DIETARY AND ASSOCIATED DETERMINANTS OF GLYCEMIC CONTROL AND TYPE 2 DIABETES SELF-MANAGEMENT AMONG ADULTS IN MALAWI

By

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ABSTRACT

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Type 2 diabetes mellitus (T2DM) is a non-communicable disease (NCD) and a growing problem in sub-Saharan Africa (SSA) in conjunction with infectious diseases, chronic undernutrition and micronutrient deficiencies. Self-management of T2DM is critical for optimal glycemic status; however, socio-environmental factors pose a challenge in achieving it. Therefore, the specific aims of this cross-sectional mixed method study conducted in urban and semi-urban districts in Malawi were to: 1) assess glycemic status (glycosylated hemoglobin-A1C) associated factors and estimate cost of care and related expenditures for T2DM based on glycemic status, 2) assess diet quality and its association with glycemic status and factors affecting diet quality such as food insecurity, 3) qualitatively assess socio-environmental factors affecting self-management of T2DM, specifically diet and physical activity.

Of a total n=428, the A1C status of 60.3% of the participants was above the acceptable clinical glycemic target (≥8%). A1C was significantly inversely associated with age and physical activity level and positively with distance to the clinics, underweight status, number of comorbidities, duration of diabetes, additional blood glucose monitoring at home/private clinics and diabetes peer group and participant perceptions of fluctuating blood glucose. The total median expenditure for diabetes care was significantly higher in the urban than semi-urban areas per quarter year and A1C was negatively associated with total out-pocket expenditure. Additionally, consumption of a diet high in carbohydrates and consuming ≤3 meals per day

increased the odds of not achieving the recommended clinical A1C target. The severity of food insecurity positively associated with A1C and negatively with dietary diversity. The socio-environmental barriers to an appropriate diet included cost and access to food; household size; lack of knowledge on what and how much to eat; separate preparation and purchase of food; dilemmas of what to eat during functions and travel; and conflicting dietary information from different sources. Comorbidities and fear of public ridicule were primary barriers reported by participants being physically active. The facilitators to diet and physical activity were similar such as family and friends, health workers, diabetes support groups, as well as social support systems.

The majority of adults with T2DM were not meeting the acceptable clinical glycemic target and incurred significant amount of expenses associated with diabetes care. The diet quality was poor especially relative to high carbohydrate intake and meal irregularities, which were primarily impacted by food insecurity, unreliable dietary information and inadequate nutrition knowledge. The findings provide important health and nutrition implications for Malawi to strengthen existing health systems and improve services to decrease diabetes-related complications and reduce the economic burden of this vulnerable population and the nation. Additionally, dietary interventions that focus on carbohydrate counting, portion size control, total dietary quality, and meal planning are urgently needed in Malawi. Furthermore, the focus on socio-environmental factors should be prioritized by nutritionists, dietitians, and health workers when developing and providing nutrition and physical activity education in Malawi.

God Almighty for the grace, favor and mercy

and

my loving mother and sister Esther; who taught me that the best legacy one can have is education

and

all those adults diagnosed with Type 2 diabetes in Malawi

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CHAPTER 1- INTRODUCTION

This chapter provides background information on the magnitude of the problem of Type 2 diabetes mellitus in Malawi, rationale, research specific aims, significance and innovativeness of the study as well as the conceptual framework based on the socio-ecological model of self-management of diabetes.

A. Background

In developing nations, the incidence of nutrition-related non-communicable diseases (NCDs) such as Type 2 diabetes mellitus (T2DM) is increasing rapidly [1, 2]. Globally, as of 2017, 8.8% (425 million) of adults between 20 and 79 years of age had diabetes, and it is estimated that by 2045, 629 million will be diagnosed with the disease, with a 48% increase [3] if serious prevention measures are not taken. In Africa, it is estimated that in 2017 about 16 million adults (20-79 years of age) were afflicted with diabetes with a prevalence of 4.4%, and it is predicted to increase to about 41 million by 2045 [3]. Additionally, about 69.2% of those with diabetes in Africa are unaware of their condition and 55.3% of people with diabetes live in urban/semi-urban areas [3]. Mbanya and Ramiaya (2006) indicated that in sub-Saharan Africa (SSA), the prevalence of diabetes is 1.5 to 4.0 times higher in urban than rural areas [4]. Furthermore, Jones et al., (2016) reported higher odds of overweight/obesity, which is highly correlated with risk for diabetes, among women of the reproductive age residing in urban and peri-urban areas in SSA [5]. Nutrition transition in Africa, mainly due to changes in agricultural and food systems, urbanization and modern technologies, has affected the physical activity and dietary behaviors among the population and likely the risk for diet-related diseases such as obesity and T2DM [5-9]. Compared to other regions in the world, Africa has reported high diabetes-related death rates

(77.0%) among adults under the age of 60 years and rates are highest among those 30-39 years and 1.6 times higher in women than men [3].

Malawi is currently experiencing the triple burden of malnutrition: chronic undernutrition, micronutrient deficiencies and nutrition-related NCDs such as T2DM. Although these three conditions are perceived as different problems, they coexist in communities and within the same household, perpetuating the vicious cycle of malnutrition [5, 10-12]. The prevalence of T2DM is estimated at 5.6% among adults 25 to 64 years of age [13, 14], higher in urban (3.0%) than rural (1.7%) areas and 41% are undiagnosed, indicating that the prevalence might be even higher than currently estimated [15]. NCDs in Malawi account for at least 12% of total Disability Adjusted Life Years (DALYs) and are the second leading cause of death in adults after Acquired Immunodeficiency Syndrome (AIDs) complications [14]. The risk factors for NCDs in Malawi are higher in urban than rural areas: overweight (38.6% vs. 21.9%), obesity (13.6% vs. 4.4%) and physical inactivity (24.1% vs. 8.7%). Furthermore, Jones (2015) reported similar trends for intake of food and beverages linked to the nutrition transition such as sugar-sweetened beverages (urban 41% vs. rural 12%) and processed vendor foods such as potato-chips (urban 51% vs. rural 32%) [9]. According to a study targeting health professionals in Malawi, poor diet and inadequate knowledge on healthy eating habits were deemed important factors reported for the increase in NCDs [16]. Therefore, promoting healthy diets and warranted changes in dietary behavior for the general population will help prevent a further rise in T2DM [10].

According to the American Diabetes Association (ADA) 2019, self-management of diabetes is critical for optimal clinical glycemic status as measured by glycosylated hemoglobin levels (A1C). It consists of eating a healthy diet, engaging in regular physical activity, medication compliance, foot care and self-monitoring of blood glucose [17]. Unacceptable glycemic

(A1C≥7%) in T2DM is a risk for the development and progression of diabetes-related complications and aggravates public health problems [18-21], such as sight-threatening diabetes retinopathy (29.4%), retinopathy (50.1%), and proliferative retinopathy (7.3%) [22] as observed in the Southern region of Malawi. Additionally, Cohen et al., (2010) [18] reported high rates of diabetes-related complications such as nephropathy (34.7%), retinopathy (34.7%), and neuropathy (46.4%) in Blantyre city [18]. There is currently a paucity of data in Malawi on the factors associated with acceptable and unacceptable levels of clinical glycemic target, because A1C tests are not being done in most public hospitals in Malawi [18, 21], even though it is the gold standard and recommended because it reflects long-term glycemic exposure for over a period of two to three months [23-26].

Educating patients and their families on diabetes self-management is vital for optimal clinical glycemic status. In other developing countries, such as Tanzania, Kenya and Botswana, factors such as low income, lack of exercise partners and lack of information have been reported to affect diabetes self-care practices [27-29], although there may be variations in economic and socio-cultural factors that could affect the management of diabetes from country to country. In Malawi, no in-depth research has been done to understand the socio-environmental factors that might affect self-care behaviors like diet and physical activity among adults diagnosed with T2DM. Therefore, documenting these habits and experiences is needed to fill this gap in knowledge.

Dietary studies in Malawi focus on specific nutrient intakes [30, 31] without assessing overall diet quality, which is vital for health [30] and can contribute to disease if not adequate [32-35]. Dietary advice for the management of T2DM in Malawi is based on a general food guide, which is not specific to the condition; hence, it is difficult to translate into daily nutrition

counseling and education [36]. In addition, nutrition labeling is voluntary and not well understood by the majority of Malawians, making informed food choices difficult [37, 38]. This leads to unhealthy dietary patterns and poor dietary compliance for those diagnosed with diabetes [31, 39, 40]. Achieving a quality diet is negatively impacted by food insecurity, and 61% (66% rural and 42% urban) of the population were estimated to be food insecure in 2016-2017 [41]. Furthermore, nutrition education on the dietary management of diabetes is provided by health workers, who are not trained in nutrition, and the involvement of nutritionists in NCD service provision is very low, as reported by 35% of senior health officers [16]. Assessing diet quality in patients with T2DM is important because little is known about the contribution of local Malawian's diets to their clinical glycemic status. It is also imperative to understand the relationship of eating habits to disease management based on location of residence (urban and semi-urban) to identify challenges and guide strategies for dietary counselling.

