a summary of the responses of nurses and medical doctors. In the third column, any action taken by researchers regarding difficulties, observations and suggestions is also shown. At the end of the clinical utility, the instrument had 64 items as the item "I can not afford the glucometer and test strips" was split into two items: "I cannot afford a glucometer" and "I cannot afford test strips".

**Table 7.8: Summary of comments of nurses and medical doctors from clinical utility**

| **Difficulties** | **Frequency** | **Action taken** |
|---|---|---|
| Some tests like Glycated Hb are not done here, patients do not understand what it is | 5 | Item removed |
| Patients do not remember their glucose results | 1 | |
| Patients stop you to ask questions about diabetes and self-management | 4 | |
| Some concepts indicated in some items are not heard for the first time, you need to explain them | 1 | Concepts revisited |
| **Observations** | | |
| Some grammar error on indicated items | 2 | Grammar error corrected |
| It is easy to administer the instrument with educated people | 1 | |
| It became easy to administer instrument as you do many patients | 4 | Training of data collectors |
| No more comment, most of barriers are included in the instrument | 10 | |
| **Suggestions** | | |
| Split item of glucometer and test strip | 5 | Item split into 2 |
| Revise indicated items in local language | 3 | Items indicated revised |

## 7.4 Discussion

The study assessed the content and face validity of the newly developed instrument. The clinical applicability of the instrument was also assessed. The content validity is documented in literature as an essential step in the process of instrument development as it can support the construct validity of an instrument (Yaghmaie, 2003; Eklund and Gunnarsson, 2008; Zamanzadeh *et al.*, 2014; Shrotryia and Dhanda, 2019). In this study, it was assessed as an ongoing process and started with an accurate definition of construct and content domains. It continued with involvement of experts who judged the items.

When developing an instrument, the literature recommends that it is preferable that patients living in the local context answer questions on the instrument to assign their own priority to the domain which they find to be most relevant (Sandström and Lundin-Olsson, 2007). Even though the items of BE-SEED2 were selected based on the results of interviews Polit and Beck, (2010) suggest that using the target population in face validity appears to confirm what was found. Thus, patients were recruited for that purpose and all of them tended to be positive towards the instrument with few comments or suggestions for change, hence confirming the self-management barriers that were identified in this community.

Whilst care was taken to use a professional translator to translate items, this stage made it clear that in the process of instrument development, the researcher should emphasise on the content validity to the target population. Patients were able to provide common, local words that are used in self-management and diabetes, thereby removing ambiguity. A similar suggestion was made by (Connell *et al.*, 2018) in their study to show the importance of using the target population in the assessment of face validity.

Literature (Patrick *et al.*, 2011) proves that the participation of clinicians in the validation of the instrument is paramount. The clinical utility study done helped in rewording some of the items; clinicians chose to reword some items in the local language that they felt were sensitive and ambiguous, their frequent contact with patients making them able to do this. They suggested splitting items on the affordability of test strips and glucometer (an item that considered them as a kit), arguing that one could afford a glucometer but fail to afford test strips. In addition, they suggested removing an item, the answer to which would be unknown by the patient; clinicians

agreed that patients would not differentiate glycaemia from Glycated Hb and suggested removing these items. Therefore, a key step in the development of an instrument that of clinical utility.

## 7.5 Conclusion

The BE-SEED2 is an instrument developed based on the conceptual framework and supported by clinicians and patients' views. It is now available to identify barriers to T2DM self-management. The results of the content validity indicated the relevance of items, its clarity, its simplicity as well as its significance. The target population appraised the instrument and nurses and doctors found it to be applicable in the clinical setting. After all these process was completed, a valid instrument with 64 items was developed with an I-CVI ranging from 0.8-1 mean of and S-CVI of 0.92, and which can be used by both clinicians and patients. The evaluation of its reliability and construct validity in the next chapter will determine the instrument's accuracy and insures whether it measures barriers to self-management.

# CHAPTER 8: INVESTIGATION INTO CONSTRUCT VALIDITY OF THE BE-SEED2

## 8.1 Introduction

This chapter presents the methods, results and discussion of the construct validity of the BE-SEED2. Construct validity seeks to establish whether each questionnaire item contributes something unique to the construct that the instrument or questionnaire purports to measure, that is, T2DM self-management in the case of the current study.

## 8.2 Methods

### 8.2.1 Study design

The study employed a cross-sectional descriptive design. A cross-section design is a type of study "where data are collected at one point in time to describe the status of phenomena or relationships among phenomena" (Polit and Beck, 2010; p.239). In this study, the BE-SEED2 was administered to a sample of people with T2DM, that is a once-off data collection. The aim was not to report on how good or bad the self-management of the participants was but rather to describe how the different items contributed (or did not contribute) to the overall construct of self-management.

### 8.2.2 Study setting

The study was carried out in the same hospitals in which the qualitative study was conducted except in the Eastern Province where Kirehe Hospital was replaced by Gahini Hospital which had a large number of patients (Table 8.1).

### 8.2.3 Study population

The study population was composed of T2DM patients attending the outpatient departments of selected hospitals as listed in Table 8.1.

### 8.2.4 Sampling, sampling strategies and sample size

For purification of the assessment instrument in factor analysis, several authors (Augustine *et al.*, 2012; Newman, Lim and Pineda, 2013; Boateng, Neilands and Frongillo, 2018) suggest a 10 participants for each item. Based on these criteria to determine sample size, the initial total sample

size of 640 (items *10 = 640) was estimated since the BE-SEED2 has 64 items. The sample size was increased to 650 participants to anticipate the possibility of missing data. After obtaining the total sample for the study, the researcher then determined the sample size in each hospital. For this purpose, the researcher first contacted the data management unit officer of each hospital and obtained an estimate of the total number of T2DM patients in the outpatient department. The sample size in each hospital was calculated by taking its total estimated number of T2DM patients ($x$) times the total sample of the study (n=650) divided by the total estimated population from 10 hospitals (N=2384). Thus, the formula becomes $x$ ×n/N. Table 8.1 shows the sample size drawn from each hospital.

**Table 8.1: Sample size**

| Code of hospital | Hospital | Approximate Population = $x$ | Sample ( $x$ ×n/N) |
|---|---|---|---|
| 1 | CHUK | 300 | 82 |
| 2 | Kibagabaga | 300 | 82 |
| 3 | Gahini | 220 | 60 |
| 4 | Remera Rukoma | 204 | 56 |
| 5 | Muhororo | 120 | 33 |
| 6 | CHUB | 250 | 68 |
| 7 | Nyamata | 150 | 41 |
| 8 | Ruhengeli | 257 | 70 |
| 9 | Gisenyi | 473 | 129 |
| 10 | Ruli | 110 | 30 |
| **Total** | | **2384=N** | **650=n** |

Depending on the hospital, 10 to 30 patients with Type 1 and Type 2 diabetes mellitus may come for their appointments at the same time. All patients with T2DM who were eligible and willing to participate were recruited until the desired sample size was achieved.

### 8.2.5 Data collection

#### 8.2.5.1 Data collection instrument

The objective of the study was to establish the construct validity of the BE-SEED2 instrument and therefore BE-SEED2 itself was used to collect data (ANNEXURE 26).

#### 8.2.5.2 Training of data collectors and pilot study

To collect the data, the researcher recruited eight nurses who held a minimum of a Bachelor's degree and were trained in data collection. The training was done in two sessions. The first session was done in one day when the instrument and rating system were explained. A pair of data collectors did the exercise while the others observed. The second session took place in the real setting in one of the hospitals (Gahini) where the instrument was piloted. In the second session the researcher assisted and collected data from five participants. Debriefing sessions were held for additional explanations and consensus on the use of the BE-SEED2.

#### 8.2.5.3 Data collection procedure

Data were collected between the period May 2019 to June 2019. With assistance from the nurse in charge, data collectors approached participants in the waiting hall and invited their participation. Data collectors introduced themselves, took time to briefly explain the purpose of the study and clarified the selection criteria. Patients who accepted to participate were provide with the information letter and consent form to be signed. There were no incentives for participation.

The data collectors explained the instrument scoring system to the participants and administered it on spot in one of the offices availed by the health facility. Instruments in both the English and Kinyarwanda translation of the BE-SEED2 (ANNEXURE 26) were available and among two languages used (Kinyarwanda and English), participants were able to choose the easiest language in which the instrument would be administered.

### 8.2.6 Data analysis

Data were entered using a statistical software SPSS (Statistical Package for Social Sciences) version 25, then double checked for accuracy. The analysis was done following various steps:

(1) The descriptive analysis serving as the first step in all quantitative analysis (Polit and Beck, 2010) was performed. Frequencies, means and SD (standard deviation) for each item were used to display the summary of the sample characteristics.
(2) Missing values and unusual values were detected and for each variable were identified using the frequencies.

The unusual values were for example, any scoring number which was not between one and four. In addition, the high extreme scorings on items were observed.

(3) Exploratory Factor Analysis (EFA) which is normally used to determine an underlying factor structure that exists in a set of questionnaire items was used to assess the construct validity. The purpose of EFA is to establish whether all items can load onto factors. In other words, the focus was to reveal structure patterns within questionnaire items. For instance, it might be assumed that item 1,2,3 and 4 measure one construct of medication. EFA is conducted to determine whether that assumption is correct. The suitability of the study for EFA was first checked as follows:

(3.1) The sample adequacy for factorability was ensured using the Kaiser-Meyer-Olkin (KMO). It normally ranges from 0 to 1 and for good sample adequacy it should be >.5.

(3.2) To assume reliable correlations, the test of sphericity from Bartlett's test was used with a significant level set at <.05. Bartlett's test measures the strength of the bivariate relationship between items under investigation.

(3.3) The correlation matrix was observed to consider individual items that exhibit correlation >.30 to other variables. If there are many, the EFA is feasible.

(3.4) Additionally, KMO MSA of individual items was considered by examining the principal diagonal of the anti-image correlation matrix.

(3.5) The determinant of the correlation matrix values, close to .0 and those between 0.80-0.90. was observed to checked whether multicollinearity may be a problem. The value of the determinant should be <10

(4) After being sure of the suitability of the EFA, the extraction methods were determined. The Principal Component Analysis (PCA) was used as extraction method. The PCA is descriptive, it converts data to produce a description that is not complex. In the current study, the instrument was newly developed and there was a needed to determine the number of items that measure the construct which was the reason for using PCA.

(5) The number of factors to be extracted was then determined. The number of criteria came into play (1) the Eigenvalue cut-off >1. The Eigen-values represent the total number of variances explained. Only factors with Eigen-values higher than 1 were taken as significant (Plichta and Kelvin, 2013), (2) in addition to that the scree plot was examined to choose factors that accounted for at least 50% of the total variance explained, (3) A parallel

analysis was done (Monte Carlo Parallel analysis) to confirm the number of factors and considered the variation of > 50%.

(6) A factor matrix was generated indicating the factor loadings. The loading is understood as the weight with which an item correlates with other items under the same factor. Field (2009) suggested a weight of at least .4 for an item to be considered part of a factor.

(7) The orthogonal variation (Varimax rotation) was chosen for better understanding of underlying factors. Factor rotation offers a clear picture of variables that correlate with one factor (Plichta and Kelvin, 2013). The identification of factors was based on the instrument items loaded under the factor and the review informed the grouping of items under the same factor.

(8) The internal consistency of the BE-SEED2 items and factors was established using the Cronbach Alpha. The value of Cronbach Alpha is considered as acceptable and adequately reliable when equal to or larger than 0.7 (Ramezankhani *et al.*, 2015).

(9) The factors that emerged from the factor analysis were named and described.

## 8.3 Results

### 8.3.1 Demographic characteristics of the sample

**Table 8.2: Individual characteristics of the sample (n=650)**

| **Characteristics** | |
|---|---|
| **Age mean (SD)** | 54.24 (7.4) |
| **Profession** | **n (%)** |
| Farmer | 300(46.2) |
| Government employee | 142(21.8) |
| Private employee | 50(7.7) |
| Personal business | 150(23.1) |
| Retired | 8(1.2) |
| **Gender** | **n (%)** |
| Male | 218(40.5) |
| Female | 432(59.5) |
| **Level of education** | **n (%)** |
| None | 144(22.2) |
| Primary | 306(47.1) |
| Secondary | 180(27.7) |
| Tertiary | 20(3.1) |
| **Type of health insurance** | **n (%)** |
| Community | 450(69.2) |
| Public | 150(23.1) |
| Private | 50(7.7) |
| **T2DM duration, mean (SD)** | 7.08(6.7) |
| **Marital status** | **n (%)** |
| Single | 27(4.2) |
| Married | 435(66.9) |
| Widow | 174(26.8) |
| Separated | 14(2.2) |
| **Ubudehe category** | **n (%)** |
| Category 1 | 73(11.2) |
| Category 2 | 205(31.5) |
| Category 3 | 370(56.9) |
| Category 4 | 2(.3) |
| **Type of medication** | **n (%)** |
| Insulin | 256(39.4) |
| Tablets | 394(60.6) |
| **Alcohol** | **n (%)** |
| Yes | 160(24.6) |
| No | 490(75.4) |
| **Smoking** | **n (%)** |
| Yes | 38(5.8) |
| No | 612(94.2) |

Table 8.2 shows that the mean age was 54.24± 7.4 and the majority were female (59.5%). Regarding profession, the majority were farmers (46.2%). Only 30% had secondary and tertiary education. However, 144 (22%) participants with no formal education attended adult short courses in learning to write and read the local language. Most participants (69.2%) used the community health insurance and the T2DM duration mean was 7.08±6.7. Two thirds of the participants were married (66.9%) and the majority (56.9%) were classified under financial category 3. Most participants (60.6%) were on oral hypoglycaemic agents and only 39.4% used insulin. The overwhelming majority reported that they did not take either alcohol (75.4%) or tobacco (94.2%).

### 8.3.2 Data cleaning

Using descriptive analysis for all items in the questionnaire, data were checked for missing and unusual values.

#### 8.3.2.1 Response rate

The response rate of BE-SEED2 was 99.5% indicating that 99.5% of respondents fully completed the questionnaire without a missing response (Table 8.3).

**Table 8.3: Missing data in Be-SEED2's questionnaire**

| Number of missing data | Frequency | Percent |
|---|---|---|
| 0 | 647 | 99.5 |
| 1 | 1 | .2 |
| 2 | 2 | .3 |
| **Total** | **650** | **100** |

#### 8.3.2.2 Unusual values

With reference to scores indicated in the questionnaire, three unusual values were observed (12,33,44) and were corrected after checking the hard copies of questionnaires (1,3,4).

#### 8.3.2.3 Instrument redundant items

Items were checked to determine the distribution of the responses According to Hearnshaw *et al.* (2007) if at the end of the scale items for 90% or more of the responses are in one category, they

have to be removed to avoid the possibilities of response aggregation in category. Following this principle 10 items were eliminated and 54 items remained (Table 8.4).

**Table 8.4: Eliminated items**

| Sub-scales | Number of items | Name |
|---|---|---|
| **Health facility** | 1 | 1. I feel self-management activities have not been clearly explained to me |
| **Behaviour and psychological issues** | 2 | 2. I am not psychologically stable, T2DM has put stress in my life<br>3. I am desperate I keep thinking that this disease is not curable and that affects self-management of diabetes |
| **Diet** | 1 | 4. I cannot buy special food items for myself like when I have not enough money, I first think about my family |
| **Medication** | 5 | 5. I think that food supplements (abagorozi) seem to be as good as diabetes treatment<br>6. I have a feeling that the medication prescribed to me is not effective<br>7. Sometimes I get a depressed mood, during such a period, I would stop medication for sometimes then I would decide to resume.<br>8. When I find that the blood glucose level is fine, I may sometimes stop medication<br>9. I miss medication when travelling because I do not have mean to transport my drugs |
| **SMBG** | 2 | 10. I fear injections I cannot check blood glucose at home |

### 8.3.3 Exploratory Factor Analysis

#### 8.3.3.1 Assumptions

As indicated in the analysis, before running EFA, different assumptions were made and had to do with the determinant of correlation matrix, Kaiser-Meyer-Olkin (KMO) and Bartlett Test.

**Table 8.5: EFA assumptions**

| | Obtained value | Standard |
|---|---|---|
| Determinant | 3.01 | < 10 |
| KMO | .918 | >0.60 |
| Bartlett Test of Sphericity | .000 | <0.5 |

Table 8.5 shows the results of assumptions to EFA. The determinant of 3.01 is less than < 10 suggesting that there is no multicollinearity, thus the items of BE-SEED2 are not highly correlated.

The KMO of .918 is ideal as it is greater than .60 suggesting sample adequacy for EFA. Regarding the Bartlett Test of Sphericity, the value (0.000) obtained is significant, that is, less than <.05. This implies that the strength of the bivariate relationship between items under investigation is good enough. Considering the results of these assumptions, the EFA is suitable and the items are expected to appear in clusters or load onto factors.

#### 8.3.3.2 Extractions of factors

EFA was done and included 54 items and 12 factors with an eigenvalue of >1 explained 58.8% of items' variance. The item-to-factor loadings was set at 0.40. In order to confirm the exact number of factors considerer, the parallel analysis or Monte Carlo Parallel Analysis (Field, 2009) was used, and nine factors generated by the data had eigenvalues greater than those randomly generated. Hence nine factors, accounting for 53.269 % of the total variance (Table 8.3), were retained. In this study, varimax rotation was used, given that what is at issue is to reveal independent factors underlying the BE-SEED2 questionnaire. Three items did not load sufficiently (items that are not numbered), Table 8.6) on all factors, and were removed from the analysis. During the analysis, an attempt to decline the number of factors to less than nine through rotation was done, but was not possible and the number of factors was remained at nine.

**Table 8.6: Factors extraction and structure**

| No | Items | Factor Loadings |
|---|---|---|
| | **1. Health care barriers α=.829 (Eigenvalue = 12.52, Variance% = 24.56)** | |
| 1 | I don't have one specific health provider who can regularly and exclusively follow-up on me | .676 |
| 2 | Health care providers rush, they do not find time to listen to me | .666 |
| 3 | I would say that I am not consulted regarding diabetes management decisions | .656 |
| 4 | I feel I am given guidance without considering my individual problems | .650 |
| 5 | I feel I am not well guided | .556 |
| 6 | I live far from hospital and getting here is so challenging | .523 |
| 7 | I have to wait for long time when I come for appointment | .522 |
| 8 | I face the issue of stock outs of my medication | .452 |
| | Nurses/doctors use bitter /unpleasant words I fear to ask more information about self-management | .327 |
| | **2. Diet, behavioural change and psychological barriers (Eigenvalue = 2.56, Variance% = 5.03)** | |
| 9 | It is hard to take appropriate diet when I am away from home | .659 |
| 10 | It is difficult to change my habits in accordance with T2DM condition | .628 |
| 11 | I am not in a position to impose my diabetes diet on my family/I do not have the power | .620 |
| 12 | Having a special diet different from my family members makes me feel isolated, I sometimes prefer to share what others eat | .600 |
| 13 | It is being long time taking diet, I am really tired | .556 |
| 14 | I feel like I am useless to my family | .474 |
| 15 | I end up eating unhealthy food as it is what I can afford | .460 |
| 16 | I feel hopeless, T2DM has put stress in my life | .454 |
| 17 | I think that information about diet is not consistent | .444 |
| 18 | In my area, it is not easy to get vegetables and other food items recommended | .443 |
| | **3. Knowledge and SMBG barriers (Eigenvalue = 2.15, Variance% = 4.22)** | |
| 19 | I can't pretend and confidently say that I have enough knowledge about type 2 diabetes | .710 |
| 20 | I may fail self-management in one way or another either because I am not aware or because of ignorance | .665 |
| 21 | I may fail to understand written self-managements instructions/literature | .556 |
| 22 | I don't think I know the effects, be it good or bad, that diabetes treatments can have on my health. | .524 |
| 23 | I was not given as much information as I needed about SMBG | .523 |
| 24 | I lack self-confidence and necessary skills to manage my T2DM | .504 |
| 25 | I cannot afford test strips | .500 |
| 26 | I cannot afford a glucometer | .475 |
| 27 | My working condition does not facilitate me to control blood glucose | .411 |
| | I do not think that regular self-management of blood glucose (SMBG) will change anything to diabetes | .301 |
| | **4. Lack of support from family and friends barriers α= .723 (Eigenvalue = 2.06, Variance% = 4.05)** | |
| 28 | I have a feeling that my family members do not give me enough support | .702 |
| 29 | I feel I get little support from my friends | .701 |
| 30 | People may have wrong perception of diabetes, show me stigma and discrimination | .577 |
| 31 | I fail to open up to tell others that I have diabetes | .471 |
| | **5. Physical exercise barriers (Eigenvalue = 1.993, Variance% = 3.02)** | |
| 32 | There is no culture of doing physical exercise in this community | .691 |
| 33 | I don't feel interested by physical exercise; that is something I don't easily enjoy | .677 |
| 34 | I do not think physical exercise will change anything to my diabetic condition | .644 |
| 35 | I was not given as much information as I needed about physical activity | .621 |
| 36 | The general environment in my community is not conducive for physical exercise | .600 |
| 37 | Except engaging in regular work or domestic chores, it is hard for me to have physical exercise | .577 |
| | **6. Medication barriers (Eigenvalue = 1.54, Variance% = 3.02)** | |
| 38 | My working condition may lead to skip a medication | .659 |

| | | |
|---|---|---|
| 39 | I sometimes forget to take my medication | .562 |
| 40 | I sometimes fail to get money to buy drugs for diabetes | .540 |
| 41 | I feel bad taking drugs everyday | .477 |
| 42 | When taking tablets it is hard to shift to insulin | .409 |
| | I take drugs that have been recommended for diabetes but I also take traditional medicine and the latter seems to be efficient. | .298 |
| **7.** | **Complexity of managing T2DM barriers (Eigenvalue = 1.50, Variance% = 2.95)** | |
| 43 | I spend time doing nothing that can generate income because of fatigue and diabetes complications | .744 |
| 44 | Having other diseases or diabetes complications, prevents me from adhering to self-management activities | .743 |
| 45 | Physical problems/diseases related to diabetes inhibit me from taking exercise | .689 |
| 46 | It becomes hard for me to be on diabetes medications and other treatments at the same time | .438 |
| **8.** | **Lack of support from community (Eigenvalue = 1.43, Variance% = 2.81)** | |
| 47 | There are no diabetic community programmes that support me | .669 |
| 48 | I would manage my diabetes much better if I had participated in diabetes group support | .650 |
| **9.** | **Foot care barriers (Eigenvalue = 1.37, Variance% = 2.68)** | |
| 49 | I was not given as much information as I needed about foot care | .624 |
| 50 | My feet were not examined to let me know what should specifically be done | .590 |
| 51 | My work requirements don't fully allow me to observe instruction on foot care | .544 |

After generating a factor matrix, the orthogonal variation (Varimax rotation) was chosen to offer a clear picture of variables that correlate with a factor. Table 8.6 depicts the nine factors that were extracted.

**Factor 1: Health care barriers**

Factor one has an Eigenvalue of 12.52 and accounts for 24.56 % of the total variance explained. The factor includes eight items related to barriers to self-management originating from health care. Those barriers are two fold; there are those factors linked to the health care providers (1,2,3,4,5,7) and others are related to the health care system (6,8).

**Factor 2: Diet, behavioural and psychological barriers**

Factor two has an Eigenvalue of 2.56 and accounts for 5.03 % of the total variance explained. It includes a cluster of 10 items related to barriers to adhering to a healthy diet (9,11,12, 13,15,1,18), behavioural change (10) and psychological issues (14,16).

**Factor 3: Knowledge and SMBG barriers**

Factor 3 has an Eigenvalue of 2.15 and accounts for 4.22 % of the total variance explained. The factor includes nine items; five of them describe barriers related to a low level of knowledge (18,20,21,22,24) and the other four are related to SMBG (23,25,26,27).

**Factor 4: Lack of support from family and friends**

Factor four takes an Eigenvalue of 2.06 and accounts for 4.05% of total variance explained. A total number of four items are depicted in factor four – there is one item describing the lack of support from family as a barrier (28), another, labelling the lack of support from friends (29) and then two items related to stigma (30, 31).

**Factor 5: Physical exercise barriers**

Factor five has an Eigenvalue of 1.993 and accounts for 3.02% of total variance explained. It has six items (32,33,34,35,36,37) and is related to barriers affecting physical exercise.

**Factor 6: Medication barriers**

Factor six has an Eigenvalue of 1.54 and accounts for 3.02 % of total variance explained. It includes five items describing barriers of adherence to medication (38.39,40,41,42).

**Factor 7: Complexity of managing type 2 diabetes barriers**

This factor has an Eigenvalue of 1.50 and accounts for 2.95% of total variance explained. It consists of four items (43,44,45,46) regarding barriers related to complications of diabetes or other circumstances emanating from diabetes.

**Factor 8: Lack of support from community**

This factor has an Eigenvalue of 1.43 and accounts for 2.81% of total variance explained. It comprises two items (47,48) describing the barriers related to the lack of support in the community.

**Factor 9: Foot care barriers**

The last factor has an Eigenvalue of 1.34 and accounts for 2.68% of total variance explained. It describes three items (49,50,51) indicating the barriers that hamper foot hygiene.

### 8.3.3.3 Internal consistency of the new structure of the BE-SEED2

**Table 8.7: Cronbach Alpha Reliability Coefficients for individual items and sub-scales**

| No | Items | M | M±SD | Item-Total Correlation | Squared Multiple Correlation | Cronbach's Alpha if Item Deleted |
|---|---|---|---|---|---|---|
| | **Knowledge and SMBG barriers α=.852** | | | | | |
| 1 | I can't pretend and confidently say that… | 3.34 | .795 | .313 | .412 | .936 |
| 2 | I may fail self-management in one way or another… | 3.21 | .828 | .499 | .446 | .935 |
| 3 | I may fail to understand written self-management's… | 2.81 | 1.10 | .406 | .413 | .935 |
| 4 | I don't think I know the effects, be it good or bad, that diabetes... | 3.23 | .986 | .547 | .460 | .934 |
| 5 | I was not given as much information as I needed about SMBG | 2.50 | 1.15 | .395 | .343 | .935 |
| 6 | I lack self-confidence and necessary skills to manage… | 2.80 | 1.07 | .567 | .498 | .934 |
| 7 | I cannot afford test strips | 3.30 | 1.08 | .395 | .343 | .935 |
| 8 | I cannot afford a glucometer | 2.89 | 1.08 | .387 | .337 | .935 |
| 9 | My working condition does not facilitate me to control.. | 2.45 | 1.21 | .603 | .581 | .934 |
| | **Health care barriers α=.829** | | | | | |
| 10 | I don't have one specific health provider who can regularly… | 2.75 | 1.16 | .544 | .563 | .934 |
| 11 | Health care providers rush, they do not find time to listen to me | 2.61 | 1.10 | .518 | .504 | .935 |
| 12 | I would say that I am not consulted regarding diabetes… | 2.12 | 1.11 | .558 | .545 | .934 |
| 13 | I feel I am given guidance without considering my… | 2.86 | 1.12 | .362 | .470 | .936 |
| 14 | I feel I am not well guided | 2.27 | 1.10 | .483 | .411 | .935 |
| 15 | I live far from hospital and getting here is so challenging | 3.07 | 1.16 | .258 | .220 | .936 |
| 16 | I have to wait for long time when I come for appointment | 3.22 | 1.00 | .287 | .407 | .936 |
| 17 | I face the issue of stock outs of my medication | 2.47 | 1.22 | .450 | .526 | .935 |
| | **Diet, behavioural change and psychological barriers α=. 828** | | | | | |
| 18 | It is hard to take appropriate diet when I am away from home | 3.40 | .851 | .455 | .405 | .935 |
| 19 | It is difficult to change my habits in accordance with… | 3.46 | .751 | .345 | .336 | .936 |
| 20 | I am not in a position to impose my diabetes diet on my… | 2.86 | 1.13 | .595 | .552 | .934 |
| 21 | Having a special diet different from my family members… | 2.70 | 1.09 | .613 | .551 | .934 |
| 22 | It is being long time taking diet, I am really tired | 2.69 | 1.08 | .486 | .461 | .935 |
| 23 | I feel like I am useless to my family | 2.53 | 1.16 | .554 | .519 | .934 |
| 24 | I end up eating the… | 3.12 | .929 | .534 | .514 | .935 |
| 25 | I feel hopeless, T2DM has put stress in my life | 2.86 | 1.14 | .628 | .514 | .934 |
| 26 | I think that information about diet is not consistent | 2.94 | 1.01 | .508 | .397 | .935 |
| 27 | In my area, it is not easy to get vegetables and other … | | | .541 | .425 | .934 |
| | **Physical exercise barriers α=.825** | | | | | |
| 28 | In this community there is no culture of doing physical exercise… | 2.58 | 1.17 | .462 | .513 | .935 |
| 29 | I don't feel interested by physical exercise; that is something I don't easily enjoy. | 2.70 | 1.14 | .571 | .579 | .934 |
| 30 | I do not think physical exercise will change anything… | 2.11 | 1.12 | .536 | .547 | .934 |
| 31 | I was not given as much information as I needed about … | 2.41 | 1.19 | .493 | .464 | .935 |
| 32 | The general environment in my community is not conducive… | 2.19 | 1.14 | .257 | .360 | .936 |
| 33 | Except engaging in regular work or domestic chores… | 2.85 | 1.02 | .379 | .408 | .935 |
| | **Medication barriers α= .750** | | | | | |
| 34 | My working condition may lead to skip a medication | 2.25 | 1.13 | .510 | .504 | .935 |
| 35 | I sometimes forget to take my medication | 2.00 | 1.14 | .424 | .404 | .935 |
| 36 | I sometimes fail to get money to buy drugs for diabetes | 2.29 | 1.24 | .572 | .610 | .934 |
| 37 | I feel bad taking drugs everyday | 2.61 | 1.14 | .462 | .370 | .935 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 38 | When taking tablets it is hard to shift to insulin | 2.92 | 1.11 | .322 | .341 | .936 |
| | **Complexity of managing T2DM barriers** α= **.731** | | | | | |
| 39 | I spend time doing nothing that can generate income because… | 2.98 | 1.11 | .396 | .529 | .935 |
| 40 | Having other diseases or diabetes complications… | 3.30 | .931 | .320 | .411 | .936 |
| 41 | Physical problems/diseases related to diabetes inhibit… | 2.89 | 1.13 | .386 | .462 | .935 |
| 42 | It becomes hard for me to be on diabetes medications | 2.00 | 1.18 | .493 | .452 | .935 |
| | **Support from family and friends** α= **.723** | | | | | |
| 43 | I have a feeling that my family members do not give … | 2.12 | 1.12 | .437 | .503 | .935 |
| 44 | I feel I get little support from my friends | 2.06 | 1.10 | .416 | .501 | .935 |
| 45 | People may have wrong perception of diabetes | 2.40 | 1.16 | .540 | .456 | .934 |
| 46 | I fail to open up to tell others that I have diabetes | 2.16 | 1.21 | .425 | .358 | .935 |
| | **Foot care barriers** α= **.602** | | | | | |
| 47 | I was not given as much information as I needed about foot care | 3.09 | 1.21 | .325 | .474 | .936 |
| 48 | My feet were not examined to let me know what should… | 3.49 | .93 | .042 | .335 | .937 |
| 49 | My work requirements don't allow me to observe… | 2.12 | 1.21 | .477 | .449 | .935 |
| | **Lack of support from community** α= **.601** | | | | | |
| 50 | There are no diabetic community programmes that support me | 3.71 | .689 | .096 | .278 | .937 |
| 51 | I would manage my diabetes much better if… | 3.67 | .725 | .090 | .322 | .937 |

After EFA, Cronbach's alpha (α) was used to measure the internal consistency of the 51 items. The internal consistencies of each factor (factor refer to sub-scale), and the correlation of each item with the total items are presented in Table 8.4. The overall reliability coefficient of the instrument was .936, ranging from .601 to .852 for each factor. The factors with the highest α were knowledge and SMBG barriers (.852) with nine items and the factor with the lowest α was lack of support from community (.601) with two items. The lowest Cronbach's Alpha if Item Deleted was .934 and the highest was .937.

## 8.4 Discussion

### 8.4.1 Introduction

The aim of this chapter was to assess the construct validity of BE-SEED2. The discussion will focus on the results of EFA that was done to group items under common factors. In addition, the reliability that was ensured by the internal consistency technique will also be discussed.

### 8.4.2 Item reduction

Of the initial 64 items grouped in 11 domains (the instrument after clinical utility: ANNEXURE 26), 10 items were eliminated prior to EFA for reasons such as, (1) 80-90% of responses in one category and (2) items were reliable but not valid (low mean). Therefore, the EFA was computed on a set of 54 items. Even though the experts did not think that they were irrelevant during the other validation phases, it was decided to exclude the 10 items for reasons such as a large and multicentre sample size. Moreover, this psychometric analysis for item reduction is suggested in the literature (Hearnshaw *et al.*, 2007) as it avoids redundancy and increases the internal consistency of the instrument.

### 8.4.3 Exploratory Factor Analysis

In the EFA, three items did not load sufficiently and they were also removed. There were no consequences of eliminating these items given the fact that there was a large pool of items (105) to start with and which was narrowed down in the processes of validation. In addition, when comparing the items of BE-SEED2 with the results of self-management barriers from the local population (Table 5.3), it was recognised that the items would largely represent the barriers in the target population. Thus, the final instrument was amended from 64 items in 11 sub-scales to 51 items under nine Factors. The number of items on BE-SEED2 are less when compared with the Environmental Barriers to Regimen (EBAS) = 60 items (Irvine *et al.* 1990) and to the Diabetes Obstacles Questionnaire (DOQ) = 77 items (Hearnshaw *et al.*, 2007). However, these instruments were developed as a result of studies done in high income countries. Furthermore, in comparison to this study, small sample sizes were recruited. In addition, activities of self-management differed to those in this study and EBAS recruited both Type 1 and Type 2 diabetes patients.

There are other instruments assessing barriers to self-management developed in high income countries that include fewer items than those in BE-SEED2. (Tu, Barchard and Tu, 1993); Pilv *et al.*, 2016; Tamir *et al.*, 2012). The differences can be explained by the processes according to which the instruments were developed, the settings, the populations used (T1DM or T2DM) and the validation processes. Furthermore, the activities of self-management (diet, exercise, medication, foot care and exercise) assessed differed across the instruments. An instrument with few items may have the advantage of taking less time to be completed. However, after reducing the number of items on the Diabetes Obstacles Questionnaire (DoQ-77) to its short form of 30 items, Pilv *et al.* (2016) agreed that the process of reducing the instrument lost essential items that were valid in the population and recommended that the author needed to decide on and judge the consequences.

### 8.4.4 Extracted factors

The first factor included barriers connected to the health care facility. Originally, the sub-scale validated by experts, patients and clinicians included nine items. The item, "*I feel self-management activities have not been clearly explained to me"* was eliminated as 80% of its responses were in one category Another item *"Nurses/doctors use bitter /unpleasant words I fear to ask more information about self-management"* did not sufficiently load onto a factor. Additionally, the item "*I face the issue of stock outs of my medication"* that was in initially in medication, loaded onto this factor thus, the factor totalled eight items.

Heissam, Abuamer and El-Dahshan (2015) believe that health care providers are essential in maintaining a bond that in turn enhances self-management and therefore the barriers emanating from health care may negatively affect self-management (Ramezankhani *et al.*, 2015). Despite their difference in phrasing and use of terminologies, some instruments identified two to four items related to barriers from health facility (Ramezankhani *et al.*, 2015; Pilv *et al.*, 2016). In this study however, a total of eight items (table 8.6) loaded onto the health care barriers factor but in an instrument developed by Tu, Barchard and Tu (1993). This factor had the highest Eigenvalue of 12,52 and explained the highest variance of 24.56%. The factor with the second highest Eigenvalue was "Diet, behavio*u*ral change and psychology" with an Eigenvalue of 2.56, thus much lower than

the first factor. This indicates that the health care barriers are a very strong factor that contributes towards the construct of self-management in the sample used in this study.

The second factor was named after the merging of two sub-scales that were separate in the previous version, (1) diet and (2) behavioural change and psychological issues. The diet sub-scale in previous version included eight items, seven of which sufficiently loaded in this factor (table 8.6). The sub-scale of behavioural change and psychological issues in previous version had five items and two (*I am desperate I keep thinking that this disease is not curable and that affects self-management of diabetes, I am not psychologically stable, T2DM has put stress in my life*) were eliminated after realising that their means were very low and therefore not valid. The remaining three sufficiently loaded and the second factor therefore culminated in 10 items (table 8.6).

Accessing healthy food is an issue, a situation that has been previously observed in Portugal (Laranjo *et al.*, 2015) and it was reflected in the item, *"I end up eating unhealthy food as it is what I can afford*" was a particularity of BE-SEED2. As a chronic disease, managing T2DM requires a change in one's lifestyle which is a challenge, highlighted by one item in this study, *"It is hard to take appropriate diet when I am away from home"* and is similar to the one appearing in an instrument developed by Pilv *et al.*, (2016). Psychosocial issues related to diabetes are also reflected in two items and show how patients living with T2DM can lose hope and experience a sense of irrelevance to their family. Those items have been seen in previous instruments, though with differences in phrasing and context (Pilv *et al.*, 2016).

The third factor pooled barriers to SMBG and low level of knowledge related to T2DM and self-management, which were initially in two different sub-scales (table 8.6). In terms of knowledge, all items in the original sub-scale sufficiently loaded onto the third factor. One item, *"I don't think I know the effects, be it good or bad, that diabetes treatments can have on my health"* which was primarily in the medication sub-scale loaded onto this factor. Regarding SMBG, among six items that were in the original sub-scale, four reached the accepted factor loading (table 8.6). One item, "*I fear injections I cannot check blood glucose at home"* was eliminated as 80% of the responses fell into one category and the item, "*I do not think that regular self-management of blood glucose*" did not load sufficiently.

The sub-scale of the knowledge barrier was previously found in the Personal Diabetes Questionnaire (PDG) (Stetson *et al.*, 2011) and the Diabetes Obstacles Questionnaire (DOQ-30) (Pilv *et al.*, 2016). In PDG, the lack of knowledge affected diet. In this study, however, the barriers related to knowledge were reflected in cognition and understanding of T2DM and all the self-management activities. The items in the knowledge factor of the DOQ show that participants have a problem in understanding diabetes as a disease and all self-management activities. Despite the differences in terminology or phrasing, probably due to differences in culture and context, their meaning is almost similar to the items of this study, with a slight difference in reliability; 0.82 to 0.85 of BE-SEED2. In different studies, knowledge has been identified as barrier to self-management (Mogre *et al.*, 2017; Ramezankhani *et al.*, 2015).

The items identifying barriers related to SMBG reported in the literature vary. In countries with high income, the barriers of SMBG tend to be aspects such as, frustration, not being comfortable or being busy (Pilv *et al.*, 2016), while in this study, affordability of testing strips and glucometer was observed. The lack of glucometer item was found in an Iranian study (Ramezankhani *et al.*, 2015), although the the mean was very low compared to the mean in this study. In a very early study, an instrument identifying lack of testing strips was developed but the sample only involved old people (Tu, Barchard and Tu, 1993).

The fourth factor, lack of support from family and friends with four items elucidates the loneliness that patients experience in their daily life as they lack support from the family and friends. In the previous version, lack of support from friend, family and community was one sub-scale with four items. However, during EFA, lack of community support items loaded onto another factor exclusively for community support (table 8.6). Two items that were originally in the stigma sub-scale, *"People may have wrong perception of diabetes, show me stigma and discrimination, I fail to open up to tell others that I have diabetes"* loaded onto this factor.

Waari et al. (2018) found that good family environment and mutual help from friends contribute to build social bonds that are essential in dealing with daily emotional distress related to diabetes management. Items related to lack of family and friends support were also found in the study done by Pilv *et al.*, (2016). Participants experienced stigma from outside (family or friends) but there was also self-stigmatisation when they avoided disclosure of their disease to others.

A similar item found later in the instrument developed by Ramezankhani *et al.*(2015). However, the item describing stigma from outside was particular to BE-SEED2.

The barriers specific to self-management of physical activity appear in the fifth factor. In the previous version, the physical activity sub-scale contained seven items, although only six loaded onto this factor and one regarding the physical problems that inhibit physical activity loaded onto another factor of self-management barriers related to the complexity of managing T2DM (table 8.6). An exercise factor or items were found in instruments developed by Pilv *et al.* (2016); Irvine *et al.* (1990); Ramezankhani *et al.(*2015) Stetson *et al.*(2011) and Tu, Barchard and Tu (1993), although the number of items and names are different from those of this study.

The sixth factor consists of barriers related to medication and five items sufficiently loaded under this factor (table 8.6). The previous medication sub-scale had 13 items: apart from the five that loaded in this factor, other five items scored highly in one category and were eliminated (table 8.4) Two other items, namely "*facing the stock out of medication and lack of knowledge to understand effect of medication"* loaded in other factors as described before. Lastly the item *"I take drugs that have been recommended for diabetes but I also take traditional medicine and the latter seems to be efficient"* did not sufficiently load.

The item "*I have a feeling that the medication prescribed to me is not effective*" was not considered in for EFA in BE-SEED2 as it had a low mean, referring to low validity, although it was considered in the instrument developed by Pilv *et al.*, (2016). This is probably due to the low level of knowledge revealed in this research which probably impacted on the participants' ability to be consistent in answering as they may not have known the correct and incorrect dosages of medication. The item, "*When taking tablets it is hard to shift to insulin"*sufficiently loaded in this factor and was also found in the instrument developed by Pilv *et al.*, (2016). Other items, "*I sometimes forget to take my medication, My working condition may lead to skip a medication, I sometimes fail to get money to buy drugs for diabetes*" were identified in the instrument developed by Irvine *et al.* (1990), although there is a difference in paraphrasing and naming. In addition, the instrument was developed many years ago Irvine *et al.* (1990) in a developed country and some realities such as lack of money to buy drugs could have changed since then. The item "I *feel bad taking drugs everyday*" was a particularity of BE-SEED2.

The complexity of managing T2DM is the seventh factor with four items (table 8.6). In the previous version, the sub-scale was named "*Comorbidity and complications*" and had three items. The fourth item, "*Physical problems/diseases related to diabetes inhibit me from taking exercise*" was initially in "Physical activity" but in the EFA, it loaded onto this factor. Items indicating the complexities of self-management in dealing with T2DM appear in the instrument by Ramezankhani *et al.*, (2015) and Irvine *et al.*, (1990) although with different names and meanings. However, the item, *"I spend time doing nothing that can generate income because of fatigue and diabetes complications"* was a particularity of BE-SEED2. Factor number eight has only two items related to community support and as it was discussed above, in the previous version they stood together with items describing the lack of friend and family support. After many unsuccessful attempts at seeing if these items could fall into any other factors it was decided to keep them as a "stand-alone" factor (table 8.6) as they sufficiently loaded >.6, and they were initially highly valued by both clinicians and patients as common barriers to self-management. Additionally, Philis-Tsimikas and Gallo (2015) state that the lack of community-based diabetes programmes compromise the accessibility to information and necessary support in diabetes management.

The last factor includes items related to barriers to foot care. All three items that were in the original sub-scale satisfactorily loaded onto this factor. Two items touched on the aspect of health care providers who do not provide relevant information or examine patients' feet. The third item described how the job demands could influence the ability to observe foot care. The sample used in this study included many farmers whose work involved digging with the risk of being injured and that may explain the validity of this item. Items assessing barriers to foot care were not found in previous instruments assessing self-management barriers despite the importance foot care since amputation is a common complication of T2DM (Davie-smith *et al.*, 2017).

### 8.4.5 Reliability

The overall Cronbach alpha of the total scale (51 items of BE-SEED2) was .936 suggesting a high level of internal consistency. The same results were reached in other instruments (Irvine et al. 1990) assessing environment barriers to self-management. The overall Cronbach alpha results lower than those found in this study were found in other instruments (Ramezankhani *et al.*, 2015;

Stetson *et al.*, 2011) assessing barriers or obstacles of self-management. However, these instruments had few items compared to BE-SEED2 and studies have shown that as the number of items decreases the value for Cronbach's alpha also decreases (Cortina, 1993).

The internal consistency of sub-scales ranged from .601 to.852 and the ranges corroborate with other instruments assessing barriers in self-management in T2DM (Tu, Barchard and Tu 1993; Stetson *et al.*, 2011). The two sub-scales namely, foot care barriers (three items) and lack of support by community (two items) had Cronbach alpha of .601 and .602 respectively. The mean of these factors (Table 8.3) seemed to be higher than others suggesting that the barriers of self-management linked to community and foot care were obvious. It was decided to include them regardless their low Cronbach alpha value as they sufficiently loaded and they can be further assessed in future studies. The same decision was taken in the development of DOQ-30 (Pilv *et al.*, 2016), where they obtained a sub-scale of uncertainty about diagnosis with $\alpha = .52$. They explained that the sub-scale was an important theme in the target population but they also took into consideration that the value of Cronbach alpha changes with the number of items; indeed, the subscale had two items.

Validation of instruments is an ongoing process and although this study has already investigated many aspects of validity, the BE-SEED2 will be subjected to more stringent methods of construct validity such as a Rasch analysis when more data have been collected by different clinics in Rwanda. Rasch modelling assist the researcher to identify poorly functioning items in newly developed tools. The analysis will show which items are over fitting, pointing to the redundance of the item or whether the item is erratic and thus not performing consistently. It can also indicate if the scale is measuring increasing amounts of the construct under investigation, thus indicating if all the categories in the scale are necessary. The analysis maps the ability of the sample against the difficulty of the items and one can clearly see which categories of the scale were not utilised in the sample. It will show which items are closely associated with each other which is similar to factor analysis. Rasch modelling has been used extensively in instrument development and systematically points out the variance in the data and the amount of misfit to model requirements (Andrich and Marais 2019).

## 8.5 Conclusion

The main objective of this study was to establish the construct validity of the BE-SEED2. The EFA supported a nine-factor structure with 51 items that accurately measure self-management barriers in Rwandan among T2DM population. This was the first step in the investigation of the validity of the instrument. Content and face validity, clinical utility and construct validity were all included. Thirteen items were deleted in the process of EFA and the instrument is now ready for implementation and routine administration in hospitals and clinics across Rwanda. The BE-SEED2 will be subjected to more stringent methods of construct validity such as a Rasch analysis when more data have been collected by different clinics in Rwanda.

This instrument is a valuable addition to the people suffering from T2DM in Rwanda. It is an instrument developed for the people and by the people; it is in their own language and it addresses unique issues related to T2DM which have not been addressed in other instruments, for example, footcare.

The instrument will be introduced to as many clinics and hospitals as possible in Rwanda and it could be used routinely as an instrument for collecting data on the self-management barriers experienced by people with T2DM. The data obtained can facilitate an improvement of interventions in future.

# CHAPTER 9: SUMMARY OF FINDINGS, STRENGHTS AND LIMITATIONS, CONCLUSIONS AND RECOMMENDATIONS

## 9.1 Introduction

Chapter nine gives a summary of the findings of this study, presents the strengths and limitations, draws conclusions and makes recommendations. Initially, the study sought to respond to the question: "How can self-management barriers among patients diagnosed with T2DM in Rwanda best be measured?", therefore, the study aimed at developing and validating an appropriate instrument for the Rwandan T2DM population. The study was conducted in three phases and each had its distinctive objectives. In phase one, the aim was to conceptualise the construct of self-management barriers, in phase two, a new instrument was developed and phase three aimed at validating the instrument. The development process was done following a conceptual framework of self-management of T2DM. The study employed a mix-methods approach with an exploratory sequential design.

## 9.2 Summary of findings

### 9.2.1 Findings of phase 1 – conceptualisation of the construct of self-management in type 2 diabetes patients

In this phase, two objectives were set: (1) to assess the barriers to self-management among T2DM in LICs and LMICs and (2) to assess the same barriers in Rwanda. An integrative review was carried out and included 25 studies. The results were grouped under seven themes, namely social demographic characteristics, lack of support, mental health factors, cultural characteristics, T2DM complications, comorbidities and medications and lastly, environmental factors.

The findings of the integrative review highlighted that patients from low-income countries face the burden of financial constraints inhibiting their access to a healthy diet, medication and blood glucose monitoring devices. Cultural issues were also raised suggesting a need to understand the barriers to self-management in different contexts.

The second objective in this phase required a descriptive qualitative study to assess the same barriers in Rwanda. The researcher met participants with T2DM in 10 hospitals from urban and rural areas to obtain a comprehensive account of the barriers. In total, 23 individual interviews

were conducted. Using Nvivo 11 software, data were thematically analysed. The findings were summarised in seven themes, that is, individual characteristics, implications of those delivering health care providers, access to health care services, complexity of managing diabetes, psychosocial problems, community and environment aspects and family dynamics.

The results of the integrative review confirmed that the context matters when attempting to understand barriers to self-management. There were barriers that were specific to the country's policy, culture and organisation. For example, the poverty categorisation is specific to Rwanda and was mentioned as a barrier to adherence to medication. The surprising result was the stigmatisation by the community of patients living with T2DM. This issue was invisible and was never mentioned in the health care system and in the media. Essentially a study in the region and in the neighbouring country, Uganda (De Man *et al.*, 2019) revealed that there was no stigma attached to T2DM. Also surprising was the overwhelming majority of participants who lacked support and guidance from health care providers on how to perform self-management activities. Lack of guidance was cited by many participants in comparison to the number low accessibility of health care services. This uncommon in low-income countries where poverty and lack of infrastructure are usually more prevalent. It is important to carry out further research to understand the nature of the issue and to determine its cause, for example, it is uncertain as to whether it is associated with lack of knowledge of health care providers, or failure to provide patient centred care or simply to poor service delivery.

The integrative review of self-management barriers in LICs and LMICs that was conducted during this project made no reference to participants' experiences of a lack of social clubs or community support programmes although they were reported in this study. In all study settings participants expressed the desire to be grouped in small clubs or programmes that could help them to share experiences and to support each other. The community health insurance "Mutuelle de santé", a specific community health insurance available only in Rwanda in the region, had both advantages and disadvantages; patients who were insured under that particular insurance provider had access to public hospitals but it was reported that medication was frequently out of stock in the public hospitals. Patients, mainly those taking oral drugs, would spend many days waiting for medication supplies to be replenished. Gender issues constituted another unspoken issue in this community as women appeared to enjoy less support than their male counterparts.

The two studies in phase one culminated in the conceptualisation of the construct of self-management and self-management barriers. Self-management was reduced to five activities namely, diet, medication, SMBG, physical activity and foot care. Self-management barriers were identified by updating the initial conceptual framework (Figure 6.1).

### 9.2.2 Findings of phase 2

Given the sequential design of this study, the results of phase one were integrated with findings in the second phase and were used to develop the new instrument. The first objective of Phase 2 was to generate a pool of items. To facilitate the process and for the sake of practicality, a table of specification was used and helped to make sure that all barriers to self-management from both studies and existing instruments were reflected in the items that were generated (Table 6.1). The table was designed to cross-match the barriers (themed under the concepts of the framework) with each activity of self-management (for example, diet, foot care). The process, carried out by a team of researchers, yielded a pool of 105 items.

The second objective was to refine the items. The process commenced with an assessment of the items by the researchers and and selected for the purpose of (1) checking whether all barriers were reflected, (2) eliminating duplicated and irrelevant items (3) refining the items in terms of grammar and paraphrasing. The process was completed with a total of 73 items.

Other refinement steps such as choosing the precise format, domains or sub-scales, scoring system, naming and translation were undertaken. A four point Likert scale (strongly disagree =1 to strongly agree = 4) was constructed. The items were then grouped under 11 sub-scales consisting of knowledge (4 items), stigma (2 items), health care facility (9 items), lack of family, friend and community support (4 items), comorbidity and complications (3 items), behavioural and psychological issues (5 items), diet (8 items), physical activity (6 items), medication (5 items), SMBG (6 items), and foot care (3 items). The demographic section was added for identification of participants.

The name of the newly developed instrument was extracted from **B**arri**E**rs of **SE**lf-manag**E**ment of type **2 D**iabetes (BE-SEED2) and was translated by a professional translator. At the end of this phase, the BE-SEED2 was ready for additional process of validation.

### 9.2.3 Findings of phase 3

The aim of this phase was to validate the BE-SEED2 in terms of (1) content validity, (2) face validity (3) clinical utility and (4) construct validity.

To validate the content, 10 experts judged the BE-SEED2 used a 4-point Likert scale to assess the "relevance, clarity, simplicity and ambiguity" of items. Ten items did not reach the I-VCI of .80 and were eliminated. The remaining 63 items indicated a high I-CVI ranging from 0.90-1 with SCVI of 0.92.

Face validity was assessed by four T2DM patients who mainly proposed translation revisions of some items and confirmed the relevance of all 63 items. Patients also supported the intention to incorporate the BE-SEED2 into the routine care of of T2DM patients in a health facility. Remarking on the time required to complete BE-SEED2, a participant mentioned that there seemed to be many items but was not able to indicate which of items should be removed as he considered all of them to be relevant.

The assessment of the instrument for clinical utility was conducted by 18 nurses and two medical doctors who re-phrased a number of items and confirmed the clinical applicability of the BE-SEED2. Their suggestion for splitting one item in SMBG sub-scale – the item that combined the affordability of test trips and glucometer – was accepted, leaving a total of 64 items on the instrument.

To investigate the construct validity of BE-SEED2, a cross-sectional study was conducted in which 650 T2DM patients from 10 hospitals were recruited. The EFA was done; 10 items were eliminated prior to the EFA and during the EFA, another three other items did not sufficiently load. A total of 51 items under nine factors were confirmed.

## 9.3 Strengths of the research

This study considered large sample sizes for the different phases of the study and gathered sufficient data from right people, thus ensuring reliable statistical results and validity. According to Boateng, Neilands and Frongillo (2018), a larger sample results fewer measurement errors and more stable factor loadings. Furthermore, the study sample was multicentred and represented a

balanced urban to rural ratio. The development of the instrument employed multiple methods and the target population expressed their own views in the conceptualisation of the construct during the validation phase.

The focus on the barriers to self-management in LICs and LMICs in the integrative review facilitated the incorporation of their specific socioeconomic and cultural aspects which may differ from those of HICs. In addition to the integrative review, the qualitative approach was advantageous; it facilitated exploration of the barriers by considering the views of participants and their contexts and in so doing, informed the choice of items to be included on the instrument. Each interview was recorded and transcribed verbatim and led to reach and deep interpretation of the results.

The use of a conceptual framework in the identification of barriers facilitated the integration of results and increased the representation of relevant and significant features of self-management barriers in the selection of items thereby enhancing face validity.

### 9.4 Limitations of the research

Using a number of pre-determined key words in the integrative review could possibly be limitation as some articles can be excluded if they are not in the literature search of those key words. Research articles published over a 10-year period (January 2008 to January 2018) were included. Hence, the exclusion of other publications out of this period that might have had influence on the results of the study. The search was conducted only in Science Direct, EBSCO host (CINAHL Plus), Scopus, PsyInfo, PubMed, Google Scholar with the possibilities of omitting studies published elsewhere. The study also only included English publications and omitted evidence published in other languages.

The budget and time constraints did not allow the researcher to do a number of things. For example, patients visiting private clinics were not included in the study. Patients visiting private clinics usually come on appointment at a specific time, restricting their availability for interview.

Their inclusion in the study would had taken more time to get a sufficient sample size. Due to time constraints the confirmatory factor analysis was not done and should be done in upcoming studies.

## 9.5 Recommendations

Based on the results of the study, below recommendations are discussed below.

### 9.5.1 Nursing practice and management

The barriers emanating from the health care system were enormous. Healthcare providers should re-evaluate the provision of care and support. For example, patients reported the need for individual care and this requires health care providers to be aware of challenges that patients face, and make plans that meet individual needs to ensure sustainable management. Patients also reported that they did not get health education and guidance on self-management activities. Health education to raise awareness and knowledge of T2DM and self-management should be prioritised. In addition, self-management and diabetes guidelines should be available for the patients and should be updated when new prevention and treatment options become known. Waiting times and use of unacceptable language of health care providers were mentioned as barriers to self-management. Customer care policies should be revisited, implemented and regularly monitored.

The instrument specific to the T2DM Rwandan people is now available for used in clinics and hospitals. The researcher will continuously create awareness of the availability of the instrument, through public meetings and media such as radio and television shows. Consequently, the researcher recommends the routine use of the instrument in all clinics and hospitals. If the instrument is routinely implemented, a patient will complete the instrument at intervals of 3 to 6 at least. This will allow health care providers at clinics to use the information to assess whether they have successfully addressed at least some of the barriers to self-management. Data can be captured per area, help health care providers to identify and prioritise the barriers and from there, take steps to address the barriers.

### 9.5.2 Community health nursing

The results of this research demonstrated a lack of programmes and clubs that support patients in the community; there is a need to mobilise patients to form different clubs where they can engage in mutual learning and support. Local initiatives to promote motivation to engage in physical activities are also essential and should be given priority.

Patients reported stigmatisation in their respective communities. Awareness in the general population on the causes (is not contagious) and the chronic nature of diabetes that requires life-long treatment should be created. In the results of the qualitative study patients mentioned the culture of consulting traditional healers, resulting in poor adherence to T2DM medication. There is a need to identify and work closely with legitimate traditional healers in the community to understand their practices regarding T2DM and to educate them on the causes and the management of T2DM.

Limited availability of vegetables and healthy food in some communities was a challenge to the patients. Community health nurses should work hand in hand with village representatives to enhance local agricultural alternatives and initiatives to grow seasonal vegetables and fruits.

### 9.5.3 Nursing education and training

Based on some attitudes of nurses reported by patients in this study, such as poor communication skills, lack of individualised care and lack of examination of foot care, while teaching, nurse educators need to focus on communication skills and the nursing process. Self-management in the management of T2DM should be taught and considered as the most important element for achieving good DM outcomes. As the management of T2DM is mainly done at home by patients themselves, community outreaches and internships should be given the same weight as they are in clinical setting.

The BE-SEED2 can be used to teach students in the field of health about self-management barriers and their management. In clinical settings, students can use the instrument in the assessment of patients' needs for improved monitoring and appropriate interventions.

### 9.5.4 Nursing research

Other researchers should continue with the assessment of validation and reliability of the instrument. Different areas may demonstrate different reliability and a comparison reliability across areas will be valuable in identifying the need for more training or if changes should be made to the instructions to patients. Validity aspects such as convergent and divergent validity can also be measured as well as sensitivity or responsiveness of the questionnaire.

The BE-SEED2 can be used to identify barriers related to T2DM and guide the development of locally suitable and sustainable interventions. After assessing how patients perform self-management, the researchers need to explore the barriers that patients are facing, taking into consideration the influence of context as they formulate the interventions.

### 9.5.5 Ministry of health and partners

Awareness of and incorporation of the BE-SEED2 into clinical settings for routine use in the assessment of self-management barriers is recommended. This can be achieved through formal channels usually followed to introduce new guidelines and protocols in the health care facilities.

In the light of the qualitative results of this research, participants mentioned that available government support did not accommodate them in the same way as it did to people living with HIV/AIDS. Participants suggested the provision of free medication. They also suggested assistance by their health insurance scheme for the purchase of blood glucose devices. This would take the form of the patient paying a certain percentage of the cost while the remaining percentage would be covered by health insurance scheme. Participants also mentioned the implications of T2DM complications on their income, reporting that they time doing nothing that could generate money and wished to be considered in the same way as those people living with HIV/AIDS.

Travelling and waiting times were barriers to self-management in this research. Patients reported that when they arrived at the hospital, they waited for long periods before being attended by health care providers. Other issues related to that were the lack of specialised doctors and long distances travelled to hospitals. The Ministry of Health should increase the number of trained nurses in health care facilities, build new health care facilities and review the transfer policies from one health care level to another, so that patients can consult a specialist whenever s/he thinks it is necessary.
It is further recommended to integrate the counselling services in the management of DM. In this study it was observed that patients with T2DM feel isolated and do not get support from families. They become worried, stressed and feel depressed. They reported that the burden of managing a life-long disease is not easy to bear and this can result in low adherence to self-management activities. Therefore, the mental health aspect should be given priority in the management of T2DM.

## 9.6 Conclusions

Despite the unfinished agenda of infectious diseases, T2DM is steadily increasing in low- and low-middle-income countries. Self-management is a foundation in the management of T2DM and requires active participation by the patients. The reasons for the barriers they experience should be known and monitored for relevant support. For that reason, the purpose of this research was to develop an instrument to assess self-management barriers among T2DM patients. The use of the instrument is indeed a positive and informed approach that can promoted confidence in health care providers and researchers in understanding patients' needs.