B. Specific aims

The overall goal of this study was to elucidate the clinical glycemic status and associated factors of Malawian adults with T2DM and the implication of diet quality, food insecurity and socio-environmental factors on achieving optimal glycemic targets. This will guide the development of nutrition education and extension materials for prevention and management of T2DM in Malawi as well as inform nutrition policy revisions to enhance the role of nutrition in NCD services, especially T2DM in Malawi. The hypotheses were generated and tested using the following three specific aims and research questions:

Specific Aim 1a: To assess glycemic status and associated factors

It was hypothesized that over 50% of adults diagnosed with T2DM will have unacceptable levels of clinical target glycemic status (A1C≥8%) and determinants (demographic, economic, biomedical and perceptual factors) of glycemic status would differ between urban (Lilongwe) and

semi-urban (Kasungu) areas. To achieve this aim, the following research questions were of interest.

I. What proportion of adults diagnosed with T2DM are in unacceptable vs. acceptable clinical target glycemic status in urban (Lilongwe) and semi-urban (Kasungu)?
II. What are the factors associated with unacceptable and acceptable clinical target glycemic status?

Specific Aim 1b: To estimate cost of care and related expenditures for T2DM based on glycemic status

The costs associated with diabetes care were estimated and compared between the urban and semi-urban participants. T2DM incurs extra cost despite support from the government due to inadequate resources in the hospitals. Therefore, it was deemed necessary to estimate the cost related to the purchase of additional hypoglycemic medications, blood glucose monitoring, transportation expenses and food expenditure per capita per month. To achieve this aim, the following research question was asked.

I. What are the factors associated with total out-of-pocket expenditure in T2DM management in Malawi?

Specific Aim 2: To assess diet quality and its association with glycemic status and factors affecting diet quality including food insecurity

It was hypothesized that poor diet quality among adults diagnosed with T2DM would be the primary factor contributing to unacceptable level of clinically targeted glycemic status (A1C≥8%) even when controlling for socio-demographic factors. To achieve this aim, the following research questions were the focus.

I. To what extent does diet quality influence clinical glycemic target status?
II. Does food insecurity affect both diet quality and glycemic status?

Specific Aim 3: To qualitatively assess socio-environmental factors affecting self-management of T2DM, specifically diet and physical activity

For this specific aim, facilitators and barriers to appropriate diet and physical activity including the social networks that support management of T2DM were explored. To achieve this aim, the following research question was of interest.

I. How do socio-environmental factors facilitate or hinder self-management of T2DM, especially diet and physical activity?

C. Significance

This dissertation provided insight into the proportion of adults diagnosed with T2DM who have acceptable and unacceptable targeted clinical glycemic status and elucidated relationships between diet quality and the socio-environmental factors associated with glycemic status. Findings will help nutritionists, health professionals, academics and policy makers in Malawi to better plan and develop culturally appropriate dietary guidelines, interventions/programs and nutrition education materials for the prevention and management of T2DM, especially for those also affected by food insecurity.

D. Innovation

Non-communicable diseases (NCDs), that are diet-related such as T2DM are a serious problem in Malawi, associated with high morbidity and mortality rates in adults, negatively impacting the national economy, health care, and household resources, and contributing to the vicious cycle of malnutrition and poor health outcomes. Therefore, interventions that promote healthy diets and lifestyles for the population at risk are critical for the prevention and management of diabetes. Current efforts toward T2DM intervention in Malawi focus on medications rather than prevention and self-management strategies through lifestyle behaviors (diet and physical activity). The proposed research is innovative because it determined if and

how lifestyle behaviors (diet and physical activity), critical for self-management of T2DM are associated with glycemic status, as well as cost implications among adults in Malawi. The goal was to obtain data that can be used to inform the roles of nutritionists, dietary guideline and related policies and education materials for T2DM that are culturally appropriate for Malawi.

E. Conceptual framework

The conceptual framework of the study follows the socio-ecological model (Fig 1). All specific aims in this study are guided by the socio-ecological model for self-management of diabetes as depicted in Fig 1. The main outcome variable of the study is the clinical glycemic status (A1C), which can be affected by different factors within the socio-ecological environment. This model suggests that individual behaviors related to the self-management of diabetes are influenced by multiple factors at different levels, such as intrapersonal (individual level or microsystem), interpersonal (family and friends or mesosystem), institutional and community settings (work place and homes or exosystem) and policy environments (macrosystem) [42-44]. At the core of the model is the ***intrapersonal level***: individual characteristics and behaviors such as physical inactivity, eating habits and other lifestyle practices such as excess alcohol intake and demographic characteristics such as age, gender, educational level and income potentially affect the management of T2DM. In addition, self-management at the individual level is influenced by variety of factors such as knowledge, skills, beliefs, and attitudes [42-44]. The support that an individual receives from families, friends and neighbors plays a critical part in health behaviors, which can impact self-management of diabetes and health outcomes significantly [43]. These factors all operate on the ***interpersonal level***. The ***institutional and community environment/ecosystem*** such as workplace, schools, churches, and area of residence can contribute to improved self-management and positive health behaviors because they are important

community-based locations, which have been shown to be great targets for health interventions, social support and peer influence [43]. Furthermore, the community members' attitudes toward health behaviors, the availability of space for physical activities and markets or stores that sell healthy foods play crucial roles in the health of an individual [44, 45]. The availability of nutrition and health policies (***policy systems/macrosystem***), such as guidelines on diabetes prevention and management or nutrition labeling and nutrition education, including food marketing and production are also likely to influence changes in behavior for better diabetes care [43, 44]. Furthermore, from an ecological perspective, healthy dietary and lifestyle changes among people with diabetes are not likely to occur without sources of healthy foods, resources, and a supportive environment [46]. Therefore, this model was deemed the most appropriate for the study to help examine the determinants of glycemic status and how self- management of T2DM is impacted by multiple factors which consequently also affect glycemic status. Additionally, studying the interrelationships of how different factors within the socio-ecological model affect diet quality, food insecurity and socio-support systems may provide an understanding of possible interventions to be promoted for prevention and management of T2DM at different levels.