The results of this research contribute to the body of knowledge by offering a means of reliable assessment of barriers to self-management in low- and low- middle-income countries that are dominated by financial constraints, cultural and other contextual differences. This research also offers a deep and detailed description of the processes by which the instrument was developed through a review of the literature and a study of the local population. The newly developed instrument went through different phases namely, the development, construction and validation using rigorous methods and large sample sizes. From a high number of 105 items, the BE-SEED2 has been condensed into a four-point Likert-scale measure with 51 items in nine sub-scales and has been found to have good internal reliability, external and construct validity.

The BE-SEED2 addresses a variety of self-management barriers such as social, psychological, cognitive and behavioural at individual, family and community level. The instrument is a valuable addition to the well-being of people suffering from T2DM in Rwanda. It is an instrument developed for the people and by the people; it is available in their own language and addresses issues unique to T2DM and not addressed in other instruments, for example, foot care. This instrument will create self-management awareness at least and how it can positively impact on T2DM outcomes. It could be used in clinical practice and research in Rwanda and other low-income countries as valuable instrument.

## REFERENCES


Abdullah, H. A. D. and Sameen, Y. F. (2017) 'Barriers that Preventing the Nursing Staff from Reporting Medication Errors in Kirkuk City Hospitals', *Kufa Journal for Nursing Sciences*, 7(1), pp. 145–156.

Abdulrehman, M. S., Woith, W., Jenkins, S., Kossman, S. and Hunter, G. L. (2016) 'Exploring Cultural Influences of Self- Management of Diabetes in Coastal Kenya : An Ethnography', *Global Qualitative Nursing Research*, 3, pp. 1–13. doi: 10.1177/2333393616641825.

Abreu, L., Nunes, J. A., Taylor, P. and Silva, S. (2017) 'Distributed health literacy among people living with type 2 diabetes in Portugal : Defining levels of awareness and support', *Health Socicial Care Community*, (May), pp. 1–12. doi: 10.1111/hsc.12465.

Adisa Alutudu, M. B. and Fekeye, TO., R. (2009) 'Factors contributing to non adhrence to oral hypoglycemic medications among ambulatory type 2 diabetes patients in South Western Nigeria', *Pharmacy Practice*, 7(3), pp. 163–169.

Adisa, R. and Fakeye, T. O. (2014) 'Treatment non-adherence among patients with poorly controlled type 2 diabetes in am- bulatory care settings in southwestern Nigeria', *African Health Sciences*, 14(1), pp. 1–10.

Adisa, R., Fakeye, T. O. and Fasanmade, A. (2011) 'Medication adherence among ambulatory patients with type 2 diabetes in a tertiary healthcare setting in southwestern Nigeria.', *Pharmacy practice*, 9(2), pp. 72–81. doi: 10.4321/S1886-36552011000200003.

Al-maskari, F., El-sadig, M., Al-kaabi, J. M., Afandi, B., Nagelkerke, N. and Yeatts, K. B. (2013) 'Knowledge , Attitude and Practices of Diabetic Patients in the United Arab Emirates', *PLoS ONE*, 8(1), pp. 1–8. doi: 10.1371/journal.pone.0052857.

Alrahbi, H. H. (2017) 'Factors influencing diabetes self-management among Omani patients with type-2 diabetes : Patients ' perspectives', *Journal of Nursing Education and Practice*, 7(12), pp. 64–71. doi: 10.5430/jnep.v7n12p64.

American Diabetes Association (2009) 'Standards of Medical Care in Diabetes—2009', *DIABETES CARE*, 32(Supplement 1), pp. S13–S61. doi: 10.2337/dc09-S013.

American Diabetes Association (2010) 'Definition and description of diabetes other categories of glucose', *Diabetes care*, 33((Suppl. 1)), pp. S62-69. doi: 10.2337/dc10-S062.

American Diabetes Association (2016) 'Standards of Medical Care in Diabetes d 2016 : Summary of Revisions', *Diabetes Care*, 39(Suppl 1), pp. S4–S5. doi: 10.2337/dc16-S003.

American Diabetes Association (2019a) '11 . Microvascular Complications and Foot Care : Standards of Medical Care in Diabetes d 2019', *Diabetes Care*, 42(Suppl. 1), pp. S124–S138. doi: 10.2337/dc19-S011.

American Diabetes Association (2019b) '2 . Classi fi cation and Diagnosis of Diabetes : Standards

of Medical Care in Diabetes d 2019', *Diabetes Care*, 42((Suppl. 1)), pp. S13-28. doi: 10.2337/dc19-S002.

American Diabetes Association (2020) 'Introduction : Standards of Medical Care in Diabetes d 2020', *Diabetes Care*, 43(Suppl. 1), pp. S1-2.

Anney, V. N., Dar, P. O. B. and Salaam, E. (2014) 'Ensuring the Quality of the Findings of Qualitative Research : Looking at Trustworthiness Criteria', *Journal of Emerging Trends in Educational Research and Policy Studies (JETERAPS)*, 5(2), pp. 272–281.

Arulmozhi, S. and Mahalakshmy, T. (2014) 'Self Care and Medication Adherence among Type 2 Diabetics in Puducherry , Southern India : A Hospital Based Study', *Journal of Clinical and Diagnostic Research*, 8(4), pp. UC01-UC03. doi: 10.7860/JCDR/2014/7732.4256.

Augustine, L. F., Vazir, S., Rao, S. F., Rao, M. V., Laxmaiah, A., Ravinder, P., Rao, V. V. and Nair, K. M. (2012) 'Psychometric validation of a knowledge questionnaire on micronutrients among adolescents and its relationship to micronutrient status of 15 – 19-year-old adolescent boys ', 15(7), pp. 1182–1189. doi: 10.1017/S1368980012000055.

Ayele, K., Tesfa, B., Abebe, L., Tilahun, T. and Girma, E. (2012) 'Self Care Behavior among Patients with Diabetes in Harari , Eastern Ethiopia : The Health Belief Model Perspective', 7(4). doi: 10.1371/journal.pone.0035515.

Bagonza, J., Rutebemberwa, E. and Bazeyo, W. (2015) 'Adherence to anti diabetic medication among patients with diabetes in eastern Uganda ; a cross sectional study', *BMC Health Services Research*. ???, 15(168), pp. 1–7. doi: 10.1186/s12913-015-0820-5.

Bains, S. S. and Egede, L. E. (2011) 'Associations between health literacy, diabetes knowledge, self-care behaviors, and glycemic control in a low income population with type 2 diabetes.', *Diabetes technology & therapeutics*, 13(3), pp. 335–41. doi: 10.1089/dia.2010.0160.

Banasiak, K., Hux, J., Lavergne, C., Luk, J., Sohal, P. and Paty, B. (2020) 'Health and Place Facilitating barriers : Contextual factors and self-management of type 2 diabetes in urban settings', *Health and Place*. Elsevier Ltd, 61(February 2019), p. 102267. doi: 10.1016/j.healthplace.2019.102267.

Basu, S., Khobragade, M., Kumar, A. and Raut, D. K. (2015) 'Medical adherenc e and its predictors in Diabetes Mellitus patients attending government hospitals in the Indian Capital , Delhi , 2013 : a cross sectional study', *Int J Diabetes Dev Ctries (October*, 35(Suppl 2), pp. S95–S101. doi: 10.1007/s13410-014-0232-9.

Baumann, L. C., Kenneth Opio, C., Otim, M., Olson, L. and Ellison, S. (2010) 'Self-care Beliefs and Behaviors in Ugandan Adults With Type 2 Diabetes', *The Diabetes Educator*, 36(2), pp. 293–300. doi: 10.1177/0145721709358460.

Belue, R., Diaw, M., Ndao, F., Okoror, T., Degboe, A. and Abiero, B. (2013) 'A cultural lens to understanding daily experiences with type 2 diabetes self-management among clinic patients in M ' bour , Senegal', *Int'l. Quarterly of Community Health Education*, 33(4), pp. 329–347.

Belue, R., Ndiaye, K., Ndao, F., Niass, F., Ba, N. and Diaw, M. (2016) 'Glycemic Control in a Clinic-Based Sample of Diabetics in M ' Bour Senegal', *Health Education & Behavior*, 43(IS), p. 112S–116S. doi: 10.1177/1090198115606919.

Binagwaho, A., Farmer, P. E., Nsanzimana, S., Karema, C., Gasana, M., De Dieu Ngirabega, J., et al. (2014) 'Rwanda 20 years on: Investing in life', *The Lancet*, 384(9940), pp. 371–375. doi: 10.1016/S0140-6736(14)60574-2.

Boateng, G. O., Neilands, T. B. and Frongillo, E. A. (2018a) 'Best Practices for Developing and Validating Scales for Health , Social , and Behavioral Research : A Primer', 6(June), pp. 1–18. doi: 10.3389/fpubh.2018.00149.

Boateng, G. O., Neilands, T. B. and Frongillo, E. A. (2018b) 'Best Practices for Developing and Validating Scales for Health , Social , and Behavioral Research : A Primer', *Frontiers inPubliic Health*, 6(June), pp. 1–18. doi: 10.3389/fpubh.2018.00149.

Brownson, R. C., Eyler, A. A., King, A. C., Brown, D. R., Shyu, Y. and Sallis, J. F. (2000) 'Patterns and Correlates of Physical Activity Among US Women 40 Years and Older', *American Journal of Public Health*, 90(2), pp. 264–270.

Campbell, I. W. (2001) 'Type 2 diabetes mellitus : " the silent killer "', *Pract Diab Int*, 18(6), pp. 187–191.

Caro-bautista, J., Mart, F. J. and Morales-asencio, J. M. (2013) 'Systematic review of the psychometric properties and theoretical grounding of instruments evaluating self-care in people with type 2 Diabetes Mellitus', pp. 1209–1227. doi: 10.1111/jan.12298.

Caro-bautista, J., Mart, F. J., Villa-estrada, F., Carlos, J., Cuevas-fern, M. and Morales-asencio, M. (2014) 'Using qualitative methods in developing an instrument to identify barriers to self-care among persons with type 2 diabetes mellitus', pp. 1024–1037. doi: 10.1111/jocn.12740.

Cesario, S., Morin, K. and Santa-Donato, A. (1996) 'Evaluating the Level of Evidence of Qualitative Research', *JOGNN PRINCIPLES & PRACTICE*, 31(6), pp. 708–714. doi: 10.1177/0884217502239216.

Chiwanga, F. S. and Njelekela, M. A. (2015) 'Diabetic foot : prevalence , knowledge , and foot self-care practices among diabetic patients in Dar es Salaam , Tanzania – a cross-sectional study', *Journal of Foot and Ankle Research*. Journal of Foot and Ankle Research, 8(20), pp. 1–7. doi: 10.1186/s13047-015-0080-y.

Christmals, C. D., Gross, J., Aziato, L. and Armstrong, S. J. (2018) 'The State of Nursing Research in Ghana : An Integrative Literature Review', *SAGE Open Nursing*, 4, pp. 1–25. doi: 10.1177/2377960818783820.

Connell, J., Carlton, J., Grundy, A., Taylor, E., Anju, B., Keetharuth, D., Ricketts, T., Barkham, M., Robotham, D., Rose, D. and Brazier, J. (2018) 'The importance of content and face validity in instrument development : lessons learnt from service users when developing the Recovering Quality of Life measure ( ReQoL )', *Quality of Life Research*. Springer

International Publishing, 27(7), pp. 1893–1902. doi: 10.1007/s11136-018-1847-y.

Creswell, J. W. (2009) *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. 3rd edn. California: SAGE.

Davie-smith, F., Paul, L., Nicholls, N., Stuart, W. P. and Kennon, B. (2017) 'The impact of gender , level of amputation and diabetes on prosthetic fit rates following major lower extremity amputation', *Prosthetics and Orthotics International*, 41(1), pp. 19–25. doi: 10.1177/0309364616628341.

Doná, G. (2001) 'The Rwandan Experience of Fostering Separated Children: a condensed version of a case study produced by the Government of Rwanda, Unicef and Save the Children Alliance and published by UNICEF under the title of "Umwana Wanjye ni Uwawe ni Uwacu–My Child is', *Save the children*. doi: 10.1177/0907568217753523.

Donnan, P. T. and Macdonald, T. M. (2002) 'Adherence to prescribed oral hypoglycaemic medication in a population of patients with Type 2 diabetes ':, *Diabetes UK. Diabetic Medicine*, 19(10), pp. 279–284.

Eklund, M. and Gunnarsson, A. B. (2008) 'Content validity, clinical utility, sensitivity to change and discriminant ability of the Swedish satisfaction with daily occupations (SDO) instrument: A screening tool for people with mental disorders', *British Journal of Occupational Therapy*, 71(11), pp. 487–495. doi: 10.1177/030802260807101106.

Elo, S., Kääriäinen, M., Kanste, O. and Pölkki, T. (2014) 'Qualitative Content Analysis : A Focus on Trustworthiness', *SAGE Open*, January-Ma(2014), pp. 1–4. doi: 10.1177/2158244014522633.

Fezeu, L., Fointama, E., Ngufor, G., Mbeh, G. and Mbanya, J. (2010) 'Diabetes awareness in general population in Cameroon', *Diabetes Research and Clinical Practice*. Elsevier Ireland Ltd, 90(3), pp. 312–318. doi: 10.1016/j.diabres.2010.06.029.

Foley, E. and Belue, R. (2016) 'Identifying Barriers and Enablers in the Dietary Management of Type 2 Diabetes in M ' Bour , Senegal', *Journal of Transcultural Nursing*, pp. 1–6. doi: 10.1177/1043659616649028.

Foley, E. and BeLue, R. (2017) 'Identifying Barriers and Enablers in the Dietary Management of Type 2 Diabetes in M'Bour, Senegal', *Journal of Transcultural Nursing*, 28(4), pp. 348–352. doi: 10.1177/1043659616649028.

Ganong, L. H. (1987) 'Integrative Reviews of Nursing Research', *Research in Nursrng & Heolth*, 1987(10), pp. 1–11.

Gao, J., Wang, J., Zheng, P., Haardörfer, R., Kegler, M. C., Zhu, Y. and Fu, H. (2013) 'Effects of self-care , self-efficacy , social support on glycemic control in adults with type 2 diabetes', *BMC Family Practice*, 16(66), pp. 2–7.

Gasgow, R. E. and Anderson, R. M. (1999) 'In diabetes care, moving from compliance to adherence is not enough. Something entirely different is needed', *Diabetes Care*, 22(12), pp.

2090–2092.

Gopichandran, V., Lyndon, S., Angel, M. K., Manayalil, B. P., Blessy, K. R., Alex, R. G., Kumaran, V. and Balraj, V. (2012) 'Diabetes self-care activities : A community-based survey in urban southern India', *THE NATIONAL MEDICAL JOURNAL OF INDIA*, 25(1), pp. 15–18.

Graneheim, U. . and Lundman, B. (2004) 'Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness', *Nurse Education Today*, 24(2), pp. 105–112.

Hall, V., Thomsen, R., Henriksen, O. and Lohse, N. (2011) 'Diabetes in Sub Saharan Africa 1999-2011: Epidemiology and public health implications. A systematic review', *BMC Public Health*. BioMed Central Ltd, 11(1), p. 564. doi: 10.1186/1471-2458-11-564.

Hearnshaw, H., Wright, K., Dale, J., Sturt, J., Vermeire, E. and Royen, P. Van (2007) 'Development and validation of the Diabetes Obstacles Questionnaire ( DOQ ) to assess obstacles in living with Type 2 diabetes', pp. 878–882. doi: 10.1111/j.1464-5491.2007.02137.x.

van der Heide, I., Uiters, E., Rademakers, J., Struijs, J. N., Schuit, A. J. and Baan, C. A. (2014) 'Associations among health literacy, diabetes knowledge, and self-management behavior in adults with diabetes: results of a Dutch cross-sectional study', *Journal of Health Communication*, 19 Suppl 2(October), pp. 115–131. doi: 10.1080/10810730.2014.936989.

Heijmans, M., Waverijn, G., Rademakers, J., van der Vaart, R. and Rijken, M. (2015) 'Functional, communicative and critical health literacy of chronic disease patients and their importance for self-management', *Patient Education and Counseling*, 98(1), pp. 41–48. doi: 10.1016/j.pec.2014.10.006.

Heissam, K., Abuamer, Z. and El-Dahshan, N. (2015) 'Patterns and obstacles to oral antidiabetic medications adherence among type 2 diabetics in Ismailia, Egypt: a cross section study Khaled', *PanAfrican Medical Journal*, 8688, pp. 1–7. doi: 10.11604/pamj.2015.20.177.4025.

Houtum, L. Van, Rijken, M. and Groenewegen, P. (2015) 'Do everyday problems of people with chronic illness interfere with their disease management ?', *BMC Public Health*. BMC Public Health, 15:1000, pp. 1–9. doi: 10.1186/s12889-015-2303-3.

Irvine, A. A., Saunders, J. T., Blank, M. B. and Carter, W. R. (1990) 'Validation of Scale Measuring Environmental Barriers to Diabetes-Regimen Adherence', *DIABETES CARE*, 13(7), pp. 705–711.

Jackson, I. L., Adibe, M. O., Okonta, M. J. and Ukwe, C. V. (2015) 'Medication Adherence in Type 2 Diabetes Patients in Nigeria', *Diabetes Technology & Therapeutics*, 17(6), pp. 398–404. doi: 10.1089/dia.2014.0279.

Jordan, D. N. and Jordan, J. L. (2010) 'Self-care behaviors of Filipino-American adults with type

2 diabetes mellitus', *Journal of Diabetes and Its Complications*. Elsevier B.V., 24(4), pp. 250–258. doi: 10.1016/j.jdiacomp.2009.03.006.

Kahn, S. E., Cooper, M. E. and Prato, S. Del (2014) 'Pathophysiology and treatment of type 2 diabetes : perspectives on the past , present , and future', *The Lancet*. Elsevier Ltd, 383(9922), pp. 1068–1083. doi: 10.1016/S0140-6736(13)62154-6.

Kamradt, M., Bozorgmehr, K., Krisam, J., Freund, T., Kiel, M., Qreini, et al. (2014) 'Assessing self-management in patients with diabetes mellitus type 2 in Germany : validation of a German version of the Summary of Diabetes Self-Care Activities measure ( SDSCA-G )', *Health and Quality of Life Outcomes*, 12(185), pp. 1–10. doi: 10.1186/s12955-014-0185-1.

Kashan, I. S., Alta, A. H. and Albayati, A. H. (2018) 'Study of insulin and counter regulatory hormones in patients with type II diabetes mellitus : A study of insulin and counter regulatory hormones in patients with type ii diabetes mellitus : A case control study', *Biochem. Cell. Arch.*, 18(1), pp. 77–83.

Kassahun, T., Eshetie, T. and Gesesew, H. (2016) 'Factors associated with glycemic control among adult patients with type 2 diabetes mellitus : a cross - sectional survey in Ethiopia', *BMC Research Notes*. BioMed Central, 9(78), pp. 1–6. doi: 10.1186/s13104-016-1896-7.

Kassahun, T., Gesesew, H., Mwanri, L. and Eshetie, T. (2016) 'Diabetes related knowledge , self-care behaviours and adherence to medications among diabetic patients in Southwest Ethiopia : a cross-sectional survey', *BMC Endocrine Disorders*. BMC Endocrine Disorders, 16(28), pp. 1–11. doi: 10.1186/s12902-016-0114-x.

Kasturia, S., Ali, M. K., Narayan, K. M. V., Tandon, N., Shivashankar, R., Garg, V., Kapoor, D., et al. (2018) 'Diets for South Asians with diabetes : recommendations , adherence , and outcomes', *Asia Pac J Clin Nutr*, 27(4), pp. 823–831. doi: 10.6133/apjcn.112017.03.

Kawi, J. (2012) 'Self-Management Support in Chronic Illness Care: A Concept Analysis', *Research and Theory for Nursing Practice: An International Journal*, 26(2), pp. 108–125.

Kesha, B.-R., Gary, T. L., Beckles, G. L. A., Gregg, E. W., Owens, M., Porterfield, et al. (2007) 'Family History of Diabetes , Awareness of Risk Factors , and Health Behaviors Among African Americans', *American Journal of Public Health*, 97(5), pp. 907–912. doi: 10.2105/AJPH.2005.077032.

Kueh, Y. C., Morris, T., Borkoles, E. and Shee, H. (2015) 'Modelling of diabetes knowledge , attitudes , self-management , and quality of life : a cross-sectional study with an Australian sample', *Health and Quality of Life Outcomes*. Health and Quality of Life Outcomes, 13. doi: 10.1186/s12955-015-0303-8.

Kugbey, N., Asante, K. O. and Adulai, K. (2017) 'Illness perception , diabetes knowledge and self - care practices among type - 2 diabetes patients : a cross - sectional study', *BMC Research Notes*. BioMed Central, 10, pp. 1–7. doi: 10.1186/s13104-017-2707-5.

Labrecque, M., Kagabo, L., Shattuck, D., Wesson, J., Rushanika, C., Tshibanbe, D., Nsengiyumva,

T. and Sokal, D. C. (2013) ‘Strengthening vasectomy services in Rwanda : introduction of thermal cautery with fascial interposition’, *Contraception*. Elsevier Inc., 87(3), pp. 375–379. doi: 10.1016/j.contraception.2012.08.019.

Laranjo, L., Neves, A. L., Costa, A., Ribeiro, R. T., Sá, A. B., Laranjo, L., Neves, A. L., Costa, A. and Ribeiro, R. T. (2015) ‘Facilitators , barriers and expectations in the self- management of type 2 diabetes — a qualitative study from Portugal’, *European Journal of General Practice*, 21(2), pp. 103–110. doi: 10.3109/13814788.2014.1000855.

Lee, C. M. Y., Colagiuri, S., Woodward, M., Gregg, E. W., Adams, R., Azizi, F., Gabriel, R., Gill, T. K., Gonzalez, C., Hodge, A. and Jr, D. R. J. (2019) ‘Comparing different definitions of prediabetes with subsequent risk of diabetes : an individual participant data individuals and 8208 cases of incident diabetes’, *BMJ Open Diabetes Research & Care*, 7(:e000794), pp. 1–10. doi: 10.1136/bmjdrc-2019-000794.

Legorreta, A. P., Leung, K. and Berkbigler, D. (2000) ‘Outcomes of a population-based asthma management program : quality of life , absenteeism , and utilization’, *ANNALS OF ALLERGY, ASTHMA, & IMMUNOLOGY*. American College of Allergy, Asthma & Immunology, 85, pp. 28–34. doi: 10.1016/S1081-1206(10)62430-1.

Lewis, S. L., Dirksen, S. R., Heitkemer, M. M. and Linda Bucher (2014) *MEDICAL-SURGICAL NURSING Assessment and mManagement of clinical problems*. NINTH. Canada: ELSEVIER MOSBY.

Lorig, K. R. and Holman, H. R. (2003) ‘Self-management education: History, definition, outcomes, and mechanisms’, *Annals of Behavioral Medicine*, 26(1), pp. 1–7. doi: 10.1207/S15324796ABM2601_01.

Lu, Y., Xu, J. and Zhao, W. (2016) ‘Measuring Self-Care in Persons With Type 2 Diabetes : A Systematic Review’, *Evaluation &the health profession*, 39(2), pp. 131–184. doi: 10.1177/0163278715588927.

Maguire, M. and Delahunt, B. (2017) ‘Doing a Thematic Analysis : A Practical , Step-by-Step Guide for Learning and Teaching Scholars .’, *AISHE-J*, 3(Autumn 2017).

De Man, J., Aweko, J., Daivadanam, M., Alvesson, H. M., Delobelle, P., Mayega, et al. (2019) ‘Diabetes self-management in three different income settings : Cross-learning of barriers and opportunities’, *PLOS ONE*, 14(3), p. e0213530.

Mancuso, J. M. (2015) ‘Low Health Literacy Predicts Misperceptions of Diabetes Control in Patients With Persistently Elevated A1C.’, *The Diabetes educator*, 41(3), pp. 309–19. doi: 10.1177/0145721715572446.

Maree, J. and Schmollgruber, S. (2014) ‘An integrative review of South African cancer nursing’, *Curationis*, 37(1), p. Art. #1193, 10 pages. doi: 10.4102/curationis.v37i1.1193.

Mendenhall, E. and Norris, S. A. (2015) ‘Diabetes care among urban women in Soweto , South Africa : a qualitative study’, *BMC Public Health*. BMC Public Health, 15(1300), pp. 1–7.

doi: 10.1186/s12889-015-2615-3.

Mhpe, V. M., Johnson, N. A., Tzelepis, F., Shaw, J. E. and Paul, C. (2019) 'A systematic review of adherence to diabetes self - care behaviours : Evidence from low - and middle - income countries', *Journal of Advanced Nursing*, 75(August), pp. 3374–3389. doi: 10.1111/jan.14190.

Ministry of Health (2016) 'Rwanda Annual Health Statistical Booklet 2015'. Available at: http://www.moh.gov.rw/fileadmin/templates/hmis_reports/Rwanda_Annual_Health_Statistics_Booklet_2015_.pdf.

Mogre, V., Abanga, Z. O., Tzelepis, F., Johnson, N. A. and Paul, C. (2017) 'Adherence to and factors associated with self-care behaviours in type 2 diabetes patients in Ghana', *BMC Endocrine Disorders*. BMC Endocrine Disorders, 17(20), pp. 1–8. doi: 10.1186/s12902-017-0169-3.

Mogre, V., Johnson, N. A., Tzelepis, F., Shaw, J. and Paul, C. (2017) 'Adherence to self-care behaviours and associated barriers in type 2 diabetes patients of low-and middle-income countries : a systematic review protocol', *Systematic Reviews*. Systematic Reviews, 6(39), pp. 1–6. doi: 10.1186/s13643-017-0436-4.

Mosha, T. C. E. and Rashidi, H. (2009) 'Evaluation of Self-Care Practices and Emotional Distress Among People with Type 2 Diabetes Mellitus in Dar Es Salaam , Tanzania', *Ecology of Food and Nutrition*, 48(0367-0244 print/1543-5237), pp. 89–111. doi: 10.1080/03670240802577457.

Moss, T. R. (2014) 'The Impact of Health Literacy on Clinical Outcomes for Adults with Type 2 Diabetes Mellitus', *Advances in Diabetes and Metabolism*, 2(1), pp. 10–19. doi: 10.13189/adm.2014.020103.

Mukanoheli, V., Uwamahoro, M. C., Mbarushimana, V. and Meharry, P. (2020) 'Functional Health Literacy and Self-Care Behaviors Among Type 2 Diabetic Patients at a University Teaching Hospital in Kigali', *Rwanda Journal of Medicine and Health Sciences Vol.3*, 3(1), pp. 49–59.

Mukeshimana, M. and Mchunu, G. (2016) 'The Co-morbidity of Depression and other Chronic Non-communicable Diseases : A review of literature on the epidemiology , diagnosis and health effects', *Rwanda Journal Series F: Medicine and Health Sciences*, 3(1), pp. 44–50.

Mukeshimana, M. and Mchunu, G. (2017) 'Management of Co-Morbidity of Depression and Chronic Non- Communicable Diseases in Rwanda', *Ethiopian Journal of Health Sciences*, 27(1), pp. 17–26.

Musenge, E. M., Michelo, C., Mudenda, B. and Manankov, A. (2016) 'Glycaemic Control and Associated Self-Management Behaviours in Diabetic Outpatients : A Hospital Based Observation Study in Lusaka , Zambia', *Journal of Diabetes Research*, 2016, pp. 1–9.

Nam, S., Chesla, C., Stotts, N. A., Kroon, L. and Janson, S. L. (2011) 'Barriers to diabetes

management : Patient and provider factors', *Diabetes Research and Clinical Practice*. Elsevier Ireland Ltd, 93(1), pp. 1–9. doi: 10.1016/j.diabres.2011.02.002.

Newman, I., Lim, J. and Pineda, F. (2013) 'Content Validity Using a Mixed Methods Approach : Its Application and Development', *Journal of Mixed Methods Research*, 7(3), pp. 243–260. doi: 10.1177/1558689813476922.

Ng, C. J. (2006) 'Designing a Questionnaire', *Malaysian Family Physician*, 1(1), pp. 45–58. doi: 10.4135/9781473913943.n3.

Nkosi-Mafutha, N. G., de Sward, H. C. and Mogotlane, S. (2020) 'Conveying hypertension message : An investigation into the language and content used in primary health clinics in South Africa', *African Journal of Primary Health Care & Family Medicine*.

Nsereko, E., Bavuma, C., Tuyizere, M., Ufashingabire, C., Jmv, R. and Yamuragiye, A. (2013) 'Illness Perceptions and Depression in Relation to Self-care Behaviour among Type 2 diabetes Patients in a Referral Hospital in Kigali-Rwanda', *Rwanda j. health sci.*, 2(1), pp. 1–9.

Olson, A. L. (2012) 'Regulation of GLUT4 and Insulin-Dependent Glucose Flux', *ISRN Molecular Biology*, 2012(ID856987), pp. 1–12. doi: 10.5402/2012/856987.

Ozougwu, J. C., Obimba, K. C., Belonwu, C. D. and Unakalamba, C. B. (2013) 'The pathogenesis and pathophysiology of type 1 and type 2 diabetes mellitus', *Journal of Physiology and Pathophysiology Review*, 4(4), pp. 46–57. doi: 10.5897/JPAP2013.0001.

Parajuli, J., Saleh, F., Thapa, N. and Ali, L. (2014) 'Factors associated with nonadherence to diet and physical activity among nepalese type 2 diabetes patients ; a cross sectional study', *BMC Research Notes*, 7(758). Available at: http://www.biomedcentral.com/1756-0500/7/758.

Patrick, D. L., Burke, L. B., Gwaltney, C. J., Leidy, N. K., Martin, M. L., Molsen, E. et al. (2011) 'Content Validity — Establishing and Reporting the Evidence in Newly Developed Patient-Reported Outcomes ( PRO ) Instruments for Medical Product Evaluation : ISPOR PRO Good Research Practices Task Force Report : Part 1 — Eliciting Concepts for a New PRO In', *JVALUE IN HEALTH*. Elsevier Inc., 14(8), pp. 967–977. doi: 10.1016/j.jval.2011.06.014.

Perez, L.-E. G., Alarez, M. and Dilla, T. (2013) 'Adherence to Therapies in Patients with Type 2 Diabetes', *Diabetes Ther*, 4, pp. 175–194. doi: 10.1007/s13300-013-0034-y.

Philis-Tsimikas, A. and Gallo, L. C. (2015) 'Implementing Community-Based Diabetes Programs: The Scripps Whittier Diabetes Institute Experience', *Curr Diab Rep*, 14(2), p. 462. doi: 10.1007/s11892-013-0462-0.Implementing.

Pilv, L., Vermeire, E., Rätsep, A., Moreau, A., Nikolić, D., Petek, D., et al. (2016) 'Development and validation of the short version of the diabetes obstacles questionnaire ( DOQ-30 ) in six European countries', *European Journal of General Practice*, 22(1), p. 16–22. doi: 10.3109/13814788.2015.1093619.

Pinzur, M. ., Slovenkai, M. P., Trepman, E. and Shields, N. N. (2005) 'Guidelines for Diabetic

Foot Care : Recommendations Endorsed by the Diabetes Committee of the American Orthopaedic Foot and Ankle Society', *FOOT &ANKLE INTERNATIONAL*, 26(1), pp. 113–119.

Pinzur, M. S., Slovenkai, M. ., Trepman, E. and Shields, N. N. (2005) 'Guidelines for Diabetic Care: Recommendations Endorsed by th Diabetes Committee of the American Foot and Ankle society'.

Piwonka and Merino (1999) 'A Multidimensional Modeling of Predictors Infuencincing the Adjustment to a Colostorny', pp. 298–305.

Polit, D. F. and Beck, C. T. (2010) *Essentials of Nursing Research; Appraising Evidence for Nursing Practice*. Wolters Kluwer Health | Lippincott Williams & Wilkins. Copyright.

Powers, M. A., Bardsley, J., Cypress, M., Duker, P., Funnell, M. M., Fischl, A. H., et al. (2016) 'Diabetes self-management education and support in type 2 diabetes: A joint position statement of the American Diabetes Association, the American Association of diabetes educators, and the Academy of nutrition and dietetics', *Clinical Diabetes*, 34(2), pp. 70–80. doi: 10.2337/dc15-0730.

Pun, S. P. Y., Coates, V. and Benzie, I. F. F. (2009) 'Barriers to the self-care of type 2 diabetes from both patients ' and providers ' perspectives : literature review'. doi: 10.1111/j.1365-2702.2008.01000.x.

Putra Yasa, D. P. G., Rahayu, V. E. S., Widastra, I. M., Labir, I. K., Wedri, N. M. and Sulisnadewi, N. L. K. (2018) 'Barrier of Self Care Management on Urban Type 2 Diabetic Patients in Bali', *Indian Journal of Public Health Research & Development*, 9(5). doi: 10.5958/0976-5506.2018.00469.2.

Ramezankhani, A., Soori, H., Alhani, F., Goudarzi, A. M., Promotion, S. and Prevention, I. (2015) 'Design and development of a scale of perceived barriers to self-care in patients with type 2 diabetes mellitus: an exploratory factor analysis', *Electronic Physician*, 7(7), pp. 1486–1493.

Ravi, S., Kumar, S. and Gopichandran, V. (2018) 'Do supportive family behaviors promote diabetes self-management in resource limited urban settings ? A cross sectional study', *BMC Public Health*. BMC Public Health, 18(1), p. 826.

Reisi, M., Mostafavi, F., Javadzade, H., Mahaki, B., Tavassoli, E. and Sharifirad, G. (2016) 'Impact of health literacy, self-efficacy, and outcome expectations on adherence to self-care behaviors in iranians with type 2 diabetes', *Oman Medical Journal*, 31(1), pp. 52–59. doi: 10.5001/omj.2016.10.

Rhyu, Y. A., Jang, J., Park, S., An, J. H., Kim, D. and Kim, S. K. (2019) 'Impaired Cortisol and Growth Hormone Counterregulatory Responses among Severe Hypoglycemic Patients with Type 2 Diabetes Mellitus', *E n M Endocrinology and Metabolism*, 34, pp. 187–194.

Richard, A. A. and Shea, K. (2011) 'Delineation of Self-Care and Associated Concepts', *Journal of Nursing Scholaship*, 43(3), pp. 255–264. doi: 10.1111/j.1547-5069.2011.01404.x.

Rudasingwa, G. J., Amendezo, E. and Twagirumukiza, M. (2012) 'Clinical patterns and complications of African diabetic patients : preliminary data from Kigali University Teaching Hospital , Rwanda', *African Journal of Diabetes Medicine*, 20(2), pp. 39–42.

Rwanda Diabetes Association (2015) 'WHAT IS DIABETES? DIYABETE NI IKI?', *Eureka Health Magazine*, pp. 1–16.

Rwanda Ministry of Health (2014) 'National Human Resources For Health Policy', p. 19. Available at: http://www.moh.gov.rw/fileadmin/templates/policies/Human_Ressource_for_Health_Policy.pdf.

Rwanda Ministry of Health (2015) 'Non Communicable diseases Policy', (March), pp. 1–11.

Rwanda Ministry of Health (2017) 'Policy ofTranditional ComplementaryAlternative Medicine', pp. 1–19.

Rwegerera, G. M. (2014) 'Adherence to anti-diabetic drugs among patients with Type 2 diabetes mellitus at Muhimbili National Hospital, Dar es Salaam, Tanzania- A cross-sectional study', *PanAfrican Medical Journal*, 17(252). doi: 10.11604/pamj.2014.17.252.2972.

Saeedi, P., Petersohn, I., Salpea, P., Malanda, B., Karuranga, S., Unwin, N., et al. (2019) 'Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045 : Results from the International Diabetes Federation Diabetes Atlas , 9 th edition', *Diabetes Research and Clinical Practice*. Elsevier Ireland Ltd, 157(2019), p. 107843. doi: 10.1016/j.diabres.2019.107843.

Saleh, F., Mumu, S. J., Ara, F., Begum, H. A. and Ali, L. (2012) 'Knowledge and self-care practices regarding diabetes among newly diagnosed type 2 diabetics in Bangladesh : a cross-sectional study', *BMC Public Health*. BMC Public Health, 12(1112), pp. 1–8. doi: 10.1186/1471-2458-12-1112.

Sandelowski, M. (2000) 'Focus on Research Methods Whatever Happened to Qualitative Description ?', *ResearchinNursing&Health*, 23(2000), pp. 334–340.

Sandström, M. and Lundin-Olsson, L. (2007) 'Development and evaluation of a new questionnaire for rating perceived participation1', *Clinical Rehabilitation*, 21(9), pp. 833–845. doi: 10.1177/0269215507077278.

Saudek, C. D. and Brick, J. C. (2009) 'The Clinical Use of Hemoglobin A1c', *Journal of Diabetes Science and Technology*, 3(4).

Saunders, B., Sim, J., Kingstone, T., Baker, S., Waterfiel, J., Bartlam, B., Burroughs, H. and Jinks, C. (2018) 'Saturation in qualitative research : exploring its conceptualization and operationalization', *Quality & Quantity*. Springer Netherlands, 52(4), pp. 1893–1907. doi: 10.1007/s11135-017-0574-8.

Schillinger, D., Grumbach, K., Piette, J., Wang, F., Osmond, D., Daher, C., Palacios, J., Sullivan, G. D. and Bindman, A. B. (2002) 'Association of Health Literacy With Diabetes Outcomes',

*JAMA*, 288(4), pp. 475–482.

Schlundt, D. G., Pichert, J. W., Rea, M. R., Puryear, W., Penha, M. L. I. and Kline, S. S. (1994) 'Situational Obstacles to Adherence for Adolescents with Diabetes', *THE DIABETES EDUCATOR*, 20(3), pp. 207–211.

Schlundt, D. G., Rea, M. R., Kline, S. and Pichert, J. W. (1994) 'Situational obstacles to dietary adherence for adults with diabetes', *J Am Diet Assoc*, 94(8), pp. 874–878.

Schmitt, A., Gahr, A., Hermanns, N., Kulzer, B., Huber, J. and Haak, T. (2013) 'The Diabetes Self-Management Questionnaire (DSMQ): development and evaluation of an instrument to assess diabetes self-care activities associated with glycaemic control.', *Health and quality of life outcomes*, 11(138). doi: 10.1186/1477-7525-11-138.

Schunk, M., Stark, R., Reitmeir, P., Meisinger, C. and Holle, R. (2015) 'Towards patient-oriented diabetes care: Results from two kora surveys in southern germany', *Journal of Diabetes Research*, 2015(Article ID 368570), p. 14 pages. doi: 10.1155/2015/368570.

Shrivastava, S. R., Shrivastava, P. S. and Ramasamy, J. (2013) 'Role of self-care in management of diabetes mellitus', *Journal of Diabetes & Metabolic Disorders*, 12(14), pp. 1–5.

Shrotryia, V. K. and Dhanda, U. (2019) 'Content Validity of Assessment Instrument for Employee Engagement'. doi: 10.1177/2158244018821751.

Skyler, J. S., Bakris, G. L., Bonifacio, E., Darsow, T., Eckel, R. H., Groop, L., et al. (2017) 'Differentiation of Diabetes by Pathophysiology , Natural History , and Prognosis', *Diabetes*, 66(February 2017), pp. 241–255. doi: 10.2337/db16-0806.

Slamah, T. Al, Icholl, B. I., Alslail, F. Y., Harris, L., Melville, A. and Kinnear, D. (2020) 'Cultural adaptation of self-management of type 2 diabetes in Saudi Arabia ( qualitative study )', *PLOS ONE*, 15(7), p. e0232904. doi: 10.1371/journal.pone.0232904.

Sohal, T., Sohal, P., King-shier, K. M. and Khan, N. A. (2015) 'Barriers and Facilitators for Type-2 Diabetes Management in South Asians : A Systematic Review', *PLoS ONE*, September, pp. 1–15. doi: 10.1371/journal.pone.0136202.

Souza, J. G., Apolinario, D., Magaldi, R. M., Busse, A. L., Campora, F. and Jacob-filho, W. (2014) 'Functional health literacy and glycaemic control in older adults with type 2 diabetes : a cross-sectional study', *BMJ Open*, 4(e004), pp. 1–9. doi: 10.1136/bmjopen-2013-004180.

Spellman, C. W. (2010) 'Pathophysiology of Type 2 Diabetes :Targeting Islet Cell Dysfunction', *J Am Osteopath Assoc*, 110((3suppl2)), pp. S2–S7.

Stetson, B., Schlundt, D., Rothschild, C., Floyd, J. E., Rogers, W. and Prakash, S. (2011) 'Development and validation of The Personal Diabetes Questionnaire ( PDQ ): A measure of diabetes self-care behaviors , perceptions and barriers', *Diabetes Research and Clinical Practice*. Elsevier Ireland Ltd, 91(3), pp. 321–332. doi: 10.1016/j.diabres.2010.12.002.

Tamir, O., Wainstein, J., Abadi-korek, I. and Horowitz, E. (2012) 'The patient-perceived dif fi

culty in diabetes treatment ( PDDT ) scale identi fi es barriers to care', *Diabetes Metab Res Rev*, 28, pp. 246–251. doi: 10.1002/dmrr.

Tang, J. and Teacher, A. (2019) 'Illness perceptions among patients with type 2 diabetes mellitus : A cross-sectional study', *International journal of nursing practice*, 2019(e12801). doi: 10.1111/ijn.12801.

Tapela, N., Habineza, H., Anoke, S., Harerimana, E., Mutabazi, F., Hedt-Gauthier, B., et al. (2016) 'Diabetes in Rural Rwanda: High Retention and Positive Outcomes after 24 Months of Follow-up in the Setting of Chronic Care Integration', *Int J Diabetes Clin Res*, 3(2). Available at: http://clinmedjournals.org/articles/ijdcr/international-journal-of-diabetes-and-clinical-research-ijdcr-3-058.php.

Tapela, N. M., Bukhman, G., Ngoga, G., Kwan, G. F., Mutabazi, F., Dusabeyezu, S., et al. (2015) 'Treatment of non-communicable disease in rural resource-constrained settings: a comprehensive, integrated, nurse-led care model at public facilities in Rwanda', *The Lancet Global Health*. Tapela et al. Open Access article distributed under the terms of CC BY, 3, p. S36. doi: 10.1016/S2214-109X(15)70155-5.

Tavares de Souza, M. T., Silva, M. D. da and Carvalho, R. de (2010) 'Integrative review : what is it ? How to do it ?', *einstein*, 8(1 Pt 1), pp. 102–106.

Tu, K., Barchard, K. and Tu, K. (1993) 'An Assessment of Diabetes Self-Care Barriers in Older Adults An Assessment of Diabetes Self-care Barriers in Older Adults', *Journal of Community Health Nursing*, 10(2), pp. 113–118. doi: 10.1207/s15327655jchn1002.

Waari, G., Mutai, J. and Gikunju, J. (2018) 'Medication adherence and factors associated with poor adherence among type 2 diabetes mellitus patients on follow-up at Kenyatta National Hospital, Kenya', *PanAfrican Medical Journal*, 29(82). doi: 10.11604/pamj.2018.29.82.12639.

Walker, R. J., Gebregziabher, M., Martin-harris, B. and Egede, L. E. (2014) 'Relationship between social determinants of health and processes and outcomes in adults with type 2 diabetes : validation of a conceptual framework', *BioMED Central Endocrine Disorders*, 14(82), pp. 1–10.

Webber, D., Guo, Z. and Mann, S. (2013) 'Self-Care in Health : We Can Define it , but Should We Also Measure It ?', *SelfCare*, 4(5), pp. 101–106.

Whittemore, R. and Knafl, K. (2005) 'The integrative review : updated methodology', *Journal of Advanced Nursing*, 52(5), pp. 546–553.

Wilkinson, A. and Whitehead, L. (2009a) 'Evolution of the concept of self-care and implications for nurses : A literature review', *International Journal of Nursing studies*, 46, pp. 1143–1147. doi: 10.1016/j.ijnurstu.2008.12.011.

Wilkinson, A. and Whitehead, L. (2009b) 'Evolution of the concept of self-care and implications for nurses : A literature review', *International Journal of Nursing Studies*, 46(2009), pp.

1143–1147. doi: 10.1016/j.ijnurstu.2008.12.011.

Williams, L. S. and Hopper, P. D. (2015) *Understanding Medical Surgical Nursing*. Fifth edit. Philadelphia: F.A. Davis Company.

World Bank (2018) 'World Bank list of economies ( June 2018 ) x World World Bank list of economies ( June 2018 )', (June), pp. 1–7.

World Health organization (2016) 'GLOBAL REPORT ON DIABETES'. Available at: http://apps.who.int/iris/bitstream/10665/204871/1/9789241565257_eng.pdf.

Xu, Y., Pan, W. and Liu, H. (2010) 'Self-management practices of Chinese Americans with type 2', *Nursing Health Sciences*, 12(2), pp. 228–234. doi: 10.1111/j.1442-2018.2010.00524.x.

Xu, Y., Pan, W. and Liu, H. (2011) 'The role of acculturation in diabetes self-management among Chinese Americans with type 2 diabetes .', *Diabetes Research and Clinical Practice*, 93(3), pp. 363–370. doi: 10.1016/j.diabres.2011.05.010.

Yaghmaie, F. (2003) 'Content validity and its estimation', *Journal of medical education*, 3(1), pp. 25–27.

Yamashita, T. and Kart, C. S. (2011) 'Is diabetes-specific health literacy associated with diabetes-related outcomes in older adults ?', *Journal of Diabetes*, 3, pp. 138–146. doi: 10.1111/j.1753-0407.2011.00112.x.

Zamanzadeh, V., Rassouli, M., Abbaszadeh, A., Majd, H. A., Nikanfar, A. and Ghahramanian, A. (2014) 'Details of content validity and objectifying it in instrument development', *Nursing Practice Today*, 1(3), pp. 163–171.

Zeng, B., Sun, W., Gary, R. A., Li, C. and Liu, T. (2014) 'Towards a Conceptual Model of Diabetes Self-Management among Chinese Immigrants in the United States', *Int. J. Environ. Res. Public Health*, 11, pp. 6727–6742. doi: 10.3390/ijerph110706727.

Zheng, Y., Ley, S. H. and Hu, F. B. (2018) 'Global aetiology and epidemiology of type 2 diabetes mellitus and its complications', *Reviews*. Nature Publishing Group, 14(February 2018), pp. 88–98. doi: 10.1038/nrendo.2017.151.

Zuercher, E., Diatta, I. D. and Burnand, B. (2017) 'Health literacy and quality of care of patients with diabetes : A cross-sectional analysis', *PRIMARY CARE DIABETES*. Primary Care Diabetes Europe, pp. 1–8. doi: org/10.1016/j.pcd.2017.02.003.

## ANNEXURES

## ANNEXURE 1: LOW- AND LOW- MIDDLE-INCOME COUNTRIES YEAR 2016

| **LOW-INCOME ECONOMIES ($1,005 OR LESS** | | | |
|---|---|---|---|
| Afghanistan | Eritrea | Madagascar | Sierra Leone |
| Benin | Ethiopia | Malawi | Somalia |
| Burkina Faso | Gambi | Mali | South Sudan |
| Burundi | Guinea | Mozambique | Tanzania |
| Central African Republic | Guinea-Bissau | Nepal | Togo |
| Chad | Haiti | Niger | Uganda |
| Comoros | Korea, Dem. People's Rep. | Rwanda | Zimbabwe |
| Congo, Dem. Rep | Liberia | Senegal | |
| **LOWER-MIDDLE-INCOME ECONOMIES ($1,006 TO $3,955)** | | | |
| **Angola** | Ghana | Moldova | Syrian Arab Republic |
| Armenia | Guatemala | Mongolia | Tajikistan |
| Bangladesh | Honduras | Morocco | Timor-Leste |
| Bhutan | India | Myanmar | Tunisia |
| Bolivia | Indonesia | Nicaragua | Ukraine |
| Cabo Verde | **Jordan** | Nigeria | Uzbekistan |
| Cambodia | Kenya | Pakistan | Vanuatu |
| Cameroon | Kiribati | Papua New Guinea | Vietnam |
| Congo, Rep. | Kosovo | Philippines | West Bank and Gaza |
| Côte d'Ivoire | Kyrgyz Republic | São Tomé and Principe | Yemen, Rep. |
| Djibouti | Lao PDR | Solomon Islands | Zambia |
| Egypt, Arab Rep. | Lesotho | Sri Lanka | |
| El Salvador | Mauritania | Sudan | |
| **Georgia** | Micronesia, Fed. Sts. | Swaziland | |

## ANNEXURE 2: ETHICS CLEARANCE CERTIFICATE

R14/49 Ms M Uwamahoro

**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)**
**CLEARANCE CERTIFICATE NO. M180432**

| | |
|---|---|
| **NAME: (Principal Investigator)** | Ms M Uwamahoro |
| **DEPARTMENT:** | School of Therapeutic Sciences<br>Department of Nursing Education<br>Medical School<br>University |
| **PROJECT TITLE:** | Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda |
| **DATE CONSIDERED:** | 04/05/2018 |
| **DECISION:** | Approved unconditionally |
| **CONDITIONS:** | |
| **SUPERVISOR:** | Dr N Mafuta and Professor D Casteleijn |
| **APPROVED BY:** | Professor CB Penny, Chairperson, HREC (Medical) |
| **DATE OF APPROVAL:** | 23/07/2018 |

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

**DECLARATION OF INVESTIGATORS**

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **April** and will therefore be due in the month of **April** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

**PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES**

## ANNEXURE 3: APPROVAL OF INSTITUTIONAL REVIEW BOARD (IRB)

UNIVERSITY OF RWANDA

**COLLEGE OF MEDICINE AND HEALTH SCIENCES**

*CMHS INSTITUTIONAL REVIEW BOARD (IRB)*

Kigali, 3rd /May/2018

**UWAMAHORO Marie Claire**
**School of Nursing and Midwifery, CMHS, UR**

**Approval Notice: No 156 /CMHS IRB/2018**

Your Project Title ***""Development And Pilot Testing Of An Instrument To Assess Self-Management Barriers Among Patients Diagnosed With Type 2 Diabetes Patients In Rwanda*** " has been evaluated by CMHS Institutional Review Board.

| | | Involved in the decision | | |
|---|---|---|---|---|
| | | Yes | No ( Reason) | |
| **Name of Members** | **Institute** | | **Absent** | **Withdrawn from the proceeding** |
| Prof Kato J. Njunwa | UR-CMHS | | X | |
| Prof Jean Bosco Gahutu | UR-CMHS | X | | |
| Dr Brenda Asiimwe-Kateera | UR-CMHS | X | | |
| Prof Ntaganira Joseph | UR-CMHS | X | | |
| Dr Tumusiime K. David | UR-CMHS | X | | |
| Dr Kayonga N. Egide | UR-CMHS | X | | |
| Mr Kanyoni Maurice | UR-CMHS | X | | |
| Prof Munyanshongore Cyprien | UR-CMHS | | X | |
| Mrs Ruzindana Landrine | Kicukiro district | | X | |
| Dr Gishoma Darius | UR-CMHS | X | | |
| Dr Donatilla Mukamana | UR-CMHS | X | | |
| Prof Kyamanywa Patrick | UR-CMHS | | X | |
| Prof Condo Umutesi Jeannine | UR-CMHS | | X | |
| Dr Nyirazinyoye Laetitia | UR-CMHS | X | | |
| Dr Nkeramihigo Emmanuel | UR-CMHS | | X | |
| Sr Maliboli Marie Josee | CHUK | X | | |
| Dr Mudenge Charles | Centre Psycho-Social | X | | |

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 3rd May 2018, **Approval has been granted to your study.**

EMAIL: *researchcenter@ur.ac.rw* P.O. Box: 3286, Kigali, Rwanda WEBSITE: http://cmhs.ur.ac.rw/ www.ur.ac.rw

Please note that approval of the protocol and consent form is valid for **12 months**.

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 3rd May 2018

Expiration date: The 3rd May 2019

Professor Kato J. NJUNWA
**Chairperson Institutional Review Board,**
**College of Medicine and Health Sciences, UR**

**Cc:**

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

## ANNEXURE 4: LETTER TO REQUEST PERMISSION TO CONDUCT THE STUDY

Marie Claire Uwamahoro
Department of Nursing Education
School of Therapeutic Sciences
Faculty of Health Sciences
University of Witwatersrand
7 York Road, Parktown 2050
Johannesburg South Africa

The Medical Director of ……. Hospital

**RE: PERMISSION TO CONDUCT RESEARCH**

Dear Sir/Madam,

I am Marie Claire, student number 1760159 currently enrolled in the Doctor of Philosophy in the Departement of Nursing Education, Witwatersrand University. My supervisors are Dr Nokuthula.Mafutha and Professor Daleen Casteleijn. As part of the programme requirements I have to undertake research. It is in this premise that I write to request permission to undertake a research entitled "**Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda"** at ……. Hospital. I intend to carry out the study from……to……. It is my hope that the findings will improve type 2 diabetes outcomes.

Your favourable response to my request will highly be appreciated.

Yours faithfully,

Marie Claire UWAMAHORO

Student number 1760159 Contacts: 1760159@students.wits,ac.za, Cell: +250788402547

**Contact details of supervisors.**
Dr Nokuthula Mafutha (+27 11488 3096) nokuthula.mafutha@wits.ac.za
Prof. Daleen Casteleijn daleen.casteleijn@wits.ac.za

**ANNEXURE 5: INFORMATION SHEET FOR IN-DEPTH INTERVIEWS – PATIENTS WITH TYPE 2 DIABETES IN RWANDA.**

**ENGLISH VERSION**


**Name of Principle Investigator:** **Marie Claire Uwamahoro**
**Institution:** **School of Therapeutic Sciences,**
**Nursing Education Department,**
**University of the Witwatersrand, South Africa**
**Contact Phone:** **+250-788402547**
**Email:** **1760159@students.wits.ac.za**


**Study Title:** Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes patients in Rwanda.

**Introductions**

Good morning/afternoon to you. My name is Marie Claire Uwamahoro. I am currently enrolled in the Doctor of Philosophy in Nursing at the University of Witwatersrand. I am doing research on type 2 diabetes. The study has been approved by the Research Ethics Committee (Medical) of the University of Witwatersrand and the Institution Review Board of the University of Rwanda/College of Medicine and Health Sciences. Thank you for accepting to participate in my study.

***Please kindly receive and read this information sheet and make an informed decision. This letter is yours to keep for future reference.***

**What is involved in the study**?

The whole study is about development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda. The purpose of this interview is to assess self-management barriers that you face when managing your type 2 diabetes. The results of all interviews will be used to develop the instrument that will be used to assess barriers of self-management for better support and education.

**What will you be asked to do?**

I am inviting you to participate in this study. If you accept, I will be asking you questions about type 2 diabetes self-management barriers. I will thus, be asking you to have some time for an interview with me. This could take about 45-60 minutes and could be done at any time of your convenience. The interview will be recorded then transcribed. This will help me to recall what I discussed with you without adding or retrieving any information to our conversation.

**Why have you been selected?**

I have selected you because you live with type 2 diabetes and I think you may have information on barriers in self-management.

**Risks**

There are no known or anticipated risks or discomforts associated with participating in this study.

**Benefits**

The possible benefits associated with participation in this study include informing health providers on self-management barriers of type 2 diabetes patients for better support.

**Participation is voluntary**

You reserve the right to participate in this study and you can withdraw your consent to participate in this study at any time without any negative consequences or penalties. You have the right not to answer questions if you feel uncomfortable to do so.

**Reimbursements for "out of pocket" expenses.**
You will not be compensated for your participation in this research.

**Confidentiality**:

Your name will not appear anywhere; a unique identifier will be used to refer to you to protect your identity. All data collected will remain confidential and accessible only to the investigators of this study.

If the results are published, your name will not be used. If you choose to withdraw from this study prior to initiation of the data analysis phase, your data will be removed and destroyed from our database. Information collected in this study will be kept for five years and then destroyed. Representatives of the University of Witwatersrand Research Ethics Committee (medical) may contact you or require access to your study-related records to monitor the conduct of the research.

**Getting feedback from the study**

I plan to write a thesis from these findings. The thesis will be ready by the end of 2020. This thesis will be open in the university library. I also plan to publish academic papers in online journals. You will be able to access them once you log in.

**Consent**
A Consent Form will be provided for you to sign prior to the interview.

**Contact details for further information**

If you have concerns about any aspect of this study or want to report any problem about this study, you can use the following contact details:

Professor Kato J. Junwa
The Chairperson of Institution Review Board
University of Rwanda
College of Medicine and Health Sciences
+250 7884 90522
njunwakato@gmail.com

Professor Gahutu Jean Bosco
Director of Research Center, University of Rwanda

## KINYARWANDA VERSION

**KWEMERA KUBUSHAKE KUGIRA URUHARE MU MUBUSHAKASHATSI, UMUYOBORO W'IBAZWA ___ABARWAYI BA DIYABETE YA 2, MU RWANDA.**


**Uhagarariye ubushakashatsi:** **Marie Claire Uwamahoro**
**Aho abarizwa:** **Ishuli ry'ubuvuzi,**
**Ishami ry'abaforomo,**
**Kaminuza ya Witwatersrand, Afrika y'epfo**
**Numero ya telefone:** **+250-788402547**
**Aderese ya interinete:** **1760159@students.wits.ac.za**


**Inyito y'ubushakashatsi: "**Gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya 2 ahura nazo igihe akurikirana indwara ye ku giti cye atari kwa muganga, mu Rwanda"

### IBARUWA IMENYESHA

### INTANGIRIRO

Mwaramutse/Mwiriwe. Nitwa Uwamahoro Marie Claire nkaba niga icyiciro cya gatatu cya kaminuza muri Kaminuza ya Witwatersrand Afurika yepfo, ishami ry'abaforomo. Kugirango mbone impamya bushobozi y'kirenga itangwa nyuma yo kurangiza icyo cyiciro ngomba gukora ubushakashatsi. Ndimo ndakora ubushakashatsi kuri dibete y'ubwoko bwa kabiri. Ubushakashatsi bukaba bwaremewe n'ikigo gishinzwe ubushakashatsi muri Kaminuza ya Witwatersrand Afrika y'epfo ndetse n'ikigo gishinzwe ubushakashatsi muri Kaminuza y'u Rwanda mu ishami ry'ubuvuzi. Nkaba ngushimiye ko wemeye kumenya ibikorerwa muri ubu bushakashatsi.

***Nimwakire iyi nyandiko muyisome hanyuma mufate icyemezo cyo kwemera kugira uruhare muri ubu bushakashatsi. Iyi baruwa ni iyawe, uzakomeze uyibike ushobora kuyikenera mu minsi iri mbere mu bijyanye nubu bushakashatsi.***

**Ni ibiki bikubiye muri ubu bushakashatsi**?

Ubu bushakashatsi bugamije gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya 2 ahura nazo igihe akurikirana indwara ye ku giti cye. Ikigamijwe muri iki kiganiro tugiye kugirana ni ukugira ngo menye ingorane uhura nazo mugihe wikurikira ubwawe utari kwa muganga. Ibizava muri iki kiganiro bizifashishwa mu gukora ifishi izajya ifasha abakuvura kumenya byihuse ingorane uhura nazo kugira ngo baguhe ubufasha bujyanye n'ikibazo ufite kandi barusheho ku kwigisha ibyagufasha.

**Icyo ngusaba muri aka kanya?**

Ndagutumira kwitabira ubu bushakashatsi Nimba ubyemeye, ndaza kukubaza ibibazo ku ngorane uhura nazo mugihe ugerageza kwikurikirana. Ndifuza kumenya mu buryo bw'imbitse uko ubyifatamo, ndetse n'ingorane uhura nazo. Ndagusaba rero ko twamarana umwanya tuganira. Ikiganiro kirafata hagati y'iminota 45-60 kandi tukaba twagikora mu mwanya ukoroherye. Ikiganiro kandi kiraza gufatwa amajwi kugirango bizadufashe kwibuka neza ibyo twaganiriye.

**Kuki nagutoranije?**

Watoranyijwe kubera ko urwaye iyo ndwara kandi nkaba ntekerea ko ufite amakuru ahagije kubijyanye n'ingorane abarwayi ba diabete ya 2 bahura nazo igihe bakurikirana indwara yabo.

**Ibyago cgangwa Ingaruka**

Nta ngaruka mbi uzahura nazo kuko witabiriye ubu bushakashatsi

**Inyungu**

inuyungu zirimo ni uko iyo fishi izajya ifasha mu buryo bwihuse abaganga bavura abarwayi ba diabete ya 2, kumenya ingorane bahura nazo kugirango babafashe.