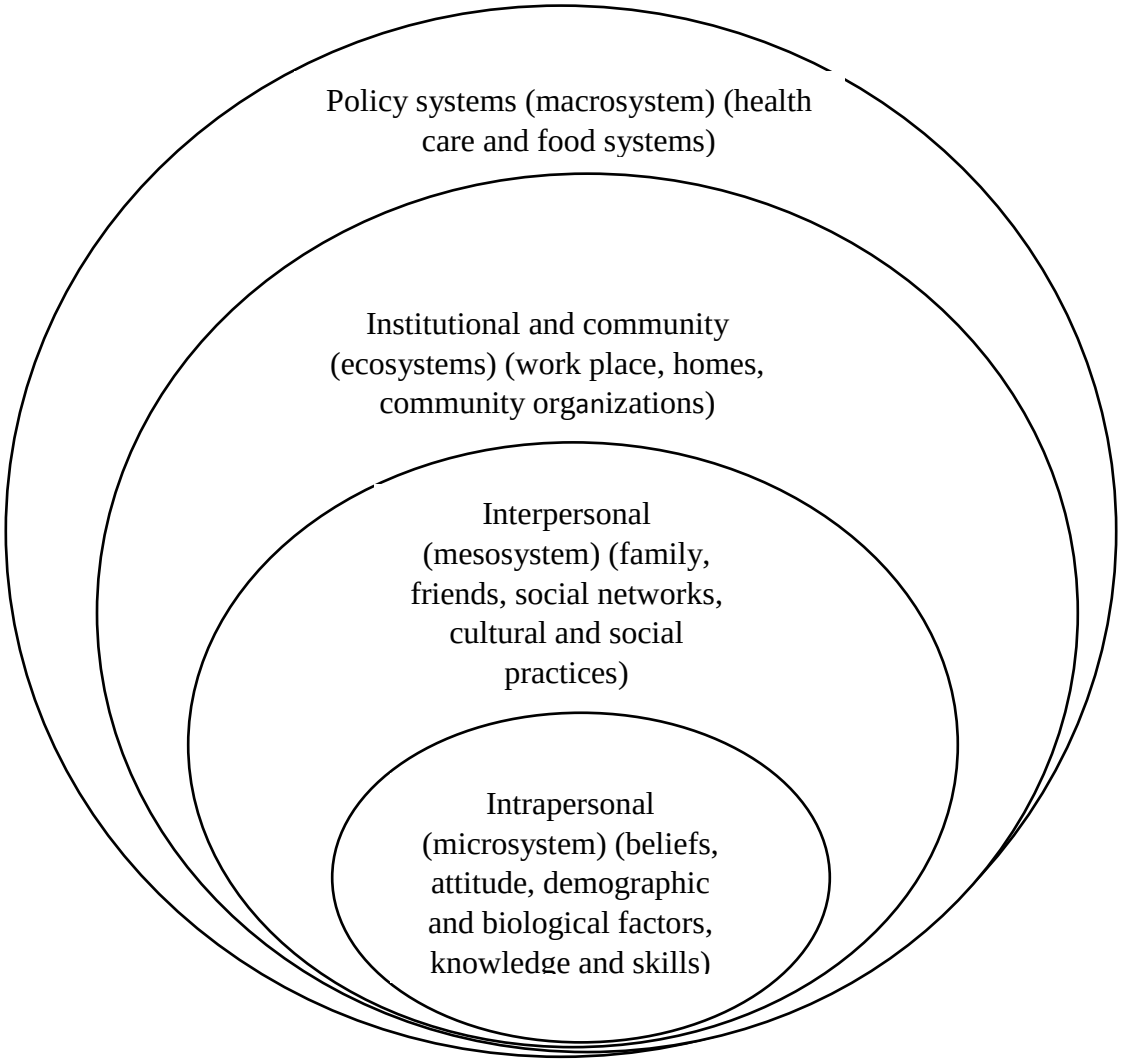


Figure 1: Socio-ecological model of self-management of diabetes: Adapted from Whittmore et al., 2004 [42], Contento, 2016 [41] and Story et al., 2008 [43]

CHAPTER 2- REVIEW OF THE LITERATURE

This chapter provides evidence of the previous studies on T2DM. The following sections provide an overview what T2DM, prevention and management of T2DM, glycosylated hemoglobin, glycemic status and associated factors, cost and related expenditures on diabetes care, diet quality, food insecurity and socio-environmental factors impacting self-management of diabetes, specifically diet and physical activity.

A. Type 2 Diabetes Mellitus (T2DM)

Type 2 diabetes mellitus (T2DM), metabolic condition that occurs when insulin hormone, which is responsible for regulation of blood glucose fails to function normally, either through decreased production or resistance [47-51]. The insulin resistance occurs due to dysfunction of cell receptors to use glucose from the bloodstream in response to insulin, resulting in increased blood glucose (hyperglycemia) [52, 53]. Additionally, insulin resistance is also due to the increase in visceral triglycerides and elevated levels of circulating non-esterified free fatty acids and glycerol [51, 53]. Furthermore, deposition of ectopic fat in non-adipose tissues (heart, liver skeletal muscles, and pancreases) is also linked to insulin resistance because it disrupts the functioning of the cells and organs especially in non-obese individuals [54, 55].

T2DM is a rising public health problem not only in the developed world, but also in developing countries such as Malawi. The increase in T2DM in developing nations has been explained in the context of nutrition transition, urbanization and economic growth, which have caused changes in dietary patterns, increased sedentary lifestyles and a rise in overweight and obesity, which are associated with insulin resistance [6, 7, 56, 57]. According to the American Diabetes Association (ADA) (2019), patients with T2DM who are not obese have increased central abdominal adiposity [17]. Additionally, the increased risk of T2DM has been associated

with gestational diabetes, undernutrition in early childhood and a family history of diabetes [8, 48, 55-60]. However, it was estimated that about 24-66% of adults with diabetes in Africa and Asia are either underweight or normal weight; although it is not clear if the weight status could be due to weight loss related to diabetes complications [55]. The general symptoms include weight loss, frequent urination, excessive thirst and blurred vision [58]. Diabetes, if not diagnosed or adequately controlled incurs serious ramifications, which include blindness, lower-limb amputation, kidney failure and early death [58].

B. Prevention and management of T2DM

Nolan et al., (2011) and WHO (2016) indicated that life course measures are required for prevention of T2DM through provisions of: a healthy diet, appropriate feeding practices for children including breastfeeding, exercise, good quality of healthcare and lifestyle education to groups at risk and their families [48, 56]. The ADA (2019) recommends that interventions aimed at the prevention of T2DM should include: physical activity and lifestyle changes such as weight loss for those who are overweight or obese and dietary changes such as reduction in intake of calories and dietary fats [17]. Furthermore, WHO (2016) indicated that emphasis on nutrition labelling for consumers is required for healthy food choices and direct policies that will help in the reduction in consumption of foods high in fats, sugars and salts [56].

The core component of diabetes management as stated by WHO (2016) is patient education, which should provide a clear understanding on the importance of a healthy diet, adherence to medication, foot care and lifestyle behaviors such as adequate physical activity and refraining from excess consumption of alcohol [56]. The aim of nutrition therapy in diabetes management is to support appropriate dietary patterns, especially quality and diversified diets for optimal health outcomes [61]. Evert et al., (2014) and Ley et al., (2014), indicated that the quality of diets

in terms of fats and carbohydrate is critical in diabetes management and improved glycemic status [61, 62]. Carbohydrate sources from vegetables, fruits, whole grains and legumes are recommended [61, 62] because they are high in fiber and improve insulin response [62, 63]. The quality of fat such as polyunsaturated fatty acids and monounsaturated fatty has been associated with improved insulin sensitivity [62, 63]. Oral hypoglycemic agents such as metformin (first-line drug for the treatment of T2DM), which decreases liver glucose production and increases liver insulin sensitivity, and glibenclamide (class of sulfonylureas) stimulate releases of insulin (increase insulin secretion) by the pancreatic β cells [51] and are also commonly recommended in Malawi by the Ministry of Health [64].

C. Glycosylated hemoglobin (A1C)

Hemoglobin A1C is a component of hemoglobin mainly used to reflect the average plasma glucose concentration over a period of eight to 12 weeks—equivalent to 120 days or 3 months—an indication of chronic hyperglycemia [24-26, 50, 65]. It has a similar lifespan to that of red blood cells (120 days), and during this period the red blood cell glucose molecule combines with hemoglobin to form glycosylated hemoglobin (A1C) [24-26, 65]. The advantage of using A1C is that it can be done at any time and does not require fasting [24, 56]. Furthermore the recommendation is that in patient who have been diagnosed with T2DM, A1C should be measured twice a year for those with stable clinical glycemic status and every three months (quarterly) for those not meeting the glycemic status goal [56, 66]. However, the A1C is affected by certain diseases that affect red blood cells, like malaria and anemias due to a deficiency of iron and vitamin B12, because of decreased erythropoiesis (red blood cell production/erythrocytes), resulting in elevated A1C [24, 50, 67] . WHO (2011) and the ADA (2019) indicated that A1C ≥6.5% is the cut point for diagnosing diabetes [17, 24]. According to

the ADA (2019), the acceptable levels of A1C in patients managing diabetes is <7% [17]. A1C ≥7% is an indication of suboptimal glycemia, which has been associated with macrovascular and microvascular complications such as retinopathy and blindness [17, 24]. However, a less strict A1C clinical target goal of <8% is used in resource-deprived settings where life expectancy is limited and very challenging to achieve the glycemic status goal even though diabetes patients are on hypoglycemic agents and receiving diabetes self-management education [17]. For instance in Malawi as of 2017, life expectancy at birth was estimated at 64 years [68] and overall acute diabetes care coverage is 3.3%, higher in urban (7%) than rural (1.5%) areas [64]. Therefore, the use of less stringent A1C target in this study is appropriate.

D. Health service delivery in Malawi

The health service delivery in Malawi is in three components: the public service, private for-profit (private hospitals and clinics) and private not for profit (religious, statutory and non-governmental organization hospitals; of which religious hospitals under the Christian Health Association of Malawi cover almost 29% of all health services in Malawi) [69, 70]. In both private for-profit and private not for profit hospitals, the cost of the health services is incurred by the patients [69, 70]. The public hospitals are managed by the Malawi Government through the Ministry of Health, and are organized in three categories: primary, secondary and tertiary levels, of which the tertiary/referral covers 70% of the services [69, 70]. In 2011, the Malawi Government incorporated NCD services such as screening and treatment for hypertension and diabetes in the Malawi Health Sector Strategic Plan (MHSS) (2011 – 2016) and Essential Health Package (EHP) [71, 72]. The EHP in Malawi is a poverty alleviation strategy, as costs such as health services in public hospitals are incurred by the government [71-74]. Therefore, this

dissertation focused on public hospitals where patients with T2DM receive free diabetes services.

E. Glycemic status and associated factors

1. Studies in Africa

Studies have revealed suboptimal glycemic status in T2DM patients in several African countries. For example, in Zambia it was reported that 61.3% of patients with diabetes had unacceptable (blood glucose ≥49 mmol/mL or A1C ≥6.6%) glycemic status [75]. In other countries like Senegal, only 24.8%, Kenya and Uganda, 17% and 20.8% of the patients with diabetes respectively had acceptable glycemic status (A1C<7%) [29, 76, 77]. Furthermore, a study done in Botswana found that 36.95%, 35.86% and, 27.19% had acceptable (A1C<7%), suboptimal (A1C 7-9%) and critically unstable (A1C≥9%) glycemic status respectively [78]. Another study in Kenya indicated that glycemic status was clinically unacceptable (A1C≥7%) of the 63.1% and acceptable(A1C<7%) among 36.9% of the T2DM [79]. In South Africa about 83.8% of patients with T2DM had A1C≥7% [80].

Researchers have grouped factors attributed to poor glycemic status into two components: socio-demographic factors and self-care behaviors [81, 82]. The former includes age, educational status, gender, financial constraints and duration of diabetes: and self-care behaviors include non-adherence to medication, physical activity and diet any recommendations [19, 25, 29, 76, 77, 81-83]. Additionally, desirable (A1C<7%) and suboptimal (A1C 7-9%) glycemic status was associated older age (≥66 years), attending the clinic for ≥three years and type of treatment (diet and oral hypoglycemic agents) [78]. Adeniyi et al., (2016) attributed unacceptable glycemic status among South African patients with T2DM to overweight/obesity, high low-density lipoprotein, longer duration of diabetes, obtaining information from non-health

professionals, female gender and income [80]. A study conducted in Ethiopia found that urban dwellers with T2DM had poorer glycemic status in comparison to the counterparts in rural areas [25]. Danquah et al., (2012) showed that patients with T2DM in urban Ghana were overweight, had central adiposity higher than normal increased body fat percentage and low physical activity [84].

2. Studies in other regions

Researchers in Jordan (68%), Malaysia (65.1%) and Australia (72%) found that A1C was ≥7%, and hence unacceptable in a significant proportion of patients with T2DM [20, 85, 86]. The average A1C among patients with T2DM in a Australian study was 8.2%, higher among adults <60 years; (8.6%) compared to those ≥60 years; (8.0%) [86]. The key factors contributing to high glycemic status included: <60 years, not following the dietary recommendations provided by the dietitian, being obese, high lipid profile, treatment type (diet therapy vs. combination therapy) [20, 85, 86]. A study done in Palestine indicated that only 19.5% had A1C ≤7% with a mean of 9% [87]. In the Palestine study; old age, adherence to medication and better health literacy were linked to acceptable glycemic status (A1C≤7%), but not the duration of diabetes [87]. Several studies in the U.S reported that unacceptable (A1C≥7%) glycemic status was attributed to duration of diabetes, multiple diabetes-related complications, lifestyle (physical inactivity, drinking, smoking), overweight/obesity, and young age [88-90]. However, ethnicity/race also contribute to chronic hyperglycemia in the U.S., where prevalence is higher among blacks compared to whites [91]. For instance, Chiu et al., 2010, reported elevated mean A1C levels among blacks (7.8%), followed by Hispanic/other races (7.7%) then white (7.2%) [88]. Furthermore, significant mean A1C levels of blacks (9.1%) was also noted by Bergenstal et al., 2017 compared to whites (8.3%) [91].

Some studies in China have reported that underweight versus normal weight status was also associated with chronic hyperglycemia. In a cohort study done for 12 months among Chinese, only 55.5% had A1C<8% and increased BMI was negatively associated with A1C and positively with plasma C-peptide (an indication of deficiency in insulin secretion) [92]. In another Chinese (5.8% underweight; 30.6% normal and 63.7% overweight/obese) study, underweight was associated with increased A1C, but low C-peptides and only 31.1% had an A1C<7% [93]. Among newly diagnosed Chinese patients with T2DM, a decrease in β-cell function and an increase in postprandial glucose excursion (blood glucose fluctuating parameter) correlated with underweight and healthy weight status [94]. Therefore, in all three Chinese studies, insulin deficiency contributed to elevated A1C in underweight compared to healthy weight T2DM individuals.

F. Cost of care and Type 2 diabetes mellitus-related expenditures

In 2017 it was estimated that, globally, health expenditures by people with diabetes was $727 billion United States Dollars (USD) and it is projected that the cost will increase to $776 billion USD by 2045, representing a 7% growth rate [3]. Similarly, in 2017 in Africa, it was estimated that health expenditures by people with diabetes was $3.3 billion USD, with a projection of $6.0 billion USD in 2045 [3]. Additionally, only 6% was spent on diabetes care in Africa for the budget allocated in the health system, despite the fact that the highest morbidity and mortality can be attributed to diabetes [3]. Furthermore, in Malawi, the diabetes expenditures were estimated at $4 million USD in 2010; by 2030 the projection is $9 million USD [95]. Kirigia et al., (2009) indicated that, in the SSA region, economic loss due to diabetes was estimated at $25.51 billion International Dollars (ID). Of this amount, 46.32% was incurred in countries

such as Malawi with a Gross National Income (GNI) per capita of >2000 ID, which translates into $2,144.3 ID per diabetes case per year [96] .

The average Gross Domestic Product (GDP) growth rate of Malawi has increased from 3.5% (2002–2005) to 7% during 2005–2010 [97]. About 50.7% of Malawians are living on less than one dollar a day [97], including 17% of the urban population [98], an indication of a high poverty rate. While the country is improving communicable disease and undernutrition outcomes, diet-related NCDs such as T2DM are on the rise, affecting the productive age group, which is vital for the sustainable economic growth of the country. Khowaja et al., (2007) indicated that the cost of diabetes care poses challenges to the standard of living of affected families and compromises general health, which contributes to the vicious cycle of poverty [99].

The cost of care for NCDs such as T2DM is grouped into direct and indirect costs. The direct costs are borne by the individual patient and families, such as medications, doctor consultations, travel expenses and special diet regimens [96, 100]. A study done in Kenya showed that patients with diabetes incurred extra costs for transportation, consultations with doctors and medications [29]. In Sudan, almost 65% of family expenditure was for diabetes care, if a family member was diagnosed with the disease [101]. Researchers in India and Pakistan found that low socio-economic households, especially the urban and rural poor, incurred more costs for diabetes care when compared to counterparts in higher socio-economic status [99, 102]. Furthermore, the cost increased with duration of diabetes, multiple diabetes complications and age [99, 102]. A study done in rural areas of the southern part of Malawi showed that the people who sought NCD services incurred 12.1% of their cost for travel expenses and 54.7% for medication and transportation combined [103]. In the Malawi, 2014-2015 fiscal year, household out-of-pocket

spending on NCDs (14.7%), was the highest compared to other conditions and the overall coverage for acute diabetes care was estimated to be 3.3% (7% urban and 1.5% rural) [64].

Estimating the direct cost of diabetes care is of great importance for informing policies for families and individuals with the economic burden of the disease [96, 99] relative to planning and implementation of interventions. In 2011, the Malawi Government incorporated NCD services such as screening and treatment for hypertension and diabetes in the Malawi Health Sector Strategic Plan (MHSS) (2011 – 2016) and Essential Health Package (EHP) [71, 72]. The EHP in Malawi is a poverty alleviation strategy, since the costs of health services in public hospitals are incurred by the government [72-74], but patients also spend money on the care of their condition due to limited resources. Therefore, it is necessary to also estimate the cost incurred by families who depend on public services because of the potential negative implications for self-care, and the paucity of data in this respect. Therefore, one of the aims in this dissertation was to estimate the costs borne by individuals with T2DM, especially in two different environments, urban and semi-urban areas.