**Kwitabira ubu bushakashatsi ni ubushake**

Ni amahitamo ndetse n'ubushake bwawe kuba wakwemera kugira uruhare muri ubu bushakashatsi. Igihe icyo aricyo cyose ushobora guhagarika, cyangwa ugahitamo kudasubiza ibibazo bimwe na bimwe wumva bikubangamiye, kandi nta ngaruka n'imwe byagutera. Kwitabira ubu bushakashatsi bituruka ku mahitamo. Ushobora kwanga kubwitabira, kureka
gusubiza bimwe mu bibazo cyangwa guhagarika gukomeza muri ubu bushakashatsi igihe icyo aricyo cyose kandi ibyo nta ngaruka byakugiraho.

**Kwishyurwa**

Nta bihembo uzahabwa kubwo kwitabira ubu bushakashatsi

**Ibanga**

Hazafatwa ingamba zikomeye kugirango ibyo utubwira bizagume ari ibanga. Amazina yawe ntaho azagaragara. Harakoreshwa umubare w'ibanga mu kubika ibyo wavuze. Ibyo utubwira bizakoreshwa gusa n'abagize ubu bushakashatsi. Turakwibutsa ko ufite uburenganzira bwo guhagarika ubushakashatsi, ndetse nanyuma yo gusubiza, ushobora kwanga ko ibyo wavuze tubikoresha. Ndateganya kuza kumenyekanisha ibyavuye muri ubu bushakashatsi ariko icyo gihe nta zina ryawe nzakoresha. Amakuru azabikwa igihe kitarenze imyaka itanu, nyuma yaho tuzayangiza

**Kumenya ibyavuye muri ubu bushakashatsi**

Ndateganya kugora igitabo kizasoka mumpera za 2020. Iki gitabo kizashyirwa mu isomero rya Kaminuza ya Witwatersrand. Ndateganya kandi kuzashyira ahagaragara ibyavuye byose mu bushakashatsi bityo nawe ushobora kubibona igihe buzaba burangiye.

**Kwemera kugira uruhare**

Uraza gusinya inyandiko yo kwemera kugira uruhare kubushake muri ubu bushakashatsi

**Kumenya andi makuru yisumbuye ho**

Niba ugize ikibazo kuri ubu bushakashatsi cyangwa ikindi wasobanuza ushobora guhamagara aba bakurikira:

Mwalimu Kato J. Junwa
Uhagarariye ikigo cy'ubushakashatsi
Kaminuza y'u Rwanda
Ishami ry'ubuzima
+250 7884 90522, njunwaksto@gmail.com
Mwarimu Gahutu Jean Bosco
Umuyobozi w'ikigo cy'ubushakashatsi
Kaminuza y'u Rwanda
Ishami ry'ubuzima

**KWEMERA KUBUSHAKE KUGIRA URUHARE MU MUBUSHAKASHATSI, UMUYOBORO W'IBAZWA ___ABARWAYI BA DIYABETE YA 2, MU RWANDA.**

**Uhagarariye ubushakashatsi:** **Marie Claire Uwamahoro**
**Aho abarizwa:** **Ishuli ry'ubuvuzi,**
**Ishami ry'abaforomo,**
**Kaminuza ya Witwatersrand, Afrika y'epfo**
**Numero ya telefone:** **+250-788402547**
**Aderese ya interinete:** **1760159@students.wits.ac.za**

**Inyito y'ubushakashatsi: "**Gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya 2 ahura nazo igihe akurikirana indwara ye ku giti cye atari kwa muganga, mu Rwanda"

**IBARUWA IMENYESHA**

**INTANGIRIRO**

Mwaramutse/Mwiriwe. Nitwa Uwamahoro Marie Claire nkaba niga icyiciro cya gatatu cya kaminuza muri Kaminuza ya Witwatersrand Afurika yepfo, ishami ry'abaforomo. Kugirango mbone impamya bushobozi y'kirenga itangwa nyuma yo kurangiza icyo cyiciro ngomba gukora ubushakashatsi. Ndimo ndakora ubushakashatsi kuri dibete y'ubwoko bwa kabiri. Ubushakashatsi bukaba bwaremewe n'ikigo gishinzwe ubushakashatsi muri Kaminuza ya Witwatersrand Afrika y'epfo ndetse n'ikigo gishinzwe ubushakashatsi muri Kaminuza y'u Rwanda mu ishami ry'ubuvuzi. Nkaba ngushimiye ko wemeye kumenya ibikorerwa muri ubu bushakashatsi.

***Nimwakire iyi nyandiko muyisome hanyuma mufate icyemezo cyo kwemera kugira uruhare muri ubu bushakashatsi. Uru rwandiko ni urwawe ushobora kuzakoresha mu gihe kiri imbere bibaye ngombwa.***

**Ni ibiki bikubiye muri ubu bushakashatsi**?

Ubu bushakashatsi bugamije gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya 2 ahura nazo igihe akurikirana indwara ye ku giti cye. Ikigamijwe muri iki kiganiro tugiye kugirana ni ukugira ngo menye ingorane uhura nazo mugihe wikurikira ubwawe utari kwa muganga. Ibizava muri iki kiganiro bizifashishwa mu gukora ifishi izajya ifasha abakuvura kumenya byihuse ingorane uhura nazo kugira ngo baguhe ubufasha bujyanye n'ikibazo ufite kandi barusheho ku kwigisha ibyagufasha.

**Icyo ngusaba muri aka kanya?**

Ndagutumira kwitabira ubu bushakashatsi Nimba ubyemeye, ndaza kukubaza ibibazo ku ngorane uhura nazo mugihe ugerageza kwikurikirana. Ndifuza kumenya mu buryo bw'imbitse uko ubyifatamo, ndetse n'ingorane uhura nazo. Ndagusaba rero ko twamarana umwanya tuganira. Ikiganiro kirafata hagati y'iminota 45-60 kandi tukaba twagikora mu mwanya ukoroherye. Ikiganiro kandi kiraza gufatwa amajwi kugirango bizadufashe kwibuka neza ibyo twaganiriye.

**Kuki nagutoranije?**

Watoranyijwe kubera ko urwaye iyo ndwara kandi nkaba ntekerea ko ufite amakuru ahagije kubijyanye n'ingorane abarwayi ba diabete ya 2 bahura nazo igihe bakurikirana indwara yabo.

**Ibyago cgangwa Ingaruka**

Nta ngaruka mbi uzahura nazo kuko witabiriye ubu bushakashatsi

**Inyungu**
inuyungu zirimo ni uko iyo fishi izajya ifasha mu buryo bwihuse abaganga bavura abarwayi ba diabete ya 2, kumenya ingorane bahura nazo kugirango babafashe.
**Kwitabira ubu bushakashatsi ni ubushake**
Kwitabira ubu bushakashatsi bituruka ku mahitamo. Ushobora kwanga kubwitabira, kureka gusubiza bimwe mu bibazo cyangwa guhagarika gukomeza muri ubu bushakashatsi igihe icyo aricyo cyose kandi ibyo nta ngaruka byakugiraho.

**Kwishyurwa**
Nta bihembo uzahabwa kubwo kwitabira ubu bushakashatsi
**Ibanga**
Amazina yawe ntaho azagaragara. Harakoreshwa umubare w'ibanga mu kubika ibyo wavuze. Amakuru yose azatangwa n'abazitabira ubu bushakashatsi azaguma ari ibanga kandi azaba ashobora kubonwa n'abakora ubu bushakashatsi gusa. Nuramuka uhisemo kuva muri ubu bushakashatsi mbere y'uko inyigo y'amakuru watanze itangira, amakuru watanze azavanwa mu yandi kandi akurwe mu bubiko bw'ubushakashatsi. Amakuru yose azava muri ubu bushakashatsi azabikwa imyaka itanu nyuma yaho ajugunywe mu buryo bwabugenewe. Uramutse ugize amakuru utanze agaragaza uwo uri we ntabwo azashyirwa mu bizifashishwa muri ubu bushakashatsi. Abahagarariye ikigo gishinzwe ubushakashatsi muri kaminuza ya Witwatersrand bazashobora kugira icyo bakubaza cyangwa bareba ku makuru watanze ajyanye n'ubu bushakashatsi mu rwego rwo kugenzura imigendekere yabwo.
**Kumenya ibyavuye muri ubu bushakashatsi**
Ndateganya kugora igitabo kizasoka mumpera za 2020. Iki gitabo kizashyirwa mu isomero rya Kaminuza ya Witwatersrand. Ndateganya kandi kuzashyira ahagaragara ibyavuye byose mu bushakashatsi bityo nawe ushobora kubibona igihe buzaba burangiye.
**Kwemera kugira uruhare**
Uraza gusinya inyandiko yo kwemera kugira uruhare kubushake muri ubu bushakashatsi
**Kumenya andi makuru yisumbuye ho**
Niba ugize ikibazo kuri ubu bushakashatsi cyangwa ikindi wasobanuza ushobora guhamagara aba bakurikira:

Mwalimu Kato J. Junwa
Uhagarariye ikigo cy'ubushakashatsi
Kaminuza y'u Rwanda
Ishami ry'ubuzima
+250 7884 90522, njunwaksto@gmail.com

Mwarimu Gahutu Jean Bosco
Umuyobozi w'ikigo cy'ubushakashatsi
Kaminuza y'u Rwanda
Ishami ry'ubuzima
+250783340040, jbgahutu@yahoo.com

## ANNEXURE 6: CONSENT FORM FOR PATIENT'S INTERVIEW

### ENGLISH VERSION

I, _____ (name and surname) hereby consent to taking part in the research study themed *"Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda"*. I have read the foregoing information, (or it has been read to me). I understand the purpose and what the study is about. I understand why I have been selected. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I can withdraw from the study at any time if I feel like doing so and without any adverse consequence. I have a right not to answer any questions at all. I also understood that the University of the Witwatersrand Human Research Ethics Committee (Medical), Institution Review Board of the University of Rwanda/College of Medicine and Health Sciences have approved the study.

I voluntarily consent to be a participant in this study**.** I am aware that my anonymity will be maintained throughout the study and that my information will be kept and treated with strict confidentiality.

**Participant's Name (please print):**

**Participant's Signature:**

**Date:**

**Researcher Name (please print):**

**Researcher's signature:**

**Date:**

## KINYARWANDA VERSION

Njyewe _____ (Amazina yombi) nemeye kujya muri ubu bushakashatsi bwiswe *"Gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya 2 ahura nazo igihe akurikirana indwara ye ku giti cye atari kwa muganga, mu Rwanda".*

Nasomye (Nasomewe) amakuru ajyanye nabwo.

Namenye icyo bugamije. Namenyeshejwe impamvu bantoranyije. Nabonye umwanya uhagije wo kubaza ibibazo kandi byose byasubijwe muburyo bushimishije. Nshobora kuva muri ubu bushakashatsi igihe icyo aricyo cyose nta nkurikizi bingize ho. Mfite uburenganzira bwo gusubiza cyangwa sinsubize bimwe mubibazo.

Namenyeshejwe ko ubushakashatsi bwemewe n'ibigo by'ubushakashatsi bya Kaminuza ya Witwatersrand na Kaminuza y'u Rwanda. Nemeye kubushake kujya muri ubu bushakashatsi. Kandi ndabizi ko amakuru yanjye ntawe uzamenya nimba arijye wayatanze kuko ntazina rizashyirwaho kandi azabikwa muburyo bw'ibanga.

**Amazina y'ubazwa (yandike):**
**Umukono:**
**Itariki:**

**Amazina y'ukora ubushakashatsi (yandike):**
**Umukono:**
**Itariki:**

## ANNEXURE 7: CONSENT FORM FOR RECORDING PATIENTS' INTERVIEW

### ENGLISH VERSION

I, _____ (name and surname) hereby consent to taking part in the research study themed *"Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda"*.

I have read and understood the study and the purpose for which it is being conducted.

I understand that it is at my will to have the interview recorded or not. I understand that nothing adverse happens to me if I choose not to have the interview recorded.

I also understand that I can have the recording stopped, halted, if I decide to.

I understand that my interview recording will be kept in the strictest sense possible and that my data will be treated as confidential.

Once the interview recordings are transcribed, the transcript will be kept and audio recording will be destroyed at an appropriate time following the University of the Witwatersrand regulations. The recording will be kept on only one central computer to allow comparing the transcript and the audio recording during the analysis of the data. No any other person outside the study will have access to listen to the audio recording.

**Participant's Name (please print):**

**Participant's Signature:**

**Date:**

**Researcher Name (please print):**

**Researcher's signature:**

**Date:**

## KINYARWANDA VERSION

Njyewe _____ (Amazina yombi) nemeye ku bushake kujya muri ubu bushakashatsi bwiswe *"Gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya 2 ahura nazo igihe akurikirana indwara ye ku giti cye atari kwa muganga, mu Rwanda".*

Nasomye kandi numvise icyo ubushakashati bukubiyemo nicyo bugamije.

Numvise ko nshobora kwemera ko iki kiganiro gifatwa amajwi cyangwa ntigifatwe kandi ntangaruka bishobora kungiraho.

Numvise ko igihe mbishakiye gufata amajwi byahagarara.

Numvise ko amajwi yanjya azabikwa mu ibanga kandi amajwi akazandikwa ubundi agasibwa bikurikije amategeko ya Kaminuza ya Witwatersrand. Amajwi azabikwa mu ibanga kuri mudasobwa izaba yemewe gukoresha gusa n'abafite uruhare kuri ubu bushakashatsi

**Amazina y'ubazwa (yandike):**
**Umukono:**
**Itariki:**

**Amazina y'ukora ubushakashatsi (yandike):**
**Umukono:**
**Itariki:**

**ANNEXURE 8: INFORMATION SHEET FOR A SURVEY TO ASSESS THE CONTENT VALIDITY OF INSTRUMENT**

**Name of Principle Investigator:** **Marie Claire Uwamahoro,**
**Institution:** **School of Therapeutic sciences,**
**Nursing Education Department,**
**University of the Witwatersrand, South Africa.**
**Contact Phone:** **+250-788402547**
**Email:** **1760159@students.wits.ac.za**

**The overall study title:** Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes patients in Rwanda.

**The sub-study:** "Assessement of content validity of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda"

**Introductions**

Good morning/afternoon to you. My name is Marie Claire Uwamahoro. I am currently enrolled in the Doctor of Philosophy in Nursing at the University of Witwatersrand. I am doing research on type 2 diabetes. The study has been approved by the Research Ethics Committee (Medical) of the University of Witwatersrand and the Institution Review Board of the University of Rwanda/College of Medicine and Health Sciences. Thank you for accepting to learn about my study.

***Please kindly receive and read this information sheet and make an informed decision. This letter is yours to keep for future reference.***

**What is involved in the study**?

I developed an instrument that will assess self-management barriers of type 2 diabetes patients. The purpose of this survey is to assess if the instrument developed has appropriate content to measure self-management barriers of patients with type 2 diabetes. This instrument is needed for better support and education of patients with type 2 diabetes.

**What will you be asked to do?**

You will be asked to read the items of the instrument and judge them by rating their relevance, clarity, simplicity and ambiguity. You will be provided a 4-point Likert-type scale that will be used for that purpose. It will be explained to you and it will take you 30-40 minutes to complete the task.

**Why have you been selected?**

I have selected you because of your expertise in type 2 diabetes. You have been working/teaching diabetes and I believe you are in a better position to assess whether the content of this instrument is appropriate. I would like to learn from you on these matters.

**Risks**

There are no known or anticipated risks or discomforts associated with participating in this study.

**Benefits**

The possible benefits associated with participation in this study include informing health providers on self-management barriers of type 2 diabetes patients for better support.

**Participation is voluntary**

You reserve the right to participate in this study and you can withdraw your consent to participate in this study at any time without any negative consequences or penalties. You have the right not to answer questions if you feel uncomfortable to do so.

**Reimbursements for out of pocket expenses.**

You will not be compensated for your participation in this research.

**Confidentiality**:

Your name will not appear anywhere; a unique identifier will be used to refer to you to protect your identity. All data collected will remain confidential and accessible only to the investigators of this study.

If the results are published, your name will not be used. If you choose to withdraw from this study prior to initiation of the data analysis phase, your data will be removed and destroyed from our database. Information collected in this study will be kept for five years and then destroyed. Representatives of the University of Witwatersrand Research Ethics Committee (medical) may contact you or require access to your study-related records to monitor the conduct of the research.

**Getting feedback from the study**

I plan to write a book from these findings. The book will be ready by the end of 2020. This book will be open in the university library. I also plan to publish academic papers in online journals. You will be able to access them once you log in.

**Consent**

A Consent Form will be provided for you to sign prior to the interview

**Contact details for further information**

If you have concerns about any aspect of this study or want to report any problem about this study, you can use the following contact details:

Professor Kato J. Junwa
The Chairperson of Institution Review Board
University of Rwanda
College of Medicine and Health Sciences
+250 7884 90522
njunwakato@gmail.com
Professor Gahutu Jean Bosco
Director of Research Center, University of Rwanda, College of Medicine and Health Sciences
+250783340040
jbgahutu@yahoo.com

**ANNEXURE 9: CONSENT FORM TO PARTICIPATE IN CONTENT VALIDITY SURVEY**

**ANNEXURE 9: CONSENT FORM TO PARTICIPATE IN CONTENT VALIDITY SURVEY**

I, _____ (name and surname) hereby consent to taking part in the research study themed *"Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda"* I will specifically participate in a sub-study entitled "*Assessement of content validity of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda"*. I have read the foregoing information, (or it has been read to me). I understand the purpose and what the study is about. I understand why I have been selected. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I can withdraw from the study at any time if I feel like doing so and without any adverse consequence. I have a right not to answer any questions at all. I also understood that the University of the Witwatersrand Human Research Ethics Committee (Medical), Institution Review Board of the University of Rwanda/College of Medicine and Health Sciences have approved the study.

I voluntarily consent to be a participant in this study**.** I am aware that my anonymity will be maintained throughout the study and that my information will be kept and treated with strict confidentiality.

**Participant's Name (please print):**

**Participant's Signature:**

**Date:**

**Researcher Name (please print):**

**Researcher's signature:**

**Date:**

## ANNEXURE 10: INFORMATION SHEET TO ASSESS THE FACE VALIDITY

## ENGLISH VERSION

**Name of Principle Investigator:** **Marie Claire Uwamahoro,**
**Institution:** **School of Therapeutic sciences,**
**Nursing Education Department,**
**University of the Witwatersrand, South Africa.**
**Contact Phone:** **+250-788402547**
**Email:** **1760159@students.wits.ac.za**

**The overall study title:** Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda.

**The sub-study:** "Assessement of face validity of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda"

**Introductions**

Good morning/afternoon to you. My name is Marie Claire Uwamahoro. I am currently enrolled in the Doctor of Philosophy in Nursing at the University of Witwatersrand. I am doing research on type 2 diabetes. The study has been approved by the Research Ethics Committee (Medical) of the University of Witwatersrand and the Institution Review Board of the University of Rwanda/College of Medicine and Health Sciences. Thank you for accepting to learn about my study.

***Please kindly receive and read this information sheet and make an informed decision. This letter is yours to keep for future reference.***

**What is involved in the study**?

I developed an instrument that will assess self-management barriers of type 2 diabetes patients. The purpose of this survey is to assess if the instrument developed has appropriate content to measure self-management barriers of patients with type 2 diabetes. This instrument is needed for better support and education of patients with type 2 diabetes.

**What will you be asked to do?**

You will be asked to read each item of the instrument then choose the appropriate response depending on the barrier that you face. A 4-point Likert scale (strongly disagree =1, disagree =2, agree =3 and strongly angree =4) will be used for that purpose. It will be explained; after that you will be given a face validity questionnaire for you to judge the items. The whole process will take you 30-40 minutes.

**Why have been you selected?**

I have selected you because you live with type 2 diabetes and I think you have appropriate and enough information on self-management barriers. I believe you are in a better position to assess whether the content of this instrument is appropriate for type 2 diabetic patients.

**Risks**

There are no known or anticipated risks or discomforts associated with participating in this study.

**Benefits**

The possible benefits associated with participation in this study include informing health providers on self-management barriers of type 2 diabetes patients for better support.

**Participation is voluntary**

You reserve the right to participate in this study and you can withdraw your consent to participate in this study at any time without any negative consequences or penalties. You have the right not to answer questions if you feel uncomfortable to do so.

**Reimbursements for out of pocket expenses.**

You will not be compensated for your participation in this research.

**Confidentiality**:

Your name will not appear anywhere; a unique identifier will be used to refer to you to protect your identity. All data collected will remain confidential and accessible only to the investigators of this study.

If the results are published, your name will not be used. If you choose to withdraw from this study prior to initiation of the data analysis phase, your data will be removed and destroyed from our database. Information collected in this study will be kept for five years and then destroyed. Representatives of the University of Witwatersrand Research Ethics Committee (medical) may contact you or require access to your study-related records to monitor the conduct of the research.

**Getting feedback from the study**

I plan to write a book from these findings. The book will be ready by the end of 2020. This book will be open in the university library. I also plan to publish academic papers in online journals. You will be able to access them once you log in.

**Consent**

A Consent Form will be provided for you to sign prior to the interview.

**Contact details for further information**

If you have concerns about any aspect of this study or want to report any problem about this study, you can use the following contact details:

Professor Kato J. Junwa
The Chairperson of Institution Review Board
University of Rwanda
College of Medicine and Health Sciences
+250 7884 90522
njunwakato@gmail.com

Professor Gahutu Jean Bosco
Director of Research Center, University of Rwanda, College of Medicine and Health Sciences
+250783340040
jbgahutu@yahoo.com

## KINYARWANDA VERSION

**KWEMERA KUBUSHAKE KUGIRA URUHARE MU MUBUSHAKASHATSI, UMUYOBORO W'IBAZWA ___ABARWAYI BA DIYABETE YA 2, MU RWANDA.**

**Uhagarariye ubushakashatsi:** **Marie Claire Uwamahoro**
**Aho abarizwa:** **Ishuli ry'ubuvuzi,**
**Ishami ry'abaforomo,**
**Kaminuza ya Witwatersrand, Afrika y'epfo**
**Numero ya telefone:** **+250-788402547**
**Aderese ya interinete:** **1760159@students.wits.ac.za**

**Inyito nini y'ubushakashatsi: "**Gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya 2 ahura nazo igihe akurikirana indwara ye ku giti cye atari kwa muganga, mu Rwanda"

**Agace k'inyito:** Kurebe niba ibibazo byabajijwe bireba ingorane abarwayi ba diabete y'ubwoko bwa 2 bo mu Rwanda bahura nazo igihe bikurikirana

### IBARUWA IMENYESHA

### INTANGIRIRO

Mwaramutse/Mwiriwe. Nitwa Uwamahoro Marie Claire nkaba niga icyiciro cya gatatu cya kaminuza muri Kaminuza ya Witwatersrand Afurika yepfo, ishami ry'abaforomo. Kugirango mbone impamya bushobozi y'kirenga itangwa nyuma yo kurangiza icyo cyiciro ngomba gukora ubushakashatsi. Ndimo ndakora ubushakashatsi kuri dibete y'ubwoko bwa kabiri. Ubushakashatsi bukaba bwaremewe n'ikigo gishinzwe ubushakashatsi muri Kaminuza ya Witwatersrand Afrika y'epfo ndetse n'ikigo gishinzwe ubushakashatsi muri Kaminuza y'u Rwanda mu ishami ry'ubuvuzi. Nkaba ngushimiye ko wemeye kumenya ibikorerwa muri ubu bushakashatsi.

***Nimwakire iyi nyandiko muyisome hanyuma mufate icyemezo cyo kwemera kugira uruhare muri ubu bushakashatsi. Uru rwandiko ni urwawe ushobora kuzakoresha mu gihe kiri imbere bibaye ngombwa.***

**Ni ibiki bikubiye muri ubu bushakashatsi**?

Ubu bushakashatsi bugamije gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya 2 ahura nazo igihe akurikirana indwara ye ku giti cye. Ikigamijwe muri aka gace k'ubushakashatsi ni ukugirango tumenye nimba ibibazo twabajije bihura n'ingorane abarwayi ba diyabete y'ubwoko bwa kabiri bahura mugihe bikurikira.

**Icyo ngusaba muri aka kanya?**

Ndagutumira kwitabira ubu bushakashatsi. Nimba ubyemeye, ndaza kugusaba kusubiza ibibazo biri mu ifishi twakoze ukoreshje amanota agera kuri ane (sibyo na gato=1, si byo=2, ni byo=3, nibyo cyane=4). Numara gusubiza ndaza kuguha ibindi bibazo bigufasha gusuzuma niba bya bibazo byo muri ya fishi aribyo, byuzuye cyangwa byanditse mu magambo yumvikana. Byose hamwe birafata hagati y'iminota 30-40

**Kuki nagutoranije?**

Watoranyijwe kubera ko urwaye iyo ndwara kandi nkaba ntekerea ko ufite amakuru ahagije kubijyanye n'ingorane abarwayi ba diabete ya 2 bahura nazo igihe bakurikirana indwara yabo.

**Ibyago cgangwa Ingaruka**
Nta ngaruka mbi uzahura nazo kuko witabiriye ubu bushakashatsi

**Inyungu**
inuyungu zirimo ni uko iyo fishi izajya ifasha mu buryo bwihuse abaganga bavura abarwayi ba diabete ya 2, kumenya ingorane bahura nazo kugirango babafashe.

**Kwitabira ubu bushakashatsi ni ubushake**
Kwitabira ubu bushakashatsi bituruka ku mahitamo. Ushobora kwanga kubwitabira, kureka gusubiza bimwe mu bibazo cyangwa guhagarika gukomeza muri ubu bushakashatsi igihe icyo aricyo cyose kandi ibyo nta ngaruka byakugiraho.

**Kwishyurwa**
Nta bihembo uzahabwa kubwo kwitabira ubu bushakashatsi

**Ibanga**
Amazina yawe ntaho azagaragara. Harakoreshwa umubare w'ibanga mu kubika ibyo wavuze. Amakuru yose azatangwa n'abazitabira ubu bushakashatsi azaguma ari ibanga kandi azaba ashobora kubonwa n'abakora ubu bushakashatsi gusa. Nuramuka uhisemo kuva muri ubu bushakashatsi mbere y'uko inyigo y'amakuru watanze itangira, amakuru watanze azavanwa mu yandi kandi akurwe mu bubiko bw'ubushakashatsi. Amakuru yose azava muri ubu bushakashatsi azabikwa imyaka itanu nyuma yaho ajugunywe mu buryo bwabugenewe. Uramutse ugize amakuru utanze agaragaza uwo uri we ntabwo azashyirwa mu bizifashishwa muri ubu bushakashatsi. Abahagarariye ikigo gishinzwe ubushakashatsi muri kaminuza ya Witwatersrand bazashobora kugira icyo bakubaza cyangwa bareba ku makuru watanze ajyanye n'ubu bushakashatsi mu rwego rwo kugenzura imigendekere yabwo.

**Kumenya ibyavuye muri ubu bushakashatsi**
Ndateganya kugora igitabo kizasoka mumpera za 2020. Iki gitabo kizashyirwa mu isomero rya Kaminuza ya Witwatersrand. Ndateganya kandi kuzashyira ahagaragara ibyavuye byose mu bushakashatsi bityo nawe ushobora kubibona igihe buzaba burangiye.

**Kwemera kugira uruhare**
Uraza gusinya inyandiko yo kwemera kugira uruhare kubushake muri ubu bushakashatsi

**Kumenya andi makuru yisumbuye ho**
Niba ugize ikibazo kuri ubu bushakashatsi cyangwa ikindi wasobanuza ushobora guhamagara aba bakurikira:

Mwalimu Kato J. Junwa
Uhagarariye ikigo cy'ubushakashatsi
Kaminuza y'u Rwanda
Ishami ry'ubuzima
+250 7884 90522, njunwakato@gmail.com

Mwarimu Gahutu Jean Bosco
Umuyobozi w'ikigo cy'ubushakashatsi
Kaminuza y'u Rwanda
Ishami ry'ubuzima
+250783340040, jbgahutu@yahoo.com

## ANNEXURE 11: CONSENT FORM TO PARTICIPATE IN FACE VALIDITY SURVEY

### ENGLISH VERSION

I, _____ (name and surname) hereby consent to taking part in the research study themed *"Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda"* I will specifically participate in a sub-study entitled "*Assessement of face validity of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda"*. I have read the foregoing information, (or it has been read to me). I understand the purpose and what the study is about. I understand why I have been selected. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I can withdraw from the study at any time if I feel like doing so and without any adverse consequence. I have a right not to answer any or all of the questions. I also understood that the University of the Witwatersrand Human Research Ethics Committee (Medical), Institution Review Board of the University of Rwanda/College of Medicine and Health Sciences have approved the study.

I voluntarily consent to be a participant in this study**.** I am aware that my anonymity will be maintained throughout the study and that my information will be kept and treated with strict confidentiality.

**Participant's Name (please print):**

**Participant's Signature:**

**Date:**

**Researcher Name (please print):**

**Researcher's signature:**

Date:

**KINYARWANDA VERSION**

Njyewe _____ (Amazina yombi) nemeye ku bushake kujya muri ubu bushakashatsi bwiswe *"Gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya 2 ahura nazo igihe akurikirana indwara ye ku giti cye atari kwa muganga, mu Rwanda".* Byumwihariko mu gace kabwo kitwa *"Gusuzuma niba ibibazo byabajijwe mu ifishi yakozwe irebana n'ingorane abarwayi ba diyabete y'ubwoko bwa kabiri bahura nazo igihe bikurikirana byuzuye, bimeze neza kandi bisomeka"*

Nasomye kandi numvise icyo ubushakashati bukubiyemo nicyo bugamije. Numvise impamvu bantoranije. Nagize umwanya uhagije wo kubaza ibibazo, kandi nanyuzwe n'ibisobanuro bampaye. Numvise ko nshobora kuva mu bushakashatsi igihe icyo aricyo cyose, kandi ntangaruka bingizeho. Mfite kandi uburenganzira bwo kudasubiza ikibazo igihe mbihisemo. Numvise ko ubu bushakashatsi bwemejwe n'ababishinzwe bavuye muri Kaminuza y'u Rwnda ni ya Witwatersrand.