G. Diet quality and association with glycemic status

The nutrition transition in Africa, due to changes in food systems, economic development and urbanization has affected dietary patterns, which adversely impact nutrition-related NCDs such as T2DM [5-8, 104]. The changes are attributed to affordability and availability of energy-dense and processed foods in local markets and sedentary lifestyles [5, 6, 105]. Furthermore, the changes in the diet from heathier traditional foods to consumption of more refined and processed foods—characterized by those low in fiber, high in sodium and sugars—has also contributed to the rise in NCDs [5, 6, 9, 104, 105]. Diet is one of the critical and modifiable elements for managing T2DM to ensure optimal clinical glycemic status [106]. Therefore, knowledge of the

local foods and the heathier foods that should be available and always accessible is important. Additionally, dietary practices may also be influenced by cultural factors and socio-economic status, hence making it difficult for patients with diabetes to comply with dietary recommendations [31, 107].

When explaining diet and nutrition related NCDs such as T2DM within the context of urbanization, it is important to understand specific dietary behaviors in relation to health outcomes. Previous studies done in African countries have shown that the diets of urban Ghanaian patients with diabetes were rich in carbohydrates, fat, and sodium, but moderate in protein and poor in fiber [84]. Frank et al., (2014) group the dietary pattern of urban Ghanaians with T2DM into two categories: 1) purchase, which consists of meat products, cereals such as rice, sweets, fruits and vegetables, and 2) traditional, which consists of staples (plantain and fermented maize), fruits, vegetables, animal products such as fish, and palm oil. The risk of T2DM increased by 52% with consumption of the traditional diet, while the purchase diet was inversely associated with T2DM [108]. It was also observed that the diet of urban and rural black South Africans with T2DM was overall high in carbohydrates and low in fiber. However, the diet of patients with T2DM in urban areas was higher in animal protein and lower ratio of polyunsaturated to saturated fat compared to those in rural areas [31]. In Uganda among those newly diagnosed with T2DM, contribution of carbohydrate to total energy was high (73%), which was associated with an increase in body mass index and 85.5% consumed carbohydrates above the recommendation [109]. However, protein percent of the total energy was 12.6% and fat (14.4%) [109]. A study conducted in Ethiopia aimed at assessing dietary practices of patients with T2DM. They found that the dietary practices of patients with T2DM was poor, due to non-

availability of fruits and vegetables, high cost of the foods and the lack of nutrition education in the hospitals [110].

In urban Benin, two dietary patterns were noted: 1) traditional diets, constituted grains and fruits, and 2) transitional diets, consisted of wheat products, meat and milk products, sweets, fats and legumes and seeds. The latter provided a diversified diet, high in micronutrients though low in a healthy diet score relative to WHO/FAO (2003) nutrition recommendation for prevention of chronic diseases [111]. Delisle et al., (2012) reported that the dietary quality of adult Beninese in a small city and rural area was adequate in terms of micronutrients and preventive diet scores when compared to that of adults in the main city. The small-town residents' diets were associated with the consumption of meat products and fats and oils, while adults in the main city consumed meat and milk products, vegetables and oils/fats [104]. A study among Palestinians with T2DM found that consumption of an Asian- like food pattern, which consisted of whole grains, legumes, vegetables, fruits, beans, tomatoes, and fruits decreased the odds of diabetes-related complications[112].

Previous studies have identified that dietary patterns [34, 104, 111, 113, 114] of African urban adults are associated with the risk of nutrition related NCDs such as T2DM. But none have associated diet quality with glycemic status in patients with T2DM. Although the dietary patterns have been investigated, it is appropriate to understand the food consumption patterns specific to Malawians, because of differences in food systems, agricultural seasons, production patterns, cultural values and economic status [31, 114]. In dissertation, diet quality was assessed using WHO/FAO (2003) guidelines for the prevention of chronic diseases, with an emphasis on energy-macronutrients, fruit and vegetable and sodium intakes [63]. An Individual Dietary Diversity Score (IDDS) was also used to provide a proxy of nutrient adequacy, with an

emphasis on micronutrient-rich foods [115] and the number of food groups consumed in a given time [116].

H. Food security and glycemic status

The concept of food insecurity has been primarily linked to undernutrition and rural settings, but understanding it in the context of urbanization and nutrition-related NCDs, such as T2DM, remains unclear [9]. FAO (2001) defined food insecurity as "a state when people do not have adequate physical, social or economic access to sufficient, safe and nutritious foods that meet their dietary needs and food preferences for an active and healthy life" [117]. Using the Food Insecurity Experience Scale (FIES), in 2017, it was estimated that globally, about 769.4 million people were severely food insecure, almost 33.8% in SSA and 20.1 million people in the Southern Africa [118]. The 2016-2017 Integrated Household Survey report indicated that very low food security was common among 61% of Malawians and 42% in urban areas [119]. T2DM patients living in urban areas may experience food insecurity due to competing priorities such as high cost of living and heath expenses, which compromise dietary diversity, amount as well as quality of the food consumed at the household level [120]. Jones (2015) indicated that for food-insecure urban Malawian residents, diets are high in refined and processed foods, and they have poor access to healthy nutrient dense foods increasing their susceptibility to poor health outcomes [9]. A healthy diet is a prerequisite for optimal glycemic status in patients with T2DM; however, food insecurity poses a challenge in achieving it. Studies have shown that in a state of food insecurity patients with diabetes may change their dietary patterns to unhealthy foods, skipping meals and reducing meal patterns, which could negatively impact glycemic status and aggravate overall health [121-125].

Prior studies have found that moderate to severe food insecurity is associated with poor glycemic status (A1C ≥8%) [126]. Unacceptable glycemic status and non-adherence to a healthy diet were noted in food insecure households in low-income populations in the U.S [122, 125]. Lyles et al., (2013) found that food-insecure patients with diabetes had unacceptable glycemic status at baseline but, after diabetes education intervention, no differences were observed in food-insecure versus food-secure patients [121]. Hasan-Ghomi et al., (2015) found a high prevalence of food insecurity in patients with diabetes compared to patients who did not have diabetes in urban Tehran [127].

There are high incidences of food insecurity reported in some urban areas of African countries [9, 120, 128, 129], associated with the buying of inexpensive energy-dense foods, skipping meals and reducing the quantity of meals as coping strategies [9, 120, 129]. When comparing urban and rural Kenyans, food insecurity was found to be higher in rural areas. However, incidence of overweight and obesity was higher in urban areas, which was negatively associated with a lower Household Food Insecurity Access Scale (HFIAS) score [130]. Meanwhile, Chaput et al., (2007) reported that urban food insecure women in Kampala Uganda were more likely to be overweight and had a larger than recommended waist circumference [128].

I. Socio-environmental factors affecting self-management of T2DM, especially diet and physical activity

Self-management of T2DM especially dietary behaviors and healthy lifestyles are critical for an optimal glycemic outcome. In addition to diet and physical activity, adherence to medication prescription and blood glucose monitoring, as stipulated by the ADA (2019) and WHO (2016) [17, 56] are also important. Optimal care of diabetes is to a large extent the

responsibility of the patient and families. Yet, different socio-environmental factors might pose a challenge to the management of diabetes such as income, availability and access to healthy foods, as well as safe and adequate engagement in physical activity. As such, patients with T2DM require support from family members, the communities in which they live and health systems [27, 43, 46, 131]. Qualitative research done in African countries has revealed some of the challenges in achieving healthy diets among patients with T2DM include scarcity of fruits and vegetables based on seasonal variation, income, cultural practices, portion size estimation and unwillingness of other family members to change their eating patterns [132-135]. Mayega et al., (2014) indicated that although patients with diabetes may experience difficulty achieving a healthy diet due to poverty and family size, modification of dietary behavior is a slow process because it is perceived that "*change involves sacrificing a 'good life' and replacing it with 'a life of rules"*[136]. However, inadequate diabetes education, lack of support from communities and conflicting information on diets were also barriers to diabetes care [27, 135, 137]. Facilitators, such as family support in food preparation [27], nutrition education, support from family, friends and neighbors [135], were also reported by the researchers. In urban areas in Africa, engaging in physical activity such as walking is associated with poverty as reported by Kiawi et al., (2006) in Cameroon [133]. This acts as a barrier in ensuring appropriate diabetes care. Mendenhall et al., (2014) found that not much emphasis is given to physical activity and weight loss in diabetes education in Soweto, South Africa [135]. Diabetes complications, such as loss of vision and amputation, are also factors affecting physical activity levels [138].

Even though previous researchers have identified facilitators and barriers to diabetes care in African countries, none of these studies were done in Malawi. Therefore, it is necessary to qualitatively assess issues affecting diabetes management in Malawi, especially regarding diet

and physical activity in two environments as with propounding different challenges: urban and semi-urban areas. Understanding culturally specific factors will help health and nutrition professionals develop interventions and education materials [136, 139] appropriate to Malawians, which can easily be rolled out at the community level. Therefore, one objective of this study is to qualitatively assess patient/client specific barriers and facilitators to achieving dietary and physical activity needs to elucidate issues in the target population.