Bityo rero nemeye kugira uruhare muri ubu bushakashatsi, kandi nzi neza ko ibyo nasubije ntawundi uzabimenya bizaba ibanga

**Amazina y'ubazwa (yandike):**
**Umukono:**
**Itariki:**

**Amazina y'ukora ubushakashatsi (yandike):**
**Umukono:**
**Itariki:**

**ANNEXURE 12: INFORMATION SHEET CLINICAL UTILITY OF INSTRUMENT – REGISTERED NURSES AND MEDICAL DOCTORS**


| | |
|---|---|
| **Name of Principle Investigator:** | **Marie Claire Uwamahoro** |
| **Institution:** | **School of Therapeutic sciences,** |
| | **Nursing Education Department,** |
| | **University of the Witwatersrand, South Africa** |
| **Contact Phone:** | **+250-788402547** |
| **Email:** | **1760159@students.wits.ac.za** |


**The overall study title:** Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda

**The sub-study:** Assessment of clinical utility of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda

**Introductions**

Good morning/afternoon to you. My name is Marie Claire Uwamahoro. I am currently enrolled in the Doctor of Philosophy in Nursing at the University of Witwatersrand. I am doing research on type 2 diabetes. The study has been approved by the Research Ethics Committee (Medical) of the University of Witwatersrand and the Institution Review Board of the University of Rwanda/College of Medicine and Health Sciences. Thank you for accepting to learn about my study.

***Please kindly receive and read this information sheet and make an informed decision. This letter is yours to keep for future reference*.**

**What is involved in the study**?

This study is about development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda. The purpose of this cross-sectional study is to assess the clinical utility (how easy is the instrument) of the tool that I developed. The content of the instrument was validated by the experts, now I want you to use it to see how easy it is to use in diabetes clinics. The results will be helpful and will be used to refine the instrument to make it easy to use.

**What will you be asked to do?**

I am inviting you to participate in this study. If you accept, you will be given the instrument that I developed (it will be initially explained to you). You will meet diabetes patients and use the instrument to assess self-management barriers of 10 type 2 diabetes. After assessing patients, you will be provided with a questionnaire that you will you use to assess how easy it was to administer the instrument to patients. I will be particularly interested in learning about your experience in using the instrument. Your time is valuable and I will ask you to assess two patients per day (minimum) for you to continue your daily activities. This could take about 10-15 minutes per patient and could be done at any time at your convenience.

**Why have you been selected?**

I have selected you because you have been working here in the diabetes clinic.

**Risks**

There are no known or anticipated risks or discomforts associated with participating in this study.

**Benefits**

The possible benefits associated with participation in this study include informing health providers on self-management barriers of type 2 diabetes patients for better support.

**Participation is voluntary**

You reserve the right to participate in this study and you can withdraw your consent to participate in this study at any time without any negative consequences or penalties. You have the right not to answer questions if you feel uncomfortable to do so.

**Reimbursements for "out of pocket" expenses.**

You will not be compensated for your participation in this research.

**Confidentiality**:

Your name will not appear anywhere; a unique identifier will be used to refer to you to protect your identity. All data collected will remain confidential and accessible only to the investigators of this study.

If the results are published, your name will not be used. If you choose to withdraw from this study prior to initiation of the data analysis phase, your data will be removed and destroyed from our database. Information collected in this study will be kept for five years and then destroyed. Representatives of the University of Witwatersrand Research Ethics Committee (medical) may contact you or require access to your study-related records to monitor the conduct of the research.

**Getting feedback from the study**

I plan to write a book from these findings. The book will be ready by the end of 2020. This book will be open in the university library. I also plan to publish academic papers in online journals. You will be able to access them once you log in.

**Consent**

A Consent Form will be provided for you to sign prior to the interview

**Contact details for further information**

If you have concerns about any aspect of this study or want to report any problem about this study, you can use the following contact details:

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The chairperson of Institution Review Board
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College of Medicine and Health Sciences
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njunwakato@gmail.com
Professor Gahutu Jean Bosco
Director of Research Center, University of Rwanda
College of Medicine and Health Sciences
+250783340040
jbgahutu@yahoo.com

## ANNEXURE 13: CONSENT FORM CLINICAL UTILITY

I, _____ (name and surname) hereby consent to taking part in the research study themed *"Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda"*. I will specifically participate in a sub-study entitled "*Assessment of clinical utility of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda"* I have read the foregoing information, (or it has been read to me). I understand the purpose and what the study is about. I understand why I have been selected. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I can withdraw from the study at any time if I feel like doing so and without any adverse consequence. I have a right not to answer any or all of the questions. I also understood that the University of the Witwatersrand Human Research Ethics Committee (Medical), Institution Review Board of the University of Rwanda/College of Medicine and Health Sciences have approved the study.

I voluntarily consent to be a participant in this study**.** I am aware that my anonymity will be maintained throughout the study and that my information will be kept and treated with strict confidentiality.

**Participant's Name (please print):**

**Participant's Signature:**

**Date:**

**Researcher Name (please print):**

**Researcher's signature:**

**Date:**

## ANNEXURE 14: INFORMATION SHEET CONSTRUCT VALIDITY

## ENGLISH VERSION

**Name of Principle Investigator:** **Marie Claire Uwamahoro**
**Institution:** **School of Therapeutic sciences,**
**Nursing Education Department,**
**University of the Witwatersrand, South Africa**
**Contact Phone:** **+250-788402547**
**Email:** **1760159@students.wits.ac.za**

**The overall study title:** Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda.

**Introductions**

Good morning/afternoon to you. My name is Marie Claire Uwamahoro. I am currently enrolled in the Doctor of Philosophy in Nursing at the University of Witwatersrand. I am doing research on type 2 diabetes. The study has been approved by the Research Ethics Committee (Medical) of the University of Witwatersrand and the Institution Review Board of the University of Rwanda/College of Medicine and Health Sciences. Thank you for accepting to learn about my study.

***Please kindly receive and read this information sheet and make an informed decision. This letter is yours to keep for future reference*.**

**What is involved in the study**?

This study is about the development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda. The purpose of this cross-sectional study is to establish the construct validity of the instrument developed. The content of the instrument was validated by the experts, patients and clinicians. Now I want you to complete it by showing the barriers you encounter.

**What will you be asked to do?**

I am inviting you to participate in this study. If you accept, you will be given the instrument that I developed (it will be initially explained to you) and you will complete the questionnaire. This could take about 20-30 minutes and could be done at any time at your convenience.

**Why have you been selected?**

I have selected you because you have been working here in the diabetes clinic.

**Risks**

There are no known or anticipated risks or discomforts associated with participating in this study.

**Benefits**

The possible benefits associated with participation in this study include informing health providers on self-management barriers of type 2 diabetes patients for better support.

**Participation is voluntary**

You reserve the right to participate in this study and you can withdraw your consent to participate in this study at any time without any negative consequences or penalties. You have the right not to answer questions if you feel uncomfortable to do so.

**Reimbursements for "out of pocket" expenses.**

You will not be compensated for your participation in this research.

**Confidentiality**:

Your name will not appear anywhere; a unique identifier will be used to refer to you to protect your identity. All data collected will remain confidential and accessible only to the investigators of this study.

If the results are published, your name will not be used. If you choose to withdraw from this study prior to initiation of the data analysis phase, your data will be removed and destroyed from our database. Information collected in this study will be kept for five years and then destroyed. Representatives of the University of Witwatersrand Research Ethics Committee (medical) may contact you or require access to your study-related records to monitor the conduct of the research.

**Getting feedback from the study**

I plan to write a book from these findings. The book will be ready by the end of 2020. This book will be open in the university library. I also plan to publish academic papers in online journals. You will be able to access them once you log in.

**Consent**

A Consent Form will be provided for you to sign prior to the interview

**Contact details for further information**

If you have concerns about any aspect of this study or want to report any problem about this study, you can use the following contact details:

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The Chairperson of Institution Review Board
University of Rwanda
College of Medicine and Health Sciences
+250 7884 90522
njunwakato@gmail.com

Professor Gahutu Jean Bosco
Director of Research Center, University of Rwanda
College of Medicine and Health Sciences
+250783340040
jbgahutu@yahoo.com

## KINYARWANDA VERSION

**KWEMERA KUBUSHAKE KUGIRA URUHARE MU MUBUSHAKASHATSI, UMUYOBORO W'IBAZWA ___ABARWAYI BA DIYABETE YA 2, MU RWANDA.**


**Uhagarariye ubushakashatsi:** **Marie Claire Uwamahoro**
**Aho abarizwa:** **Ishuli ry'ubuvuzi,**
**Ishami ry'abaforomo,**
**Kaminuza ya Witwatersrand, Afrika y'epfo**
**Numero ya telefone:** **+250-788402547**
**Aderese ya interinete:** **1760159@students.wits.ac.za**


**Inyito nini y'ubushakashatsi: "**Gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya 2 ahura nazo igihe akurikirana indwara ye ku giti cye atari kwa muganga, mu Rwanda"

**Agace k'inyito:** Kurebe niba ibibazo byabajijwe bireba ingorane abarwayi ba diabete y'ubwoko bwa 2 bo mu Rwanda bahura nazo igihe bikurikirana

### IBARUWA IMENYESHA

### INTANGIRIRO

Mwaramutse/Mwiriwe. Nitwa Uwamahoro Marie Claire nkaba niga icyiciro cya gatatu cya kaminuza muri Kaminuza ya Witwatersrand Afurika yepfo, ishami ry'abaforomo. Kugirango mbone impamya bushobozi y'kirenga itangwa nyuma yo kurangiza icyo cyiciro ngomba gukora ubushakashatsi. Ndimo ndakora ubushakashatsi kuri dibete y'ubwoko bwa kabiri. Ubushakashatsi bukaba bwaremewe n'ikigo gishinzwe ubushakashatsi muri Kaminuza ya Witwatersrand Afrika y'epfo ndetse n'ikigo gishinzwe ubushakashatsi muri Kaminuza y'u Rwanda mu ishami ry'ubuvuzi. Nkaba ngushimiye ko wemeye kumenya ibikorerwa muri ubu bushakashatsi.

***Nimwakire iyi nyandiko muyisome hanyuma mufate icyemezo cyo kwemera kugira uruhare muri ubu bushakashatsi. Uru rwandiko ni urwawe ushobora kuzakoresha mu gihe kiri imbere bibaye ngombwa.***

**Ni ibiki bikubiye muri ubu bushakashatsi**?

Ubu bushakashatsi bugamije gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya 2 ahura nazo igihe akurikirana indwara ye ku giti cye. Ikigamijwe muri aka gace k'ubushakashatsi ni ukugirango tumenye nimba ibibazo twabajije bihura n'ingorane abarwayi ba diyabete y'ubwoko bwa kabiri bahura mugihe bikurikira.

**Icyo ngusaba muri aka kanya?**

Ndagutumira kwitabira ubu bushakashatsi. Nimba ubyemeye, ndaza kugusaba kusubiza ibibazo biri mu ifishi twakoze ukoreshje amanota agera kuri ane. Byose hamwe birafata hagati y'iminota 20-30

**Kuki nagutoranije?**

Watoranyijwe kubera ko urwaye iyo ndwara kandi nkaba ntekerea ko ufite amakuru ahagije kubijyanye n'ingorane abarwayi ba diabete ya 2 bahura nazo igihe bakurikirana indwara yabo.

**Ibyago cgangwa Ingaruka**

Nta ngaruka mbi uzahura nazo kuko witabiriye ubu bushakashatsi

**Inyungu**
inuyungu zirimo ni uko iyo fishi izajya ifasha mu buryo bwihuse abaganga bavura abarwayi ba diabete ya 2, kumenya ingorane bahura nazo kugirango babafashe.

**Kwitabira ubu bushakashatsi ni ubushake**
Kwitabira ubu bushakashatsi bituruka ku mahitamo. Ushobora kwanga kubwitabira, kureka gusubiza bimwe mu bibazo cyangwa guhagarika gukomeza muri ubu bushakashatsi igihe icyo aricyo cyose kandi ibyo nta ngaruka byakugiraho.
**Kwishyurwa**
Nta bihembo uzahabwa kubwo kwitabira ubu bushakashatsi

**Ibanga**
Amazina yawe ntaho azagaragara. Harakoreshwa umubare w'ibanga mu kubika ibyo wavuze. Amakuru yose azatangwa n'abazitabira ubu bushakashatsi azaguma ari ibanga kandi azaba ashobora kubonwa n'abakora ubu bushakashatsi gusa. Nuramuka uhisemo kuva muri ubu bushakashatsi mbere y'uko inyigo y'amakuru watanze itangira, amakuru watanze azavanwa mu yandi kandi akurwe mu bubiko bw'ubushakashatsi. Amakuru yose azava muri ubu bushakashatsi azabikwa imyaka itanu nyuma yaho ajugunywe mu buryo bwabugenewe. Uramutse ugize amakuru utanze agaragaza uwo uri we ntabwo azashyirwa mu bizifashishwa muri ubu bushakashatsi. Abahagarariye ikigo gishinzwe ubushakashatsi muri kaminuza ya Witwatersrand bazashobora kugira icyo bakubaza cyangwa bareba ku makuru watanze ajyanye n'ubu bushakashatsi mu rwego rwo kugenzura imigendekere yabwo.
**Kumenya ibyavuye muri ubu bushakashatsi**
Ndateganya kugora igitabo kizasoka mumpera za 2020. Iki gitabo kizashyirwa mu isomero rya Kaminuza ya Witwatersrand. Ndateganya kandi kuzashyira ahagaragara ibyavuye byose mu bushakashatsi bityo nawe ushobora kubibona igihe buzaba burangiye.
**Kwemera kugira uruhare**
Uraza gusinya inyandiko yo kwemera kugira uruhare kubushake muri ubu bushakashatsi
**Kumenya andi makuru yisumbuye ho**
Niba ugize ikibazo kuri ubu bushakashatsi cyangwa ikindi wasobanuza ushobora guhamagara aba bakurikira:

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## ANNEXURE 15: CONSENT FORM CONSTRUCT VALIDITY

### ENGLISH VERSION

I, _____ (name and surname) hereby consent to taking part in the research study themed *"Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 in Rwanda"*. I will specifically participate in a sub-study entitled "*Assessment of construct validity of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda*" I have read the foregoing information, (or it has been read to me). I understand the purpose and what the study is about. I understand why I have been selected. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I can withdraw from the study at any time if I feel like doing so and without any adverse consequence. I have a right not to answer any questions at all. I also understood that the University of the Witwatersrand Human Research Ethics Committee (Medical), Institution Review Board of the University of Rwanda/College of Medicine and Health Sciences have approved the study.

I voluntarily consent to be a participant in this study**.** I am aware that my anonymity will be maintained throughout the study and that my information will be kept and treated with strict confidentiality.

**Participant's Name (please print):**

**Participant's Signature:**

**Date:**

**Researcher Name (please print):**

**Researcher's signature:**

**Date:**

**KINYARWANDA VERSION**

Njyewe _____ (Amazina yombi) nemeye ku bushake kujya muri ubu bushakashatsi bwiswe *“Gukora ifishi isuzuma ingorane umurwayi urwaye diyabete ya*

Nasomye kandi numvise icyo ubushakashati bukubiyemo nicyo bugamije. Numvise impamvu bantoranije. Nagize umwanya uhagije wo kubaza ibibazo, kandi nanyuzwe n’ibisobanuro bampaye. Numvise ko nshobora kuva mu bushakashatsi igihe icyo aricyo cyose, kandi ntangaruka bingizeho. Mfite kandi uburenganzira bwo kudasubiza ikibazo igihe mbihisemo. Numvise ko ubu bushakashatsi bwemejwe n’ababishinzwe bavuye muri Kaminuza y’u Rwnda ni ya Witwatersrand.

Bityo rero nemeye kugira uruhare muri ubu bushakashatsi, kandi nzi neza ko ibyo nasubije ntawundi uzabimenya bizaba ibanga

**Amazina y’ubazwa (yandike):**
**Umukono:**
**Itariki:**

**Amazina y’ukora ubushakashatsi (yandike):**
**Umukono:**
**Itariki:**

**ANNEXURE 16: INTEGRATIVE REVIEW DATA COLLECTION EXTRACTION TOOL**

| | | |
|---|---|---|
| 1. | Author(s) | |
| 2. | Year of publication | |
| 3. | Purpose of study | |
| 4. | Study design | |
| 5. | Study setting | |
| 6. | Sample | |
| 7. | Data collection | |
| 8. | Data analysis | |
| 9. | Results | |
| 10. | Level of evidence | |

## ANNEXURE 17: CRITERIA FOR QUALITY OF THE STUDIES INCLUDED

| Quantitative grading: Mann (1996) | |
|---|---|
| **Grade I studies** | **Randomised controlled trials** |
| Grade IA | Randomised controlled trials, sample size has been calculated and an accurate, standard definition of outcome variables provided. |
| Grade IB | Only the standard definition of outcome variables is available |
| Grade IC | When none of the above criteria is provided |
| **Grade II studies** | Prospective studies with a comparison group such as a non-randomised trial or good observational studies or retrospective studies with controls clarifying confounding variables |
| Grade IIA | Sample size has been calculated and an accurate standard definition |
| Grade IIB | Having at least one of the criteria of a Grade IIA study |
| **Grade III studies** | Studies which are not included in Grade I and II are Grade III |
| Grade IIIA | Containing a comparison group, calculated sample size and accurate standard definition of outcome variables. |

| Qualitative grading: Cesario et al.'s (2010) | |
|---|---|
| QI | Good quality; 75% to 100% (22.5 to 30); |
| QII | Fair 50% to 74% (15 to 22.4) |
| QIII | Poor quality; <50% of the criteria were met (less than a total score of 15) good evidence |
| Five categories to assess<br>- descriptive vividness<br>- methodological congruence with sub-categories (1) rigour in documentation, (2) procedure and (3) ethics and confirmability<br>- analytical preciseness<br>- theoretical connectedness<br>- heuristic relevance with sub-categories intuitive recognition, relationship to the existing body of knowledge and applicability.<br>A score of 0 to 3 was used to evaluate whether the different criteria were met, with 0 = no evidence, 1 = poor evidence, 2 = fair evidence and 3 = good evidence | |

| De Souza 2010 et al. (2010) | |
|---|---|
| Level 1 | Evidence resulting from meta-analysis of multiple randomised controlled clinical trials |
| Level 2 | Evidence from individual studies with experimental design |
| Level 3 | Evidence from quasi-experimental studies |
| Level 4 | Evidence of descriptive (non-experimental) studies or with a qualitative approach |
| Level 5 | Evidence from case reports or from experience; |
| Level 6 | Evidence based on opinions of specialists |

## ANNEXURE 18: DATA MATRIX

| No | Author, year of publication, database and level of evidence. | Purpose of the study | Components of self-management | Design, Population, sample setting | Instrument and analysis | Findings |
|---|---|---|---|---|---|---|
| 1 | Belue, R.et al., 2013<br>CNHL<br>Level 4<br>Q1 | To examine experiences with diabetes self-management among clinic patients using the PEN3 model as a cultural framework | Diet<br>Physical activity | Qualitative<br>N= 195,000<br>n= 54<br>age= mean 51.8, 65% female<br>Grand M'bour Medical Clinic Senegal,<br>*Low-income country* | ***Tool:***<br>Semi-structured interview guide<br>***Analysis:***<br>content analysis, then fit to PEN culture conceptual framework | 1. Financial constraints<br>Lack of money to buy drugs<br>Lack of money for healthy diet<br>2. Barriers related to culture<br>- Use of traditional drugs<br>-Food preferences to culture<br>- Inactivity of the population<br>-Family dynamics<br>3. Poor family relationships and lack of support<br>-Roles in family to take health decisions<br>-Family environment<br>-Availability of suitable food for diabetics<br>4. Women issues<br>-Women depending on the spouses, family and children for financial support<br>5. Non availability of vegetables<br>- Availability of low fat meat<br>6. Concerns/stress with marital relations and manhood<br>-Not having sex<br>-Not able to support the family<br>-Men do not cook women cook unhealthy food |
| **2** | Adisa Alutudu, M.B., Fekeye, TO., R., 2009.<br><br>CNHL<br>Level 4 | To evaluate the probable reasons for patients' non adherence to prescribed oral | Medication, SMBG | Quantitative<br>Cross-sectional<br>N=121, N=121<br>60 M,61F | ***Tool:***<br>Self-administered questionnaire<br>***Analysis*:** Descriptive and inferential | 1. Intentional adherence barriers<br>-Fed up with daily ingestion of medication<br>-Fear of being labelled with having diabetes and not taking medication |

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| | G3B | hypoglycaemic medications | | Health care facility in South-western Nigeria. *Low- middle-income country* | | 2. Non-intention adherence barriers leading to dose omission<br>-Busy work schedule<br>-High cost of medication<br>-Fear of taking too many drugs at a time with multiple chronic diseases<br>-Unpleasant taste and side effect of oral medication<br>3. medication inaccessibility barriers<br>Inability to get the prescribed medication refill at nearest pharmacy<br>-Scarcity of the prescribed medications<br>4. Socio-demographic characteristics associated with adherence to medication: sex, occupation and education. |
| 3 | Foley, E. & BeLue, R., 2017.<br><br>CNHL<br>Level 4<br>Q1 | To identify cultural enablers and barriers to dietary management of type 2 T2DM. | Diet | Qualitative study, Convenience sampling<br>N=41, 23 F,18 M, Mean age 58.<br>M'Bour, Senegal.<br>*Low-income country* | ***Tool:***<br>Interview guide,<br>***Analysis:***<br>Content analysis. | - Social isolation due to having a different diet or eating separately from common plate.<br>- Lack of family and patient knowledge about diet<br>-forgoing the diabetic diet so that family members have enough food.<br>-Large family, not enough means to feed the whole family<br>-Financial constraints to buying health foods<br>- Reducing servings of traditional foods feels like abandoning culture |
| 4 | Adisa,R.,Fakeye, T.O. &Fasanmade A., 2011.<br><br>CNHL<br>Level 4<br>G3B | To assess adherence to medication, level of glycaemic control, and evaluate T2DM patients' opinions on probable reasons for non-adherence. | Adherence, glycaemic control, physical activity | Quantitative, prospective cross-sectional<br>N=220, n=140<br>M=51 F=63<br>Age range 32 to 83. Ibadan hospital, South-western Nigeria. | ***Tool***<br>-Self-administered questionnaires: Morisky Adherence Predictor Scale (MMAPS) and a 5-point Likert scale<br>***Analysis:*** Descriptive Statistics Inferential Statistics | **Reasons for non-adherence**<br>- Financial constraints<br>- Gender<br>-Marital status<br>Patients who are widowed (80.0%) seemed to adhere better than the married (60.0%), singles (40.0%) and the divorced (0.0%). |

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| | | | | *Low- middle-income country* | | |
| 5 | Baumann, L.C. et al., 2010<br>CNHL<br>Level 4<br>G3B | To describe illness beliefs and T2DM self-care behaviours of Ugandan adults with T2DM. | Medication, glucose control, diet, physical activity, reducing risk behaviour, coping with T2DM | Quantitative, cross-sectional convenience sample n = 340 (50% male) from the Kampala Diabetes Centre Uganda.<br>*Low-income country* | ***Tool:***<br>58 items of modified D-SMART® and others self-administered questionnaire and | -Financial constraints lead to limited access to appropriate food, T2DM medications, blood glucose testing equipment<br>-Limited printed educational materials<br>-Modalities of keeping insulin when going out in a tropical climate.<br>-Negative psychosocial outcomes: Feeling worried, overwhelmed, and sad or depressed, sexual dysfunction which increases anxiety. |
| 6 | Saleh,F.et al.,2012<br>SCOPUS<br>Level 4<br>G3B | To assess the relationship between knowledge and practices among newly diagnosed type 2 DM patients | Diet, self-glucose monitoring, foot care, exercise, smoking | Quantitative, cross-sectional, convenience sample. Newly diagnosed adults with T2DM (N = 508) 240 M, age 45, 268F from 19 healthcare Bangladesh<br>*Low- middle-income country* | ***Tool:***<br>Modified Diabetes Knowledge Test (DKT) interviewer-administered questionnaire<br>***Analysis:***<br>Descriptive statistics Inferential statistics. | -A significant relationship between knowledge and glucose monitoring<br>-Technical knowledge and foot care were significantly related<br>-A significant relationship existed between technical knowledge and consumption of betel nuts.<br>-Total basic knowledge (TBK) and business profession were significant independent predictors of good practice (SBGM, exercise, foot care, smoking, diet). |
| 7 | Heissam, K., Abuamer, Z.& El-Dahshan, N., 2015.<br>SCOPUS<br>Level 4<br>G3B | To assess patterns and obstacles to adherence of T2DM patients to their oral hypoglycaemic drugs | Adherence to drugs and SMBG | Quantitative descriptive cross-sectional study, carried n= 372, 209M 167F.<br>The mean age 51.64±10.76<br>Fanara, Egypt<br>*Low- middle-income country* | *Tool*<br>- Adherence measure: treatment adherence scale (MTA), a self-administered questionnaire<br>*Analysis:* Descriptive and inferential analysis | - Healthcare provider's relationship predicts adherence to medication.<br><br>- Other factors:<br>Patient beliefs and motivation<br>Monitor BG level<br>Number of drugs taken<br>Drug regimen<br>Experience side-effects<br>Direct and indirect cost income<br>Patient knowledge |

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| **8** | Adisa, R. & Fakeye, T.O., 2014.<br><br>SCOPUS<br>Level 4<br>G3B | To evaluate the pattern of treatment and non-adherence among ambulatory patients with poorly controlled T2DM and to determine the possible factor(s) for non-adherence | Medication adherence, diet and exercise | Quantitative prospective cross-sectional<br>n= 176, M=68 F=108<br>mean age: 60.2±10.2<br>2 teaching hospitals in south-western Nigeria<br>*Low- middle-income country* | ***Tool:***<br>- Interviewer administered the concept of RIM mode l22 to assess non-adherence behaviour of patients.<br>-self-reported medication adherence score (SRMAS) and self-reported dietary adherence score (SRDAS)<br>***Analysis:*** Descriptive statistics<br>Inferential statistics | ***practical barriers (145; 40.1%),***<br>Non-refill of prescriptions due to high cost of medication(s) 15.5%, confusion about dosage 5.5 %, inappropriate storage of insulin 5.2 %, nature of job incompatible with dosage regimen 4.4 %, discontinue meds due to side-effects 4.1%, dose omission 2.5 %, memory or cognitive impairment 0.8 %, forgetfulness, 1.1 %, and no availability of prescribed brand of medication 0.8 %<br>***Knowledge barriers (103; 28.5%),***<br>Medication use without regard to time of meal 12.4 %, Lack understanding of indication of medication 11.6%, - Purchased unauthorised medication 1.7 %, assumption that prescribed medications could only be refilled during clinic appointment 1.4 %, unaware of continued use of hypoglycaemic medication 0.8 %, simultaneously taking two similar generic drugs 0.6 %<br>***Attitudinal (114; 31,5%)***<br>Use of herbal medicine, upward or downward self-adjustment of medication dosage, burden of daily intake of medication(s), inappropriate/irrational prescription refill, not convinced of the need for prescribed medications, dislike for insulin injection, self-medication with prescribed over-the-counter medicines, inability to carry medication around or travel for fear of stigmatisation, belief that medications need to be taken together for optimal outcome, medication discontinuation |

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| | | | | | | because of self-contentment and visiting multiple clinics for consultation |
| 9 | Chiwanga, F.S. &Njelekela,M.., 2015.<br>SCOPUS<br>Level 4<br>G3B | To determine knowledge of foot care and reported practice of foot self-care among T2DM patients. | Foot care | Quantitative, cross-sectional descriptive, systematic sampling n=404, M= 180, F=224 Mean Age 53.6 ± 12.7, patients from 3 hospitals in 2007, Dar es salaam, Tanzania.<br>*Low-income country* | ***Tool:***<br>1. Summary of Diabetes Self-Care Activities (SDSCA)<br>2. Modified Neuropathy Disability Score (NDS)<br>3. Foot risk status: IDF global guideline for T2DM<br>***Analysis***<br>Descriptive statistics<br>Inferential statistics | **Factors associated with foot self-care**<br>- Advice and examination from physician<br>-Knowledge influenced by level of education, duration of T2DM, and advice on foot care<br>-A half have never received information regarding foot care |
| **10** | Mosha, T.C.E. & Rashidi, H.,2009.<br>SCOPUS<br>Level 4<br>G3B<br><br>Interesting tool to be used to review my interview guide | To determine self-care practices and T2DM related emotional distress among people T2DM | SMBG, general and specific diet, medication, physical exercise, foot care | Quantitative, cross sectional survey, Systematic random sampling n=121 N=99,917, F=74, M=47, Mean age (years) (n = 21) in 4 diabetic clinics in Dar es Salaam, Tanzania<br>*Lo- income country* | ***Tool***:<br>- Summary of Diabetes Self Care Activities (SDSCA<br>- The PAID): psychosocial emotional distress<br>***Analysis:***<br>Descriptive statistics<br>Inferential statistics | -Low income was the major limitation for complying with diet, blood glucose testing and medication. People with high incomes scored higher in general and specific diet related practices but the score for foot-care and physical exercises was almost the same as those in low-income bracket.<br>- Those who lived with T2DM for 5 years or less had slightly higher scores in general diet, specific diet and physical exercises while those who lived with T2DM for 6 years and more scored better in foot-care. |
| **11** | Waari, G., Mutai, J. & Gikunju, J.,<br><br>SCOPUS<br>Level 4<br>G3B | to assess medication adherence among T2DM mellitus patients. | Medication adherence<br>Glycaemic control | Quantitative, cross-sectional, systematic sampling, n= 289, M= 94, F= 196,<br>Mean age 56.6 (SD ± 11.86), 18 | ***Tool***<br>Morisky Medication Adherence Scale-8<br>- CAGE test for Alcoholism screening<br>- Height, weight, BMI, HbA1C (measured). | Factors associated with poor medication adherence:<br>- Dissatisfaction with family member support<br>- duration of disease 2-10 years<br>-past hospitalisation with DM<br>-Drug access challenges |

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| | | | | years and above, Kenyatta National Hospital Kenya. *Low- middle-income country* | ***Analysis*:** Descriptive statistics, Inferential statistics | - dissatisfaction with attending clinicians |
| **12** | Parajuli, J. et al., 2014. SCOPUS Level 4 G3B | To measure the factors associated with non adherence to diet and physical activity advice among Nepalese type 2 diabetic patients. | Diet, physical activity | Quantitative, analytical cross-sectional, systematic random sampling N=385 M=187, F=198, Mean age 54.4 ± 11.5 from 18 and above Nepal<br><br>*Low-income country* | ***Tool***:<br>- a modified version of Kuppuswamy's scale,<br>- Dietary history: three days' recall method<br>- Compendium of Physical Activity and GPAQ scoring.<br>***Analysis***:<br>Descriptive statistics<br>Inferential statistics | **(a)Adherence to diet was high in those**<br>- being near hospital<br>- getting advice from hospital<br>-those who live in nuclear family rather than extended family<br>-knowledge<br>-gender (male adhered higher)<br>**Low adherence**<br>-Increasing age<br>**(b)Physical activity adherence was high in**<br>-positive family history of T2DM<br>- In those living with extended family<br>- Those with upper socio economic class<br>**Physical activity adherence was low in** - Marital status/divorced |
| **13** | Rwegerera,G.M., 2014. SCOPUS Level 4 GB3 | To assess adherence to anti-diabetic drugs and associated factors among patients with T2DM | Adherence to medication | Quantitative, cross-sectional, random systematic sampling n=216, 74M, 144 F (Age range 34-81 years). Diabetic clinic of Muhimbili Tanzania between May 2009 and February 2010. *Low-income country* | ***Tool:***<br>- Adherence: patients' recall (one week and three months).<br>- Clinical evaluation: weight, height, BMI<br>- Peripheral neuropathy: 5.07/10g-Semmens Weinstein monofilament<br>- Peripheral vascular diseases: Doppler ultrasound.<br>- Patients' mean blood pressure: Joint National Committee (JNC 7) | **Associated factors**<br>- cost of medication<br>- Patients with other medical conditions who are taking other drugs in addition to T2DM are more likely to adhere to anti-diabetic medications. |

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| | | | | | ***Analysis***: Descriptive statistics<br>Inferential statistics | |
| **14** | Bagonza et al.2015<br>PubMed<br>Level 4<br>GB3 | To assess factors associated with adherence to anti diabetic medication | Adherence to medication | Quantitative, cross sectional, Total sample period n=521 M=262, F=259, mean age 50.9, 18 and above, Iganga and Bugiri hospitals, Uganda, *Low-income country* | Semi-structured (interviewer reported) questionnaire on adherence to anti diabetic medication<br>Descriptive and inferential statistics | The level of adherence to anti diabetic medication was 83.3%<br>Factors associated with good adherence were;<br>- having been on anti-diabetic drugs for at least three years<br>-availability of diabetic drugs<br>- having had diabetic health education |
| **15** | Kassahun, Gesesew, et al. 2016<br>PubMed<br>Level 4<br>GB3 | To assess levels of knowledge about T2DM, self-care behaviours and adherence to medication | Self-care and knowledge<br><br>Self-care behaviour and medication adherence<br>SMBG | Quantitative cross-sectional survey.<br>N=325, n= 309<br>189 M, 120 F<br>Jimma University Teaching Hospital, Southwest Ethiopia.<br>*Low-income country* | ***Tool***<br>- The Diabetes Know-ledge Test (DKT)<br>- Self-care behaviours: Expanded Version of the Summary of Diabetes Self-Care Activities (SDSCA)<br>- Morisky scale<br>***Analysis***: descriptive and inferential | -Being illiterate, having BMI <18 kg/m2 and duration of DM< 5 years were significantly associated with low level of diabetic knowledge.<br>- Duration of DM< 5years was significantly associated with medium level of diabetic knowledge<br>-50.8 % had poor self-care behaviour and this was associated with level of education and adherence to medication.<br>- Being a merchant, having medium level of diabetic knowledge and having good glycaemic control level were associated with low adherence to medications<br>-use of traditional drugs<br>- tentative foods during ceremonies<br>- misconception about the effect of drugs |
| **16** | Abdulrehman et al. 2016<br><br>PubMed<br>Level 4 | To describe diabetes self-management and explore factors that affect | Diet, exercise, SMBG/complications, medications, problem solving. | Qualitative, ethno-nursing, a type of ethnographic, purposive | ***Tool:***<br>Participant observation, one-on-one interviewing, and field notes | -Educational factors limited knowledge and lead to misconceptions about the causes of DM |

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| | Q1 | diabetes self-management within the context of Swahili culture | | sampling N= 22,366, n=30, M=14, F=16 Mean age (range) in years 52.9 (29–80) Marital Lamu town, Kenya November 2012 to March 2014.<br><br>Low- middle-income country | ***Analysis:*** Manual content analysis | - Poverty level affected the affordability of oral anti-diabetic medications, food security, access to recommended foods, and access to privately owned T2DM monitoring devices (glucometer and glucose strips)<br>-Cultural values and beliefs factors such as use of traditional drugs, tentative foods during ceremonies, misconception about the effect of drugs<br>-Social factors and kinship including who is cooking at home, difficulties for individual plate, ritual obligations (wedding and social events),<br>- Religious and philosophical viewpoint like fasting during the holy month of Ramadan<br>- Eye care: Eye care was minimally practiced, only four participants consulted eye specialists. Not aware of connection between vision loss and T2DM. |
| 17 | Kugbey et al. 2017 PubMed Level 4 G3B | To examine whether T2DM patients' illness perception and T2DM knowledge significantly predict T2DM self- care practices | Diet, exercise, SMBG, foot care, medication | Quantitative, cross sectional, convenient sampling N= n= 160 M=45, F=115, 30 yrs and above. Mean = 60.3 years, general hospital in Accra, Ghana *Low- middle-income country* | ***Tool:*** - Self-care practices questionnaire for diet, exercise, blood sugar, foot care and medications. - T2DM knowledge test - Brief illness perception ***Analysis*** Descriptive and inferential statistics | 1.Illness perception and T2DM knowledge significantly predicted overall T2DM self-care practices. 2. Patients' diet was significantly predicted by perception and T2DM knowledge. 3. Exercise was significantly predicted by only illness perception 4.Blood sugar testing and T2DM foot-care were significantly predicted by T2DM knowledge. |
| **18** | Ayele et al.1012<br><br>PubMed | The objective of this study was to identify | Physical exercise, diet, medication and | Quantitative cross sectional, simple random | ***Tool:*** Interviewer reported questionnaires (names not given) | **Predictors of self- care behaviours** |

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| | Level 4<br>G3B | predictors of self-care behaviours among patients with T2DM | blood glucose measurement | sampling n= 222<br>M=88, F=124,<br>18yrs and above<br>Mean age 49.7<br>Harari town, Ethiopia<br>*Low- income country* | - Weight and height, BMI taken during routine check up<br>***Analysis:***<br>Descriptive statistics, Inferential statistics | -Patients with less frequent information were less likely to take T2DM self-care.<br>-Patients who were more educated, middle income, had high perceived severity of T2DM and less perceived barrier to self-care were more likely to take T2DM self-care.<br>**Perceived barriers and benefits**<br>-no high perceived barrier to self-care practice. |
| **19** | Nsereko et al. 2012<br>PubMed<br>Level 4<br>G3B | To gain insight into psychosocial mechanisms underlying self-care behaviour among T2DM patients in Rwandan culture | Diet, exercise, blood sugar monitoring and foot care. | Quantitative, Descriptive cross-sectional<br>n=86 M= 34.1. F= 65.1, 18 yrs and above<br>Mean age 51.96<br>University teaching hospital of Kigali, Rwanda<br>*Low- middle-country* | ***Tool :***<br>Questionnaire<br>- Revised Illness Perceptions Questionnaire (IPQ-R)<br>- Interpersonal Processes of Communication of Care in Diverse Populations questionnaire (IPC):<br>- Centre for Epidemiological Studies Depression Scale (CES-D20)<br>-Summary of Diabetes Self-Care Activities (SDSCA)<br>***Analysis:***<br>Descriptive statistics, Inferential statistics | Participants perceived T2DM as a cyclical and chronic condition associated with serious but controllable consequences.<br><br>-Time cyclical of T2DM (My symptoms come and go in cycles),<br>-Personal control (participants believe in their own self-efficacy to control T2DM)<br>-Depression<br>- People who are depressed and perceive cyclical changes in T2DM are less involved in self-care behaviour |
| **20** | Mogre, Abanga et al. 2017<br>PubMed<br>Level 4<br>G3B | To investigate adult T2DM patients' adherence to four self-care activities: diet (general and specific), | Diet (general and specific), exercise, self-monitoring of blood glucose (SMBG) and foot care | Quantitative, cross-sectional, convenience sampling=187, M=52, F=125, 18 yrs. and above<br>Mean age (years) 54.83 ± 12.32 | ***Tool:***<br>- Revised version of the Summary of Diabetes Self-Care Activities (SDSCA): Self-care behaviours (self-reported) | - Higher education levels were associated with a higher frequency of reported participation in exercise, following a healthy diet and foot care<br>-Males reported performing SMBG more frequently than their female counterparts |

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| | | exercise, self-monitoring of blood glucose (SMBG) and foot care | | Tamale Metropolis of Ghana<br>*Low- middle-income country* | - BMI Waist circumference (WC): measured<br>***Analysis:***<br>Descriptive statistics, inferential statistics | -Lower educational levels in women |
| **21** | Jackson et al. 2015 | To assess medication adherence among type 2 diabetes patients and to identify patient characteristics and probable factors associated. | Medication adherence | Quantitative, cross-sectional Survey, descriptive, M= 122, F= 171 T2D patients. Nigeria South-south health facilities<br>*Low- middle-income country* | ***Tool:***<br>Self-reported questionnaire<br>- the eight-item Morisky Medication Adherence Scale (MMAS- 8)20<br>***Analysis:***<br>Descriptive statistics, inferential statistics | Adherence to medication correlated with<br>-education level, - forgetfulness,<br>-high cost of medication, - limited access to care<br>-complexity of regimen,<br>-poor patient–provider communication,<br>-lack of trust in the provider<br>-depression |
| 22 | Basu, S. et al., 2015.<br>SCOPUS<br>Level 4<br>G3B | To assess medical adherence and their predictors in T2DM patients attending Government Hospitals in Delhi | Medication, diet and exercise | Quantitative, cross-sectional Purposive sampling<br>n=385<br>F 226, M 159<br>Mean age 53.15 +/− 10.2<br>New Delhi India<br>*Low- middle-income country* | ***Tool:***<br>Morisky Medication Adherence scale (MMAS-8)<br>- Summary of Diabetes Self Care Activities scale (SDSCA)<br>- Dietary regimen adherence in DM scale (DRADMS):<br>- HbA1c: patient file.<br>- Kuppuswamy socioeconomic scale, revised for income criteria:<br>***Analysis:*** descriptive and inferential- | -Barriers to physical activity: knee joint pain reported as most frequent, no time, household or work-related physical exercise enough, don't like exercise, pain, fatigue and dyspnoea<br>-Barriers and causes contributing to poor medication adherence: forgetfulness, side-effects and cessation of drugs in absence of symptoms<br>- Causes for poor dietary adherence: divergent food habits of family, belief in inevitability of infrequent dietary transgression, high prices of green vegetables, temptation for undesirable food items, erroneous belief that dietary adherence was useless in control of DM, unaware of proper carbs spacing, waiting for family to have dinner together, occupation-related delays for dinner<br>- Barriers to medication adherence: |

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|---|---|---|---|---|---|---|
| | | | | | | poverty, oral hypoglycaemic agent treatment alone, non-replenishment of drug stocks, skipping doses until next refill |
| 23 | Arulmozhi, S. & Mahalakshmy, T., 2014.<br>SCOPUS<br>Level 4<br>G3C | To assess medication adherence, self-care and associated factors among type 2 diabetics who were admitted to a tertiary care hospital. | Medication.<br><br>Diet and exercise studied but their factors are not shown | Quantitative cross-section al descriptive<br>Sampling strategies not clear, n=150<br>Sri Manakula Vinayagar Medical College and Hospital (SMVMCH), Pondicherry, South India<br>*Low- middle-income country* | ***Tool:***<br>- Morisky's Medication Adherence Scale (MMAS): Medication adherence<br>- Chronic Illness Resources Survey and the Diabetes Family Behaviour Checklist (scale)<br>***Analysis:***<br>Descriptive<br>Inferential<br>Chi-square and logistic regression | -Poor family support showed a significant association with low medication adherence (The social support assessed emotional support, tangible aids and appraisal that they received from their families)<br>- Newly diagnosed<br>Younger than 60 years were more likely to have low/medium medication adherence |
| 24 | Gopichandra et al. 2012.<br>Level 4 IIIB | To estimate the existing self-care behaviours and factors influencing these behaviours among adult patients with T2DM in urban Southern India | Diet<br>Exercise<br>MBS<br>Drug adherence | Quantitative, cross-sectional survey<br>n=200, 82 M, 118 F<br>Cluster and a systematic random sampling, in urban Southern India<br><br>*Low- middle-income country* | ***Tool:***<br>Summary Diabetes Self-Care Activities questionnaire (SDSCA) after minor changes were made to it to suit the Indian context<br>***Analysis:***<br>Descriptive<br>Inferential | **In Univariate regression:**<br>Male sex, married and living with spouse, not depressed and higher socioeconomic status were associated with self- care<br>**In multiple logistic regression:**<br>1. Being male (OR 3.38; 95% CI 1.541–7.407) and married (OR 5.60; 95% CI 1.242–25.212) significantly favoured good exercise behaviour.<br>2. Being married (OR 2.322; 95% CI 1.104– 4.883) and belonging to the higher socioeconomic status (OR 2.712; 95% CI 1.419–5.190) were significantly associated with monitoring of blood sugars |
| 25 | Yasa I Dewa Putu Gede (2018)<br><br>SCOPUS<br>Level 4 Q1 | To explore the barriers of T2DM self-care management to T2DM patients in | Diet, physical activity, foot care, weight management, glucose control. | Qualitative, purposive sampling, n= 20, at Mengwi | In-depth interview<br>Type of analysis: Not given | -Less knowledge of eating arrangements, knowledge of physical activity, knowledge of foot care and knowledge of weight management. |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | urban living. This study used a descriptive phenomenology design. | | village, Badung regency, Bali, Indonesia<br>*Low- middle-income country* | | - less aware of the benefits of exercise to blood glucose levels<br>- less aware of foot care for patients with T2DM. -lack of knowledge to determine blood glucose target |

**ANNEXURE19: INTERVIEW GUIDE**

**ENGLISH VERSION**

**STUDY TITLE: DEVELOPMENT AND PILOT TESTING OF AN INSTRUMENT TO ASSESS SELF-MANAGEMENT BARRIERS AMONG PATIENTS DIAGNOSED WITH TYPE 2 DIABETES PATIENTS IN RWANDA**

**Intructions**

You are requested to not reveal your identity or others' identity during the interview as it will be recorded. I ensure you that if you disclose any, it will not appear in the transcript.

**Section 1: Identification information**

| | |
|---|---|
| 1.1. Respondent's ID:<br>1.3. Date | 1.2.Interviewer:<br>1.4. Interview venue code |
| 1.5. Respondent's code: | 1.6. Starting time…….Closing time……. |

**Section 2: Demographic and clinical information**

| | | | |
|---|---|---|---|
| 2.1. Age of respondents | | 2.6. Recent weight | |
| 2.2 Gender of respondent 1= Male; 2 = Female | | 2.7. Height | |
| 2.3. Date of diabetes diagnosis | | 2.8. Comorbidity | |
| 2.4. Recent Fasting blood glucose | | 2.9. Smoking: 1 yes 2 no | |
| 2.5.Recent Glycated hemoglobin | | 3.0. Take alcohol : 1 yes 2 no | |

**Section 3: Self-management barriers (designed following the components of conceptual framework)**

**A. KNOWLEDGE**

a. Tell me when was your diabetes was first diagnosed
b. Tell me about your disease (probe to know how a patient understands his/her disease, signs and symptoms, complications)
c. Could you please describe the treatment that you are currently taking? How often do you take it?
d. Did you experience some complications of type 2 diabetes? Could you please describe them? Why do you think you experienced them? What do you think you could have done to prevent them?
e. What activities do you do to manage your diabetes? Tell me about your past 3 months, what did you do to manage your diabetes (Get detailed descriptions of self-management activities, probe for self-glucose monitoring at home, adjustment of food intake, self-medication(s), regular physical exercise, foot care).

**B. HEALTH LITERACY**

f. How do you get information to perform self-management activities? Did you have problems learning about your condition because of difficulty understanding written information?
g. Do you need someone help to read hospital materials?
h. How confident are you in the following activities?
    - Filling out medical forms by yourself
    - Adjusting the treatment
    - Adjusting diet

**C. SELF-MANAGEMENT**

i. What challenges /barriers are you experiencing that you can say they are the reason why you would not effectively take care of yourself? (Get detailed descriptions of barriers on each activity of self-management. Probe for barriers to all self-management activities
j. How can these challenges be overcome? How do you think the health provider could best help you in this regard?
k. Are there any positive factors that help you to manage your diabetes?

**D. SUPPORT (SOCIAL SUPPORT, FAMILY AND FRIENDS, FINANCIAL SUPPORT)**

l. What public health or community programmes are available for type 2 diabetes patients in this area? Are these programmess effective/not-effective? Why?
m. Who helps you when you are not feeling healthy? What help did he/she/they give?
n. Do you find your family, friends /environment supportive in the management of your diabetes? (Get a clear description of support in all self-management activities).
o. Do you think that your income is enough to manage your diabetes?

**E. BEHAVIOURAL, PSYCHOLOGICAL CHARACTERISTICS**

p. Are you worried with your diabetes?
q. How confident are you that you could perform self-management activities? (Get a clear description in all self-management activities)

F. **OTHERS**

Tell me if there are others barriers or challenges that have not been discussed

**Thank you!**

## KINYARWANDA VERSION

**<u>Inyito y'ubushakashatsi:</u> Gukora no Kugerageza ifishi yo kugenzura ingorane abarwayi ba diabete ya 2 bahura nazo mu kwita kuri diyabete 2 ku giti cyabo**

Mu gihe cy'ifatwa ry'amajwi, usabwe kugira ibanga ry'amakuru yatuma uwabyumva yamenya ubazwa uwo uriwe cyangwa abandi abavugwa mu makuru watanga. Amakuru yose yatuma ibanga rititabwaho, ntabwo agenewe kwandikwa cyangwa kubikwa.

**UMUYOBORO W'IBAZWA RITAZIGUYE**

**IGIKA CYA 1: UMWIRONDORO**

| | |
|---|---|
| 1.1. Numero y'usubiza: | 1.2.Izina ry'ubaza: |
| 1.3. Italiki: | 1.4. Aho ibazwa ryabereye: |
| 1.5. Akarere akomokamo: | 1.6. Igihe ibazwa ritangiriye…….Igihe ibazwa rirangiriye……. |
| 1.7.Age of respondents: | 1.8. Gender of respondent 1= Male; 2 = Female |

**IGIKA CYA 2: AMAKURU KURI DIYABETE**

| | |
|---|---|
| 2.1. Italiki wamenyeshejwe ko urwaye diyabete bwa mbere | |
| 2.2. Ibisubizo by'Isukali iheruka yafashwe utariye | |
| 2.3. Ibisubizo by'ibizami bireba uko ucunga isukari biheruka<br>2.4. Ibiro bya vuva | |
| 2.5. Uburebure | |
| 2.6. Ibiro bya vuba ubwo uheruka kwipimisha | |
| 2.7. Uburebure | |
| 2.8. Izindi ndwara | |
| 2.9. Unywa itabi 1 Yego 2 Oya | |
| 3.0 Unywa inzoga 1yego 2 oya | |

**IGIKA CYA 3: INGORANE Z'UMURWAYI MU GUKURIKIRANA DIYABETE KU GITI CYE**

**A. UBUMENYI**

a. Ni ryari wamenye ko urwaye diabete y'ubwoko bwa 2?
b. Nagirango tuganire kuri diabete y'ubwoko bwa kabiri, uyizi ho iki? (baza icyo azi nk'ibimenyetso, ingaruka)
c. Ese wambwira muri make imiti uri gufata ubu ngubu? Uyifata gute?
d. Ese wigeze ugira ingaruka ziterwa na diabete y'ubwoko bwa Kabiri? Ni izihe? Wakowe iki kugira ngo uzirinde?
e. Ni ibihe bikorwa ukora wowe ubwawe kugirango uhangane na diabete? Reka dufate amezi atatu ashize umbwire ibyo ukora (Gerageza kubona amakuru kubyo akora ngo akurikirane ibipimo by'isukari, imirire, uko afata imiti, imyitozo, kwita kw'isuku y'ibirenge)

**B. UKO ABONA AMAKURU N'UBURYO AYAKORESHA AFATA IBYEMEZO**

f. Ni gute ubona amakuru agufasha kwikurikirana wowe ubwawe? Ese wigeze ugira ibibazo mu gusobanukirwa ibijyanye n'indwara yawe kubera kutumva ibyo usoma bijyanye nayo?
g. Ese ukenera umuntu ugufasha kumva cyangwa gusoma inyandiko zo kwa muganga.
    - Kuzuza ifishi
    - Kumenya uburyo wako ngera cyangwa kugabanya imiti ufata
    - Kumenya uburyo wafata ibyo kurya bitandukanye

**C. SELF-MANAGEMENT**

h. Ni izihe ngorane/ibibazo uhura nabyo mugukurikirana diabete wavuga ko aribyo bituma udakurikirana neza diabete ku giti cyawe (Musobanuze neza kubijyanye n'uburyo akurikirana ibipimo by'isukari, imirire, uko afata imiti, imyitozo, kwita kw'isuku y'ibirenge)
i. Ese wumva ibyo bibazo byakemuka bite? Ese wumva hari icyo abaganga, abaforomo n'abandi bakozi bakora kwa muganga hari icyo bagufasha ngo bikemuke?
j. Ese hari ibintu biguha imbaraga cyangwa bigufasha mugukurikirana diabete ku giti cyawe?

**D. UBUFASHA (SOSIYETE, UMURYANGO CYANGWA INSHUTI, UBUFASHA BUJYANYE N'AMAFARANGA**

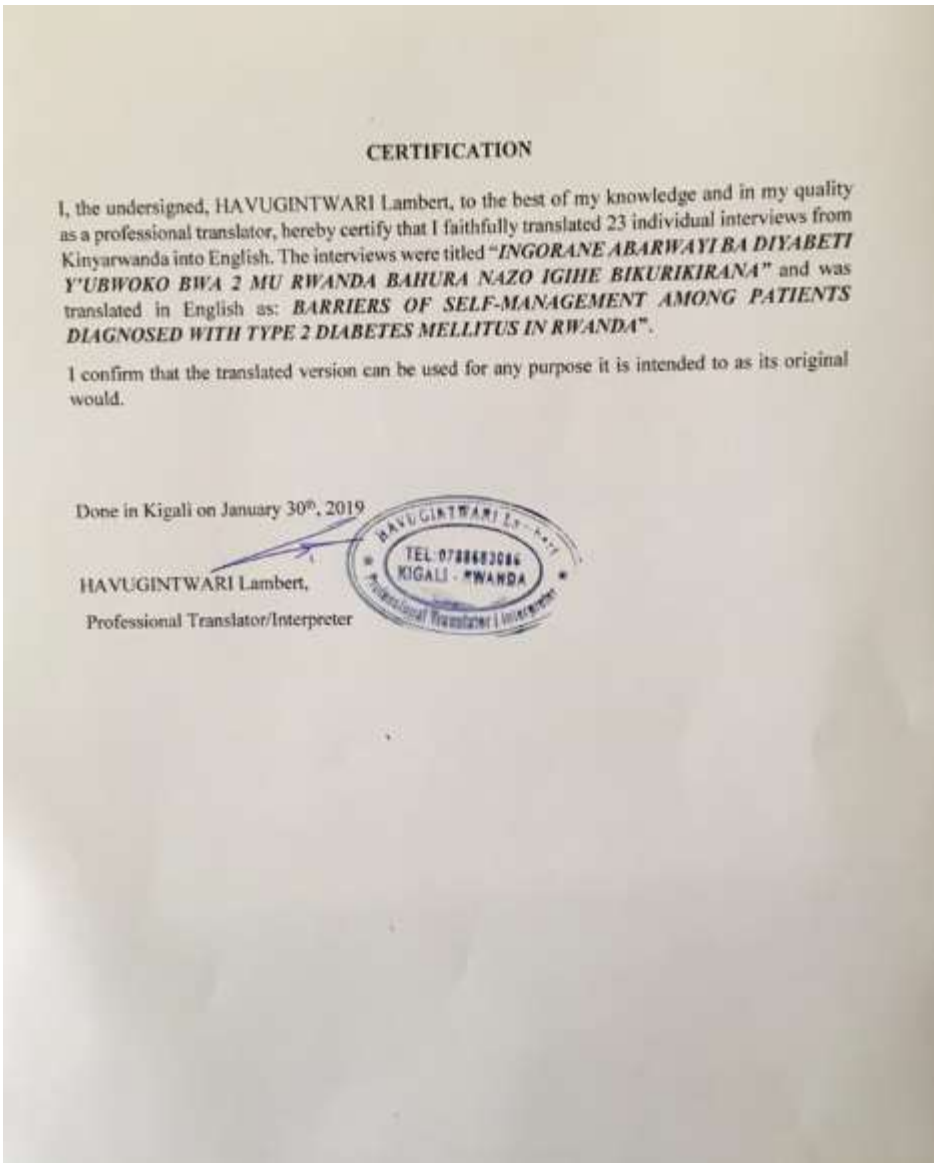
k. Ni izihe gahunda ziri aho utuye cyangwa mu gihugu zifasha abarwayi bafite diyabete y'ubwoko bwa kabiri? Ese ubona ubwo bufasha urabushima ubona bufite akamaro? Kubera iki?
l. Ni nde ugufasha gukurikirana diabete yawe igihe wumva utabishoboye cyangwa utameze neza? Agufasha mubuhe buryo?
m. Ese ubona umuryango wawe ugufasha mu gukurikirana diabete? Gerageza kubona amakuru k'ubufasha ahabwa ku bikorwa byose bijyanye no kwikurikirana).
n. Ese ubona ufite ubushobozi buhagije ngo wite kuri diabete yawe?

**E. IMYITWARIRE N'IMITERERE YE**

o. Ese diabete iraguhangayikishije
p. Ese uriyizeye mu kwita kuri diabete wowe ubwawe? ubwawe? (Gerageza kubona amakuru k'ubufasha ahabwa ku bikorwa byose bijyanye no kwikurikirana, ubury akurikirana ibipimo by'isukari, imirire, uko afata imiti, imyitozo, kwita kw'isuku y'ibirenge

**Murakoze gusubiza ibibazo mwabajijwe!**

## ANNEXURE 20: TRANSLATION CERTIFICATE OF INTERVIEWS TRANCRIPTS



**CERTIFICATION**

I, the undersigned, HAVUGINTWARI Lambert, to the best of my knowledge and in my quality as a professional translator, hereby certify that I faithfully translated 23 individual interviews from Kinyarwanda into English. The interviews were titled "***INGORANE ABARWAYI BA DIYABETI Y'UBWOKO BWA 2 MU RWANDA BAHURA NAZO IGIHE BIKURIKIRANA***" and was translated in English as: ***BARRIERS OF SELF-MANAGEMENT AMONG PATIENTS DIAGNOSED WITH TYPE 2 DIABETES MELLITUS IN RWANDA***".

I confirm that the translated version can be used for any purpose it is intended to as its original would.

Done in Kigali on January 30th, 2019

HAVUGINTWARI Lambert,

Professional Translator/Interpreter

## ANNEXURE 21: TRANSLATION CERTIFICATE OF BE-SEED2

**CERTIFICATION**

I, the undersigned, HAVUGINTWARI Lambert, to the best of my knowledge and in my quality as a professional translator, hereby certify that I faithfully translated the instrument titled ***"BARRIER OF SELF-MANAGEMENT OF TYPE 2 DIABETES (BE-SEED2)"*** from English into Kinyarwanda as ***"INYANDIKO-BAZA KU BARWAYI BA DIYABETE Y'UBWOKO BWA KABIRI KU NGORANE BAHURA NAZO BIKURIKIRANA".***

I confirm that the translated version can be used for any purpose it is intended to as its original would.

Done in Kigali on March 25th, 2019

HAVUGINTWARI Lambert,

Professional Translator/Interpreter

HAVUGINTWARI Lambert
TEL:0788663886
KIGALI - RWANDA
Professional Translator / Interpreter

## ANNEXURE 22: EDITING CERTIFICATE

**Lesley Ann Fletcher**

No. 57 Vuurlelie Street
Roodekrans
1732
Mobile: 083 628 8756
Email: sirisee06@gmail.com

**CERTIFICATE OF EDITING**

**TO WHOM IT MAY CONCERN**

This letter confirms that the thesis detailed below was edited for English language grammar, language, spelling and punctuation.

| | |
|---|---|
| **Date:** | 11 January 2021 |
| **Thesis Title:** | Development and pilot testing of an instrument to assess self-management barriers among patients diagnosed with type 2 diabetes in Rwanda: a mix-method study |
| **Thesis Author:** | Marie Claire Uwamahoro |
| **Student Number:** | 1760159 |
| **Institution:** | Department of Nursing Education<br>School of Therapeutic Sciences<br>Faculty of Health Sciences<br>University of Witwatersrand |

**LA Fletcher**

## ANNEXURE 23: CONTENT VALIDITY GUIDE

### Instructions

This guide aims to gather information relevant to the content of the instrument that the researchers developed regarding barriers that diabetic patients face. Please assess each item for "relevance, clarity, simplicity and ambiguity". The criteria to be used are provided. For the demographic characteristics, use √ for the corresponding space or write the necessary information.

### 1. Socio-demographic characteristics

1.1. Expert code: _____
1.2. Age: ……. /……/……
1.3. Sex 1= Male___2 = Female___
1.4. Qualification: 1. Bachelor_____2. Master_____3. PhD_____
1.5. Working area: Practice 1. _____ 2. Academic
1.6. Specialty:1: Nursing____ Specify_____
2. Medicine___ Specify_____
3. Social work__ Specify_____
4: Nutrition_____ Specify_____

**Criteria for Measuring Content Validity**

| Relevance | Clarity | Simplicity | Ambiguity |
|---|---|---|---|
| 1 = not relevant | 1= not clear | 1 = not simple | 1 = doubtful |
| 2 = item needs some revision | 2 = item needs some revision | 2 = item needs some revision | 2 = item needs some revision |
| 3 =relevant but needs minor revision | 3 =clear but needs minor revision | 3 = simple but needs minor revision | 3 = no doubt but needs minor revision |
| 4 = very relevant | 4 = very clear | 4 = very simple | 4 = meaning is clear |

### 2. Please use the criteria described above and assess the items below

| No | Items | Relevance | Clarity | Simplicity | Ambiguity |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**Thank you!!!**

## ANNEXURE 24: FACE VALIDITY TOOL

## ENGLISH VERSION

### Instructions

This questionnaire aims to gather information relevant to the instrument you completed regarding self-management barriers of T2DM patients. Use the reverse side of this page, if more space is required for more comments.