CHAPTER 3- METHODS

This chapter describes the research location, study design and two phases (quantitative and qualitative). Additionally, it also provides an explanation of study tools and variables, statistical analyses and ethical approvals.

A. Description of the study area: Lilongwe (urban) and Kasungu (semi-urban)

In 2008, Malawi's population was estimated at 13 million, with 15.3% living in urban areas, and an average annual growth rate of 2.8% [140]. In 2009, the United Nations Department of Economic and Social Affairs (UNDESA) estimated that the urbanization rate for Malawi will increase from 15.3% to 28.8% and 48.5% by 2025 and 2050 respectively [141]. It has been reported that one in every five people in an urban area lives in poverty with less than a dollar per day [98]. Therefore, this rapidly developing urban society warrants investigation into various contexts—including health. The study was conducted in the central region of Malawi. Purposively, two areas were targeted: Lilongwe (urban) and Kasungu (semi-urban) districts, because nutrition-related NCDs such as T2DM have been reported to be high in urban areas [4, 13, 58].

The Lilongwe district, found in the Central region, is the largest and main city of Malawi. By 2008, Lilongwe had a population of 1.8 million people, of which 669,021 lived in the main city, with a 4.3% growth rate [140]. About 22% of the people in the main city are living below the poverty line [98]. It was projected that, by 2015, the number of people living in urban Lilongwe will increase to over one million with a growth rate of 5.8% [140]. Additionally, about 76% of the population in the main city lives in informal/unplanned settlements/low-income housing [142, 143]. Urban Lilongwe is demarcated into residential areas based on population

density: high density (areas 1 [fall estate], 7 [*Kawale*], 8 [*Mchesi*], 21, 22, 23, 24, 25, 26, 27, 36, 39, 49 & 46 , slum areas such as *Phwetekere, Mgona, Kandikole, Chinsapo, Kauma, Mtandire*), medium density (areas 2, 5, 6, 11, 15, 17, 18, 26, 30, 32, 33, 35 & 38) and low density (areas 3, 9, 10, 12, 14 ,43 & 47) [143]. Other areas are commercial, industrial and government offices. Mkwambisi et al., (2014) indicated that the population density is related to income levels, with low-density areas more likely to be associated with high-income levels and vice versa [144].

Kasungu is a town in the central region, 127 km (approx. 78.91 miles) north of Lilongwe [145]. It is also a breadbasket district for Malawi, producing both food and cash crops (primarily tobacco). According to the National Statistical Office (NSO) (2009), in the year 2008, the population census report noted there were about 629,123 people, with an annual growth rate of 2.7% [140]. It was projected that, in 2015, the population would increase to over 800,000 people with an annual growth rate of 3.9% [140, 145] and a poverty rate of 44.9% [145]. The Kasungu district has 13 Traditional Authorities (T/A), of which three are found in the urban area [145]. Urban Kasungu consists of Bomas and town planning areas, which are demarcated by T/A, namely *Kaomba, Mwase and Lukwa,* and the Group Village Heads (GVH): *Chimbuna, Gundani, Chiteyeye, Kasankha, Chilanga, Selemani, Yasenya, Mbeta, Moffart, Kaning'a, Mtondo, Feza, Kampingo Juma, Chambala, Katchembele, Katema, Kasankha, Mtambalala, Kasalika, Maplot, Moyousana.*

Description of the study sites: Kamuzu Central Hospital and Kasungu District Hospital

Located in the main city, the Kamuzu Central Hospital (KCH) is the resident hospital for training health professionals and provides primary and secondary care to the urban and semi-urban populations of Lilongwe (over one million) [21]. It is also a referral care center for the central region in Malawi and serves over five million people [21]. The diabetes clinic at KCH is

managed by the out-patient department and is offered twice a week—Tuesdays and Fridays [21]. During the diabetes sessions, patients are provided with general information on the management of diabetes by a nurse. The only available measure of clinical glycemic status at KCH is fasting blood glucose, and reviews are done on a quarterly basis (every three months) [21], depending on the first appointment of the patient. In all public hospitals, the cost of care and prescribed diabetes medications are incurred by the government, because NCDs such as diabetes have been incorporated into the EHP as a poverty alleviation strategy [18, 21, 73, 74, 146].

The Kasungu District Hospital is the only referral hospital in the district and offers services to over 800,000 people residing in rural and urban areas [145]. The hospital provides services for both communicable and NCDs such as T2DM [145]. The diabetes clinic at the Kasungu District Hospital is under the out-patient department and is offered once a week—Wednesdays. Furthermore, in 2012, it was the first district in the country to pilot the WHO Essential Package for NCDs prevention and control (WHO PEN) designed to facilitate the implementation of prevention and management strategies in low resource settings [147]. WHO provided the district with glucometers for measuring blood glucose, blood pressure machines, weight scales and tape measures [147].

B. Study design: Cross-sectional

A cross-sectional study, using mixed quantitative and qualitative research methods was conducted, targeting Malawian adults (≥25 years of age) diagnosed with T2DM. The age range of 25 to 64 years was previously used to estimate national prevalence of NCDs including diabetes in Malawi [13]. The study was conducted from June to August 2017 and in two phases. The first phase was quantitative in nature to address specific aims 1 (a & b) and 2 from early

June to early August 2017, while the second phase employed a qualitative approach specifically for aim 3 and was done from early to the end of August 2017.

C. Phase 1: Quantitative study

1. Sample size calculation

The primary researcher with assistance from the Center for Statistical Training and Consulting (CSTAT) at Michigan State University (MSU) used Power Analysis and Sample Size software (PASS version 14) to calculate the sample size [148]. More specifically, multiple regression analysis was used in the sample size calculation, with the assumption that our coefficient of multiple determination (R^2) is 0.25, meaning that the percentage of the response variable variation was explained by the model [148]. The following are the parameters considered in the sample size calculation:

- Anticipated R^2: 0.25
- Statistical power level: 0.85
- Probability level: 0.05

Therefore, the required total sample size was calculated to be 400 subjects. Given the total number of patients with T2DM at Kasungu District Hospital of 845 and 1,689 at KCH, provided by the hospital in September 2016, the sample estimations were deemed realistic. The Probability Proportional to Size (PPS) was applied to estimate the required sample size for each study site. The PPS is a "sampling method under which the probability of a unit being selected is relative/proportionate to the size of the ultimate unit" [149]. Therefore, the estimates were a minimum of 133 participants for Kasungu (semi-urban) district and 267 participants for

Lilongwe (urban) area. However, we sampled 140 participants in semi-urban and 288 from urban, to total 428 participants.

2. Inclusion and exclusion criteria

The following are the inclusion and exclusion criteria used in the study.

Inclusion criteria:

- Malawian adults aged 25 years and above diagnosed with T2DM by the physician
- Out-patient diabetes clinic attendance at the same hospital at least twice for the past year
- Native Malawians
- Patients with a clinical appointment between May and August 2017

Exclusion criteria:

- Patients diagnosed with type 1 diabetes mellitus by the physician
- Pregnant and lactating mothers
- Non-native Malawians
- Patients who came to the emergency department because of very high/low blood glucose
- Adults with diabetes who were blood transfused within the last 3 months, because A1C, which circulates for about 120 days, has a similar lifespan to that of erythrocyte [24, 25], and may be impacted.
- Patients with diabetes who came to the emergency department.

3. Sampling procedure

Convenience sampling was used to recruit participants. About 450 individuals with diabetes volunteered to participate in the first phase of the study. However, only 428 participants met the inclusion criteria, 19 were excluded, (17 were under the age of 25 years, and two-came

to the emergency department because their blood glucose levels were very high), two-dropped before the individual interviews, and one-was incomplete. Each selected participant provided written informed consent before individual interviews were conducted followed by anthropometric measurements (weight, height, waist and hip circumference) by trained research assistants (human nutrition students from Lilongwe University of Agriculture and Natural Resources, Bunda Campus). Then the participants provided blood samples. The recruitment and interview procedures are outlined in Fig 2:

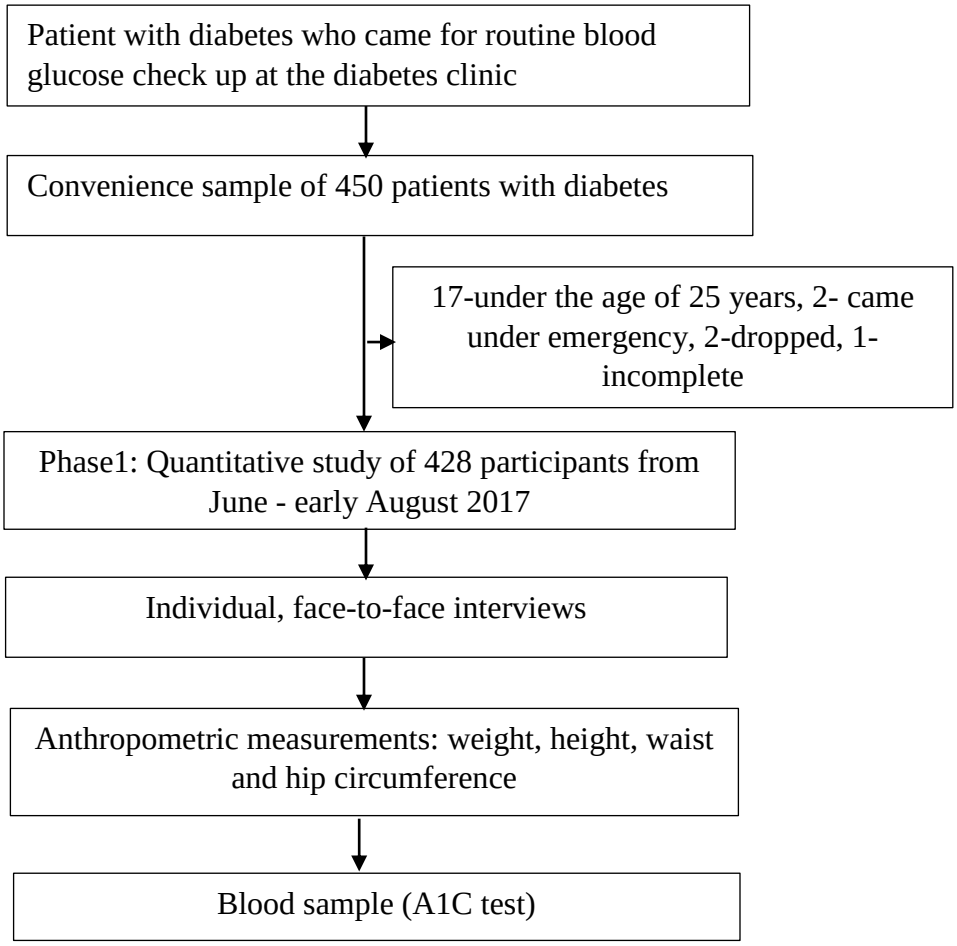


Figure 2: Recruitment and interview framework for quantitative study (phase 1)

4. Blood sample for A1C test

About 10 mL of venous blood samples were drawn from each participant by a laboratory technician and nurse trained by the Ministry of Health in Malawi. Approximately 5 mL of the blood was transferred in ethylenediaminetetraacetic acid (EDTA) tubes for the A1C test and 5 ml of blood was kept in a plain tube (red top) for other analyses. The blood samples were kept in the in a cooler box with ice packs at an average temperature of 12 ^{O}C. The blood samples were then taken to the laboratory (Partners in Hope private clinic in Lilongwe) the same day. The blood samples in EDTA tubes were kept at a temperature of 2-4 ^{O}C, while samples in plain tubes were kept at -20 ^{O}C. A1C analysis was done using the blood samples in EDTA tubes with a DCA Analyzer (Siemens, Tarrytown, NY, USA).

5. Study tools

The survey tool for specific aims 1 and 2 (Appendix 1), was adapted from validated, previously used tools, namely the Malawi Integrated Household Survey tool [150] for socio-demographic questions, WHO Stepwise approach to chronic disease risk factor surveillance [151] for lifestyle questions such as physical activity, Food and Agriculture Organization (FAO) for dietary diversity [115] and Food and Nutrition Technical Assistance (FANTA) for household food insecurity [152]. The survey tools were pre-tested by five graduate African students at MSU to refine and establish time for completion. On average, the approximate time for completion is 50 minutes.

6. Variables for specific aim 1a and b

Specific aim 1a: To assess glycemic status and associated factors

The semi structured questionnaire, developed by the primary researcher from validated used tools to collect information included: 1) *socio-demographic characteristics* such as age, gender, location, marital; status, household income per month and distance to the hospital for diabetes services, 2) Self-reported *perceptual factors* such as how they perceived the blood glucose results after the nurse/clinician has checked and if their blood glucose was lower than first diagnosed with the condition, 3) *Biomedical factors* included: diabetes-related information such as treatment, blood glucose monitoring, comorbidities, frequency of blood glucose monitoring at the government hospital, additional blood glucose monitoring at private clinic/home/diabetes peer groups and purchase of additional oral hypoglycemic agents, physical activity level, A1C and weight status.

Physical activity levels: The total physical activity metabolic equivalent (MET)-minutes per week was calculated as a continuous variable, and categorized <3000 MET-minutes per week as low-moderate physical activity level and ≥3000 MET-minutes per week as vigorously intense physical activity [151].

Glycosylated hemoglobin (A1C): The categorization of the A1C was according to the clinical target recommendation of the ADA potential for treatment adjustment: A1C<8% acceptable and A1C≥8% unacceptable [153].

Anthropometric measurements such as height, weight, waist and hip circumference collected to assess the weight status and central abdominal obesity of the participants. Height was measured using a portable stadiometer (Seca 213, SECA GmbH & Co.KG. German) to the nearest 0.1 cm and weight using a scale (Seca 803, SECA GmbH & Co.KG. German) to the

nearest 0.1 kg. Body mass index (BMI) kg/m^2 was derived and categorized according to the WHO cut-off points: underweight <18.5, normal 18.5-24.9, overweight 25.0-29.9 and obesity ≥30.0 [154]. Central abdominal obesity has been associated with increased risk of NCDs and relate closely with abdominal adipose tissue [154, 155]. Moreover, the increase in abdominal adipose tissue has been associated with reduced insulin resistance the primary abnormality in T2DM [63, 155, 156]. Hence, it was imperative to assess waist and hip circumference in addition to the weight status. Waist and hip circumference were taken using a non-stretchable seca 210 measuring tape to the nearest 0.1 cm to derive waist: hip ratio and waist circumference. Repeated measures (at least twice) of waist and hip circumference were taken, and the average was calculated [154]. The waist: hip ratio and waist circumference categorization was according to WHO cut-off points for substantially increased risk of metabolic complications: waist-hip ratio of ≥0.90 cm for male and ≥0.85 cm for women, while waist circumference is <102 cm for men and <88 cm for women [154].

Specific aim 1b: To estimate cost of care and related expenditures for T2DM based on glycemic status

Variables collected included additional expenses that the participants incurred despite getting the medical support from the public hospitals. Theses variables were transportation cost per hospital visit for blood glucose monitoring, cost for purchasing oral hypoglycemic agents and strips, expenses for additional blood glucose monitoring, and monthly household food expenditure. Additionally, cost of medications, strips and blood glucose monitoring were combined into a cost of care variable.

7. Variables for specific aim 2

Specific aim 2: To assess diet quality and its association with glycemic status and factors affecting the diet quality including food insecurity

Diet quality was measured using two indicators, namely Individual Dietary diversity score (IDDS) and the preventive diet score. Dietary diversity (DD) is the variety of foods or number of food groups consumed within a certain period usually the previous 24-hours, that reflects nutrient adequacy of the diet" [115].

7.1 Preventive diet scores

A quantitative 24-hour and typical day recalls were done to collect data on food intake to derive preventive diet scores. The calibrated typically used kitchen utensils were used to guide the respondents in estimating portion sizes. The preventive diet score was assessed using WHO/FAO nutrition recommendations for the prevention of chronic diseases [63]. These recommendations are based on the percent contribution of energy-providing macronutrients (fat, protein and carbohydrate) to total energy intake, sodium, fruit and vegetable intakes [63]. These guidelines are total fat (15-30%), saturated fatty acid (<10%), polyunsaturated fatty acids (6-10%), total carbohydrate (55-75%), protein (10-15%), cholesterol (<300 mg/day), sodium chloride (<5 g/day or sodium: 2 g/day) and fruits and vegetable intake of $\geq$ 400 g per day [63]. The preventive diet scores ranged from 0-8. A score of one was given if the recommendation is met for a specific dietary factor and zero if not met [104, 111, 157].