### 1. Socio-demographic characteristics

1.1. Code: _____
1.2. Age: ……. /……/……
1.3. Sex 1= Male___2 = Female___
1.4. Level of education: 1. Primary_____2. Secondary_____3. Tertiary_____
1.5. Living area 1. Urban _____ 2. Rural_____

**2. Please follow the instructions and fill the questionnaire. Please (√) in corresponding score or write the response in corresponding place.**

| | **SD 1** | **D 2** | **A 3** | **SA 4** | **If you score below 4 provide your comments and suggestions** |
|---|---|---|---|---|---|
| The instrument included all relevant barriers in self-management of T2DM | | | | | |
| I would be happy to complete the instrument as part of routine care | | | | | |
| I was able to read and understand | | | | | |
| The time was reasonable | | | | | |
| Do you have any comments or suggestions on how the questionnaire you used could be improved (e.g., its items, structure, appearance or design)? | | | | | |

**Thank you!**

## KINYARWANDA VERSION

### Amabwiriza

Iri bazwa rigamije gukusanya amakuru ku bibazo wasubije birebana ni ingorane abarwayi ba diabete y'ubwoko bwa 2 bahura nazo igihe bikurikirana. Ushobora gukoresha urundi ruhande rw'uru rupapuro mu gihe umwanya ukubanye muto

### 1. Umwirondoro

1.1. Numero y'ibazwa: _____
1.2. Imyaka: ……. /……/……
1.3. Igitsina 1= Gabo___2 = Gore___
1.4. Mashuli wize: 1. Abanza_____2. Ayisumbuye_____3. Amakuru_____
1.5. Living are 1. Urban _____ 2. Rural_____

### 2. Twabasabaga gukurikiza amabwiriza mu gasubiza ibibazo bikurikira (Koresha aka kamenyets √ mu mwanya w'amanota watanga kuri buri kibazo cyangwa wandike mu magambo igisubizo ahari ngombwa habajijwe)

| | Sibyo na gato 1 | Sibyo 2 | Nibyo 3 | Nibyo cyane 4 | Igihe utanze amanota ari munsi yane, tanga ibisobanuro birambuye |
|---|---|---|---|---|---|
| Ibibazo byose bijyanye ni ingorane abarwayi ba diabete y'ubwoko bwa 2 bahura nazo igihe bikurikirana birakwiye kandi byabajijwe byose | | | | | |
| Numva nakwishimira kuzuza ibi bibazo igihe nje kwa muganga | | | | | |
| understand Nashoboye gusoma no kumva ibibazo byose | | | | | |
| Igihe nakoresheshe cyari kiringaniye | | | | | |
| Ese waba ufite ikindi wakongera ku bibazo biri mu iyi fishi (ibibazo ubwabyo, uko bibajije, n'uburyo byanditse)? | | | | | |

**Urakoze !**

## ANNEXURE 25 : CLINICAL UTILITY QUESTIONNAIRE

### Instructions

This questionnaire aims to gather information relevant to the instrument you used to assess self-management barriers of T2DM patients. Use the reverse side of this page, if more space is required for more comments.

### 1. Socio-demographic characteristics

1.1. Code: _____

1.2. Profession: 1. Nurse____2. Medical Doctor____

1.3. Experience: 1. 1- 4 years___2. 5 years and more_____

1.4. Hospital: 1. Gahini___ 2. Kibagabaga___ 3. CHUB____ 4. Ruli___

**8 Please follow the instructions and fill the questionnaire**

| **1. How easy is the instrument? (Please √ in corresponding score)** | **SD 1** | **D 2** | **A 3** | **SD 4** | **Comments or suggestions** |
|---|---|---|---|---|---|
| The instrument was easy to administer | | | | | |
| Language and terminology in the instrument were easily understood | | | | | |
| Participants were able to understand the concepts used and get what I am asking | | | | | |
| **The format (Please √ in corresponding score)** | | | | | |
| The format of the instrument allowed for easy recording | | | | | |
| **2. Relevance (Please √ in corresponding score)** | | | | | |
| The tool identified self-management barriers | | | | | |
| **3. Time (Please write the minutes)** | | | | | |
| Minutes used to administer the instrument for the first round | | | | | |
| Minutes used to administer the instrument for the second round | | | | | |
| Minutes used to administer the instrument for the third round | | | | | |
| How reasonable was the time consumption for the instrument? **(Please √ in corresponding score)** | **Not reasonable** | **Slightly reasonable** | **Reasonable** | **More reasonable** | |
| | | | | | |
| **4. General comments** (If you have more suggestions you may continue on reverse of this page) 1. Briefly describe any difficulties you experienced in administering the BE-SEED2 & how you dealt with them. 2. Do you have further comments/suggestions for this instrument. | | | | | |

**Thank you!**

## ANNEXURE 26: INTRUMENT TO ASSESS SELF-MAMAGEMENT BARRIERS AMONG TYPE 2 DIABETIC PATIENTS

## ENGLISH VERSION

| No | Items | SD | D | A | SD |
|---|---|---|---|---|---|
| | **1. Knowledge** | | | | |
| 1 | I can't pretend and confidently say that I have enough knowledge about diabetes | | | | |
| 2 | I may fail self-management in one way or another either because I am not aware or not very sure of what I have to do | | | | |
| 3 | I lack self-confidence and necessary skills to manage my diabetes | | | | |
| 4 | I may fail to understand written self-managements instructions/literature | | | | |
| | **2. Stigma** | | | | |
| 5 | People may have the wrong perception of diabetes, stigmatise and discriminate against me | | | | |
| 6 | I fail to disclose to others that I have diabetes. | | | | |
| | **3. Health facility** | | | | |
| 7 | I don't have one specific health provider who can regularly and exclusively follow-up on me | | | | |
| 8 | I feel I am not well guided to set achievable goals for each activity of self-management | | | | |
| 9 | I feel self-management activities have not been clearly explained to me | | | | |
| 10 | Health care providers rush, they do not find time to listen to me | | | | |
| 11 | I live far from hospital and getting here is so challenging | | | | |
| 12 | I have to wait for long time when I come for my appointment | | | | |
| 13 | I feel I am given guidance without considering my individual problems | | | | |
| 14 | Nurses/doctors use bitter /unpleasant words and I fear asking more information about self-management | | | | |
| 15 | I would say that diabetes management decisions are not discussed with me | | | | |
| | **4. Family, friends and community support** | | | | |
| 16 | I have a feeling that my family members do not give me enough support | | | | |
| 17 | I feel I get little support from my friends | | | | |
| 18 | There are no community programmes supporting me | | | | |
| 19 | I would manage my diabetes much better if I had participated in diabetes group support | | | | |
| | **5. Comorbidity and complications** | | | | |
| 20 | I spend time doing nothing that can generate income because of fatigue and diabetes complications | | | | |
| 21 | Having other diseases/complications related to diabetes prevents me from adhering to self-management activities | | | | |
| 22 | I have treatments other than for diabetes and it becomes hard for me to be on different treatments at the same time | | | | |
| | **6. Behaviour and psychology** | | | | |
| 23 | I am desperate I keep thinking that this disease is not curable and that affects self-management of diabetes | | | | |
| 24 | I feel like I am useless to my family | | | | |
| 25 | I am not psychologically stable, type 2 diabetes has put stress in my life | | | | |
| 26 | I feel hopeless, type 2 diabetes has put stress in my life | | | | |
| 27 | It is difficult to change my habits in accordance with type 2 diabetes condition | | | | |
| | **7. Diet** | | | | |

| | | | | | |
|---|---|---|---|---|---|
| 28 | In my area, it is not easy to get vegetables and other food items recommended | | | | |
| 29 | Having a special diet or having different dishes among my family members makes me feel isolated, I sometimes prefer to share what others eat | | | | |
| 30 | It is hard to take appropriate diet when I am away from home | | | | |
| 31 | I don't attach a lot of importance to special diet recommended to diabetes patients, I just eat what I like | | | | |
| 32 | I think that information about diet is not consistent | | | | |
| 33 | I cannot buy special food items for myself like when I do not have enough money, I first think about my family | | | | |
| 34 | I have been taking the diet for a long time, I am really tired | | | | |
| 35 | I end up eating unhealthy food very often as it is all I can afford | | | | |
| | **8. Physical activity** | | | | |
| 36 | The general environment in my community is not conducive for physical exercise (security, appropriate venues and equipment etc.) | | | | |
| 37 | There is no culture of doing physical exercise in this community | | | | |
| 38 | I was not given as much information as I needed about physical activity | | | | |
| 39 | Physical problems/diseases related to diabetes inhibit me from taking exercise | | | | |
| 40 | I don't feel interested by physical exercise; that is something I don't easily enjoy | | | | |
| 41 | I do not think exercise will change anything about diabetes | | | | |
| 42 | Except engaging in regular work or domestic chores, it is hard for me to have physical exercise | | | | |
| | **9. Medication** | | | | |
| 43 | When I find that the blood glucose level is fine, I may sometimes stop medication | | | | |
| 44 | I sometimes forget to take my medication | | | | |
| 45 | I take drugs that have been recommended for diabetes but I also take traditional medicine and the latter seems to be efficient. | | | | |
| 46 | I think that food supplements (abagorozi) seem to be as good as diabetes treatment | | | | |
| 47 | I have a feeling that the medication prescribed for me are not effective | | | | |
| 48 | I don't think I know the effects, be it good or bad, that diabetes treatments can have on my health | | | | |
| 49 | I face the issue of stock outs of my medication. | | | | |
| 50 | I miss medication when travelling because I do not have means to transport my drugs | | | | |
| 51 | Sometimes I get a depressed mood, during such a period, I would stop medication for sometimes then I would decide to resume. | | | | |
| 52 | My working conditions may lead me to skip a medication | | | | |
| 53 | I sometimes fail to get money to buy drugs for diabetes | | | | |
| 54 | I feel bad taking drugs everyday | | | | |
| 55 | When taking tablets it is hard to shift to insulin | | | | |
| | **10. SMBG** | | | | |
| 56 | I fear injections I cannot check blood glucose at home | | | | |
| 57 | My working condition does not make it easy for me to control blood glucose | | | | |
| 58 | I have not been given enough information about blood glucose testing and control | | | | |
| 59 | I do not think that regular self-management of blood glucose (SMBG) will change anything about diabetes | | | | |
| 60 | I cannot afford a glucometer | | | | |
| 61 | I cannot afford test strips | | | | |
| | **11. Foot care** | | | | |
| 62 | I was not given as much information as I needed about foot care | | | | |
| 63 | Given the nature of my job, I think it is too hard for me foot hygiene as it is recommended. | | | | |
| 64 | I was not examined by health care providers to know what I am supposed to do | | | | |

## KINYARWANDA VERSION

| | Ibibazo | Sibyo namba | Sibyo | Nibyo | Nibyo cyane |
|---|---|---|---|---|---|
| | **1. Ubumenyi** | | | | |
| 1 | Ntago nakwihadagaza ngo mvuge ko mfite ubumenyi buhagije kuri diyabete | | | | |
| 2 | Hari ibintu bitandukanye ntakora mu kwikurikirana kubera kutabimenya cyangwa kubera kujijwa | | | | |
| 3 | Numva ntiyizeye neza mubyo nkora ngo ni kurikirane, numva nkeneye kwiga ibindi birushijeho | | | | |
| 4 | Hari ubwo ntasobanukirwa nibyo banditse bijyanye no kwiyitaho | | | | |
| | **2. Akato** | | | | |
| 5 | Abantu ntabwo bumva abarwayi ba diyabete; usanga bagenda babaninura; bakababaha akato. | | | | |
| 6 | Ntabwo nisanzuye kubandi kuburyo nababwira ku burwayi bwa diabete mfite ngo mbe nabwira abandi ko ndwaye diyabete. Numva kuba ndwaye diabete bintera isoni. | | | | |
| | **3. Ubuvuzi** | | | | |
| 7 | Ntabwo mfite umuganga unkurikirana ku giti cyanjye, abakozi bo kwa muganga batwitwaho barahindagurika, ku buryo amakuru bampa ku birebana no kwiyitaho usanga agenda ahindagurika; Ibyo umwe akubwiye sibyo undi akubwira. | | | | |
| 8 | Njyewe mbona abakozi bo kwa muganga batampa ibisobanuro byumvikana kandi bihagije, kugira ngo mbashe kwikurikirana | | | | |
| 9 | Numva ntarasobanuriwe neza uburyo bwo kwikurikirana | | | | |
| 10 | Hari igihe usanga abakozi bo kwa muganga bifitiye akazi kenshi, bakatuvura biruka ku buryo ubona nta mwanya wo kudutega amatwi uhagije bafite | | | | |
| 11 | Ntuye kure yo kwa muganga; kugera hano birangora | | | | |
| 12 | Binsaba gutegereza umwanya munini kugira ngo mbonane na muganga iyo naje kuri randevu | | | | |
| 13 | Iyo abakozi bo kwa muganga baduha inama, baziduha muri rusange, usanga batita ku bibazo by'umuntu ku giti cye | | | | |
| 14 | Abakozi bo kwa muganga usanga bakoresha amagambo atari meza cyangwa akakaye ku buryo hari ighe ugira ubwoba bwo gusobanuza kurushaho, cyangwa ukumva ntiwishimiye uko bakwakira | | | | |
| 15 | Navukaa ko ibyemezo bijjyanye no kuvura diayabete batabiganira nanjye | | | | |
| | 4. **Umuryango, inshuti, Kominote** | | | | |
| 16 | Mbona abagize umuryango wanjye basa naho nta kintu gikomeye bamfasha | | | | |
| 17 | Mbona inshuti zanjye basa naho nta kintu gikomeye bamfasha | | | | |
| 18 | Nta porogaramu ziba aho dutuye zimfasha nk'umurwayi wa diabete diyabete, ndirwariza | | | | |
| 19 | Nta mashyirahamwe ya diyabete tugira kandi mbona tuyafite yatugirira akamaro | | | | |
| | **5. Ubundi burwayi n'ingaruka** | | | | |
| 20 | Kubera umunaniro n'ibindi bibazo biterwa na diyabete, nirirwa nicaye nta kintu nkora cyanyinjiriza amafaranga | | | | |
| 21 | Diabete yangizeho ingaruka n'uburwayi bitandukanye birangora kwikurikirana (kutabona, umunaniro, kudatera akabariro, izindi ndwara….) | | | | |
| 22 | Nywa imiti yindi itari iya diyabete, kuyifatira icyarimwe biragoye, bitumpa ntafata neza imiti ya diyabete. | | | | |
| | **6. Imyitwarire n'imitekerereze** | | | | |
| 23 | Hari igihe ntekereza ku ngaruka diyabete ishobora kuntera ngacika intege, nkiheba | | | | |

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| 24 | Numva ntacyo mariye umuryango wanjye kubera diayabete | | | | |
| 25 | Numva ntatuje diabete yanyangirije ubuzima mpora ntatuje | | | | |
| 26 | Kurwara diabetes byanteye kwiheba cyane | | | | |
| 27 | Iyo urwaye diyabete bisaba guhindura uko wabagaho mbere, usanga bigoye kureka ibintu bimwe na bimwe wari umenyereye | | | | |
| | 7. **Imirire** | | | | |
| 28 | Ntago byoroshye kubona imboga n'ibindi biryo bigenewe abarwayi ba diyabete aho ntuye | | | | |
| 29 | Kurya isahane yanjye yihariye (cyangwa kudasangira n'abandi bagize umuryango wanjye ku bintu bariye) bituma numva ndi mu kato. Hari igihe nyuzamo tugasangira | | | | |
| 30 | Iyo umuntu atari murugo biragorana gukurikiza rejime/imirire iboneye ya diabete | | | | |
| 31 | Ibintu bya rejime/indyo iboneye si ibintu nitaho cyane. Nirira ibyo numva nkunze | | | | |
| 32 | Usanga abaganga basobanura regime ya diyabeti mu buryo butandukanye, nta wumbwira regime/imirire y'ukuri nakurikiza. | | | | |
| 33 | Iyo ntafite amafaranga ahagije mbanza kugura ibihaza umuryango nkabona kuba nagura ibyange | | | | |
| 34 | Maze igihe kirekire kuri rejime, igeraho ikandambira nkanyuzamo nkirira ibisanzwe | | | | |
| 35 | Nshobora kurya ibiryo bibonetse bitajyanye na diyabete kubera ko ari byo mbasha kugura bijyanye n'ubushobozi bwanjye | | | | |
| | **8. Imyitozo ngororamubiri** | | | | |
| 36 | Ahantu ntuye ntabwo hafasha umuntu kuba yakora imyitozo ngororamubiri ( umutekano, nta hantu habugenewe henshi hahari…). | | | | |
| 37 | Muri aka gace, umuco wo gukora imyitozo ngororamubiri ubona ntawuhari, ubura abantu bagutera imbaraga | | | | |
| 38 | Ntabwo nahawe amakuru ahagije mu bijyanye n' imyitozo ngorora mubiri | | | | |
| 39 | Ubundi burwayi/ibibazo biterwa na diabete bimbuza gukora imyitozo ngororamubiri | | | | |
| 40 | Gukora imyitozo ngorora mubiri ntibimbangukira ngo numve binshishikaje | | | | |
| 41 | Ntabwo ntekereza ko gukora imyitozo ngororamubiri hari icyo byahindura ku burwayi bwanjye bwa diyabete | | | | |
| 42 | Uretse akazi gasanzwe/imirimo yo mu rugo, birangora kubona umwanya wo gukora imyitozo ngororamubiri | | | | |
| | **9. Imiti** | | | | |
| 43 | Kuva ku binini ukajya ku nshinge, ni ibintu abarwayi ba diyabete tutumva vuba iyo tubibwiwe nabaganga, tubanza kubyanga | | | | |
| 44 | Hari ubwo nibagirwa gufata imiti | | | | |
| 45 | Imiti ya diyabete banyandikiye ndayifata ari ko nkoresha n' iya gakondo kuko iramfasha | | | | |
| 46 | Imiti y'abagorozi mbona igira akamaro kanini kuri diabete. | | | | |
| 47 | Numva imiti/ingano y'imiti mfata atari byo nagakwiye kuba mfata. | | | | |
| 48 | Ntabwo numva nsobanukiwe ibyiza n'ibibi by'imiti mfata<br>Ntabwo numva nsobanukiwe ibyiza n'ibibi by'imiti mfata | | | | |
| 49 | Nkunda kubura imiti muri farumasi z'ibitaro bityo kuri jye kubasha kwigurira imiti muri farumasi zigenga bikangora | | | | |
| 50 | Iyo mfashe urugendo nta miti mfata kuko nta bwo mbona uko nyitwara. | | | | |
| 51 | Hari ubwo numva nihebye cyane, ngahagarika imiti byazagera aho nkongera nkayifata. | | | | |
| 52 | Kubera akazi nkora hari igihe ntafatira imiti ku gihe cyagenwe | | | | |
| 53 | Hari igihe mbura amafaranga yo kugura imiti ya diabete | | | | |
| 54 | Numva mbihiwe no kumva ko ngomba kunywa imiti buri munsi | | | | |

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| 55 | Kuva ku binini ukajya ku nshinge, ni ibintu abarwayi ba diyabete tutumva vuba iyo tubibwiwe nabaganga, tubanza kubyanga | | | | |
| | **10. Gukurikirana ibipimo by'icukali** | | | | |
| 56 | Ntinya inshinge ntabwo nakwipima isukali mu rugo | | | | |
| 57 | Kubera akazi nkora ntibinyorehera kwifata ibipimo by'isukari | | | | |
| 58 | Nta makuru ahagije nahawe/mfite ku bijyanye n'ibipimo by'isukali no kubikurikirana | | | | |
| 59 | Si ntekereza ko guhora umuntu yipima isukali byatuma hari igihinduka ku burwayi bwa diyabete afite. | | | | |
| 60 | Ntabwo mfite ubushobozi bwo kugura akamashini ko kwipima | | | | |
| 61 | Ntabwo mfite ubushobozi bwo kugura bandelete | | | | |
| | **11. Isuku y'ibirenge** | | | | |
| 62 | Nta bwo nahawe amakuru ahagije ku bijyanye ni isuku y'ibirenge | | | | |
| 63 | Nkurikije akazi nkora kubahiriza ibijyane ni isuku y'ibirenge ni ibintu kuri jye mbona bigoye | | | | |
| 64 | Ntabwo muganga ajya ansuzuma ibirenge ngo menye nanjye ibyo nkwiye kuba nkora | | | | |

### 1.1.1. 24.2 KINYARWANDA VERSION

| No | Ibibazo | SN | S | N | NC |
|---|---|---|---|---|---|
| | **1. Ubumenyi** | | | | |
| 1 | Ntago nakwihadagaza ngo mvuge ko mfite ubumenyi buhagije kuri diyabete | | | | |
| 2 | Hari ibintu bitandukanye ntakora kubera kutabimenya cyangwa kubera kujijwa | | | | |
| 3 | Numva ntiyizeye neza mubyo, numva nkeneye kwiga ibindi birushijeho | | | | |
| 4 | Amabwiriza n'imiti banyandikira biba byanditse mu ndimi z'amahanga, hari ubwo ntasobanukirwa nibyo banditse | | | | |
| | **2. Akato** | | | | |
| 5 | Abantu ntabwo bumva abarwayi ba diyabete; usanga bagenda babaninura; bakabaha akato. | | | | |
| 6 | Ntabwo nisanzuye kubandi kuburyo nababwira ku burwayi bwa diabete mfite. Numva kuba ndwaye diabete bintera isoni. | | | | |
| | **3. Ibigo by'ubuvuzi n'abavuzi** | | | | |
| 7 | Ntabwo mfite umuganga unkurikirana ku giti cyanjye, amakuru bampa ku birebana no kwiyitaho agenda ahindagurika; Ibyo umwe akubwiye sibyo undi akubwira. | | | | |
| 8 | Ntago banyerekera neza uko niyitaho kandi mu butyo nshoboye | | | | |
| 9 | Numva abakozi bo kwa muganga batampa ibisobanuro byumvikana kandi bihagije, kugira ngo mbashe kwikurikirana | | | | |
| 10 | Hari igihe usanga abakozi bo kwa muganga bifitiye akazi kenshi, bakamvura biruka ku buryo nta mwanya wo kutega amatwi uhagije bafite | | | | |
| 11 | Ntuye kure yo kwa muganga; kugera hano birangora | | | | |
| 12 | Binsaba gutegereza umwanya munini kugira ngo mbonane na muganga iyo naje kuri randevu | | | | |
| 13 | Iyo abakozi bo kwa muganga baduha inama, baziduha muri rusange, usanga batita ku bibazo by'umuntu ku giti cye | | | | |
| 14 | Abakozi bo kwa muganga usanga bakoresha amagambo atari meza cyangwa akakaye ku buryo hari ighe ugira ubwoba bwo gusobanuza kurushaho, cyangwa ukumva ntiwishimiye uko bakwakira | | | | |
| 15 | Ntabwo muganga ajya ansaba ibitekerezo byanjye haba ku miti n'ibizami anyandikira cyangwa amabwiriza runaka yo kwikurikirana | | | | |

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| | **4. Ubufasha bw'umuryango, inshuti cyangwa aho atuye** | | | | |
| 16 | Mbona abagize umuryango wanjye basa naho nta kintu gikomeye bamfasha | | | | |
| 17 | Mbona inshuti zanjye nta kintu gikomeye zimfasha | | | | |
| 18 | Nta porogaramu ziba aho dutuye zimfasha nk'umurwayi wa diabete diyabete, ndirwariza | | | | |
| 19 | Nta mashyirahamwe ya diyabete tugira kandi mbona tuyafite yatugirira akamaro | | | | |
| | **5. Ibibazo cyangwa indwara bishamikiye kuri diabetes** | | | | |
| 20 | Kubera umunaniro n'ibindi bibazo biterwa na diyabete, nirirwa nicaye nta kintu nkora cyanyinjiriza amafaranga | | | | |
| 21 | Diabete yangizeho ingaruka n'uburwayi bitandukanye birangora kwikurikirana (kutabona, umunaniro, kudatera akabariro, izindi ndwara….) | | | | |
| 22 | Nywa imiti yindi itari iya diyabete, kuyifatira icyarimwe biragoye, bitumpa ntafata neza imiti ya diyabete. | | | | |
| | **6. Guhindura imyitwarire n'imitekerereze** | | | | |
| 23 | Iyo ntekereje ko diabete idakira bintera kwiheba cyane bigatuma ntezuka mu kwikurikirana | | | | |
| 24 | Diyabete iranyihebesha cyane nkumva ntacyo maze cyangwa mariye umuryango wanjye | | | | |
| 25 | Ntabwo numva ntuje, diabete yashize inkeke ku buzima bwanye | | | | |
| 26 | Numva narataye ikizere, diyabetes yashyize ubuzima bwanjye ku nkeke | | | | |
| 27 | Iyo urwaye diyabete bisaba guhindura uko wabagaho mbere, usanga bigoye kureka ibintu bimwe na bimwe wari umenyereye | | | | |
| | **7. Indyo iboneye** | | | | |
| 28 | Ntago byoroshye kubona imboga n'ibindi biryo bigenewe abarwayi ba diyabete aho ntuye | | | | |
| 29 | Kurya isahane yanjye njyenyine bituma numva ndi mu kato. Hari igihe nyuzamo tugasangira | | | | |
| 30 | Iyo umuntu atari murugo biragorana gukurikiza rejime/imirire iboneye ya diabete | | | | |
| 31 | Ibintu bya rejime/indyo iboneye si ibintu nitaho cyane. Nirira ibyo numva nkunze | | | | |
| 32 | Usanga abaganga basobanura regime ya diyabeti mu buryo butandukanye, nta wumbwira regime/imirire y'ukuri nakurikiza. | | | | |
| 33 | I cannot buy special food items for myself like when I have not enough money, I first think about my family | | | | |
| 34 | Maze igihe kirekire kuri rejime, igeraho ikandambira nkanyuzamo nkirira ibisanzwe | | | | |
| 35 | Nshobora kurya ibiryo bibonetse bitajyanye na diyabete kubera ko ari byo mbasha kugura bijyanye n'ubushobozi bwanjye | | | | |
| | **8. Imyitozo ngorora mubiri** | | | | |
| 36 | Muri aka gace, umuco wo gukora imyitozo ngororamubiri ubona ntawuhari, ubura abantu bagutera imbaraga | | | | |
| 37 | There is no culture of doing physical exercise in this community | | | | |
| 38 | Ntabwo nahawe amakuru ahagije mu bijyanye n' imyitozo ngorora mubiri | | | | |
| 39 | Ubundi burwayi/ibibazo biterwa na diabete bimbuza gukora imyitozo ngororamubiri | | | | |
| 40 | Gukora imyitozo ngorora mubiri ntibimbangukira ngo numve binshishikaje | | | | |
| 41 | Ntabwo ntekereza ko gukora imyitozo ngororamubiri hari icyo byahindura ku burwayi bwanjye bwa diyabete | | | | |
| 42 | Uretse akazi gasanzwe/imirimo yo mu rugo, birangora kubona umwanya wo gukora imyitozo ngororamubiri | | | | |
| | **9. Imiti** | | | | |
| 43 | Iyo isukali iri ku bipimo byiza hari igihe nshobora kuba mpagaritse imiti | | | | |
| 44 | Hari ubwo nibagirwa gufata imiti | | | | |
| 45 | Imiti ya diyabete banyandikiye ndayifata ari ko nkoresha n' iya gakondo kuko iramfasha | | | | |

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| 46 | Imiti y'abagorozi mbona igira akamaro kanini kuri diabete | | | | |
| 47 | Numva imiti mfata atari byo nagakwiye kuba mfata | | | | |
| 48 | Numva ntafite ubumenyi buhagije ku miti ya diyabeti | | | | |
| 49 | Nkunda kubura imiti muri farumasi z'ibitaro bityo kuri jye kubasha kwigurira imiti muri farumasi zigenga bikangora | | | | |
| 50 | Iyo mfashe urugendo nta miti mfata kuko nta bwo mbona uko nyitwara | | | | |
| 51 | Hari ubwo numva nihebye cyane, ngahagarika imiti byazagera aho nkongera nkayifata. | | | | |
| 52 | Kubera akazi nkora hari igihe ntafatira imiti ku gihe cyagenwe | | | | |
| 53 | Hari igihe mbura amafaranga yo kugura imiti ya diabete | | | | |
| 54 | Numva mbihiwe no kumva ko ngomba kunywa imiti buri munsi | | | | |
| 55 | Kuva ku binini ukajya ku nshinge, ni ibintu abarwayi ba diyabete tutumva vuba iyo tubibwiwe nabaganga, tubanza kubyanga | | | | |
| | **10. Kugenzura ibipimo by'isukali** | | | | |
| 56 | Ntinya inshinge ntabwo nakwipima isukali mu rugo | | | | |
| 57 | Kubera akazi nkora ntibinyorehera kwifata ibipimo by'isukari | | | | |
| 58 | Nta makuru ahagije nahawe/mfite ku bijyanye n'ibipimo by'isukali no kubikurikirana | | | | |
| 59 | Si ntekereza ko guhora umuntu yipima isukali byatuma hari igihinduka ku burwayi bwa diyabete afite. | | | | |
| 60 | Ntabwo mfite ubushobozi bwo kugura akamashini ko kwipima | | | | |
| 61 | Ntabwo mfite ubushobozi bwo kugura bandelete | | | | |
| | **11. Isuku y'ibirenge** | | | | |
| 62 | Nta bwo nahawe amakuru ahagije ku bijyanye ni isuku y'ibirenge | | | | |
| 63 | Nkurikije akazi nkora kubahiriza ibijyane ni isuku y'ibirenge ni ibintu kuri jye mbona bigoye | | | | |
| 64 | Ntabwo muganga ajya ansuzuma ibirenge ngo menye nanjye ibyo nkwiye kuba nkora | | | | |

SN: sibyo nabusa, S: sibyo. N : nibyo, NC : nibyo cyane