7.2 Individual Dietary Diversity Scores

Information collected from the 24-hour recall method was also used to derive dietary diversity parameter recommended by FAO to derive Individual Dietary Diversity scores (IDDS) [115]. IDDS uses 14 food groups: 1) cereals, 2) vitamin A rich vegetables and tubers, 3) white tubers 4) dark-green, leafy vegetables, 5) other vegetables, 6) vitamin A rich fruits, 7) other

fruits, 8) organ meat, 9) flesh meat, 10) eggs, 11) fish, 12) legumes, nuts and seeds, 13) milk and milk product, 14) oils and fats (including red palm oil). The response options were "consumed" (score=one) or "not consumed" (score=zero) for each specific food group. The IDDS is the sum of the scores of the 14 food groups and the scores range from 0-14. The higher the score the more diverse the diet. Consumption of ≤3 food groups was defined as low dietary diversity, 4 to 5 food groups medium dietary diversity and ≥6 food groups, high dietary diversity [115].

7.3 Household Food Insecurity Access Scale Scores

Household food insecurity was assessed using questions developed by the Food and Nutrition Technical Assistance (FANTA) in 2007 [152]. Household Food Insecurity Access Scale (HFIA) scores were calculated for each household by summing up the response to all questions regarding the frequency of occurrences. The HFIA scores range from 0-27. The higher the score, the more food insecurity (access) the household experienced and vice versa [152]. In addition, The Household Food Insecurity Access Prevalence (HFIAP) indicator was used to categorize households as food secure, mild food insecure, moderate food insecure and severe food insecure according to the criteria by FANTA, 2007 [152]. The criteria are as follows:

1) "Food secure household just experiences worry, but rarely" [152].
2) "Mildly food insecure (access) household worries about not having enough food sometimes or often, and/or is unable to eat preferred foods, and/or eats a more monotonous diet than desired and/or some foods considered undesirable, but only rarely" [152].
3) "Moderate food insecure household sacrifices quality more frequently, by eating a monotonous diet or undesirable foods sometimes or often, and/or has started to cut back

on quantity by reducing the size of meals or number of meals, rarely or sometimes" [152].

4) "Severe food insecure household has graduated to cutting back on meal size or number of meals often, and/or experiences any of the three most severe conditions (running out of food, going to bed hungry, or going a whole day and night without eating), even as infrequently as rarely"[152].

However, it is best to use both the HFIAP indicator and HFIA scores because the latter is reported to be sensitive to detecting smaller changes over time [152].

8. Additional variables

The following additional information which could affect diet quality and food access were also collected such as market access, type of markets, type of food individuals purchased from the market, monthly expenditure on foods and main source of food at household level. Furthermore, data was also collected on number of meals per day, adherence to the dietary recommendations and reasons for not adhering to the recommended diet.

D. Phase 2: Qualitative study

The qualitative study was implemented to achieve specific aim 3: to qualitatively assess socio-environmental factors affecting self-management of T2DM, specifically diet and physical activity.

1. Sampling procedure

After the first phase of data collection, a simple descriptive statistic (age categories) was calculated to identify the group that is largely represented to participate in the second phase of the study. Purposively, of the 428 participants only 39 participated in the second phase of the

study with age of ≥40 years. The qualitative study was conducted from early to end of August 2017 at KCH and Kasungu District Hospital.

2. Focus group discussions

To explore the socio-environmental factors supporting and hindering dietary intake and physical activities in diabetes self-management, data was obtained through focus group discussions (FGDs) of at-least 10 adults per group who were diagnosed with T2DM. Two FGDs (one- female FGDs and one-FGDs) in each location. FGDs were conducted in a private room (KCH) and quite open space (Kasungu District Hospital), which was identified at the hospital by the primary researcher with assistance from staff at each hospital. FGDs were guided by a set of questions (Appendix 2) with key elements of the socio-ecological model. The three key elements of the socio-ecological model that were included are interpersonal, intrapersonal and community and institutional. The FGDs were conducted by the primary researcher and two research assistants. The FGDs were facilitated by the primary researcher while the research assistants took field notes, conducted voice recordings and noted any non-verbal cues such as facial and body expressions. As a way of ensuring confidentiality, each respondent was assigned a unique identifier. After each focus group, the primary researcher and two research assistants shared the notes to check the consistency of information captured. Audit trails were documented and kept by the primary researcher.

3. Eco-maps

In order to clearly understand the importance of the support-networks, which may act as barriers and facilitators to healthy diet and physical activity within their socio-environment, eco-maps were developed/drawn during the FGDs. An eco-map is a visual/graphical representation

of social support networks that diabetes patients receive from the families and communities [158-161]. To maximize discussions and interaction during FGDs the eco-maps were developed/drawn together with the participants. The primary researcher first demonstrated how the eco-maps are drawn and explained the use of symbols. The participants were given papers to draw their own eco-maps depending on where they received diet and physical activity support and resources for diabetes management. The sample of the blank eco-maps as depicted in Fig 3, with well-explained symbols, was presented to the participants. The commonly used symbols are: strong/positive support (─), tenuous/weak support (------), stressful support (~~~~), energy flows in both direction (↔), energy flows in one direction (→) [159-161]. The symbols show the strength of support diabetes patients get in relation to health eating and physical activity.

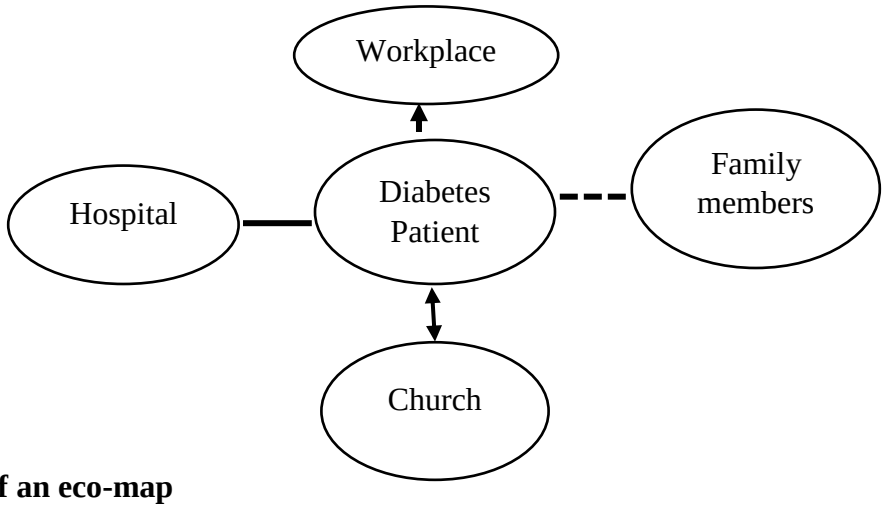


Figure 3: Sample of an eco-map

E. Statistical analyses

Statistical analyses for specific aims 1a and 1b and 2 were performed using IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp. Quantitative 24-hour recall data on the amount of foods consumed was entered into Nutri-survey for windows copy ©2007, SEAMEO-TROPMED RCCN-University of Indonesia

(www.nutrisurvey.de) computer package, to derive the nutritive value of the foods. For the foods that were not found in the Nutri-survey database, the food composition table for Mozambique [162] and Tanzania [163] were used to determine the nutrient content, and then the values were entered to the Nutri-survey to form part of the dataset.

1. *Specific Aim 1a:* Descriptive analyses was conducted to examine the socio-demographic characteristics of the participants. The chi-square test was used to test for statistical significance of the differences in the proportion of acceptable and unacceptable A1C. Additionally, independent sample t-tests and chi-square tests were used to examine the differences in the characteristics of the participants with A1C≥8%. Pearson correlation was conducted to check for variables that were highly correlated to prevent multicollinearity when conducting multivariate analyses. Multivariate linear regression examined the factors associated with A1C. The A1C was the continuous dependent variable, and the independent variables were socio-demographic characteristics, biomedical and perceptual factors (Table 1).
2. *Specific Aim 1b:* To compare the characteristics of the participants from urban and semi-urban areas, chi-square and independent sample t-tests were performed. The median test (interquartile range) was used to compare urban and semi-urban expenditures per quarter a year on total expenses, cost of care, transportation, blood glucose monitoring and medication costs. Then Pearson correlation assessed the correlation of the variables. Multiple linear regression examined the factors associated with total expenses per quarter a year (Table 1).
3. *Specific Aim 2:* The differences in the characteristics of the participants stratified by gender were assessed using chi-square and independent sample t-tests. Descriptive

statistics were used to indicate the proportion of the participants who were meeting or not meeting the WHO/FAO nutrition guidelines for prevention of chronic diseases. Additionally, a chi-square test was used to test for differences between participants with A1C<8% and A1C≥8% relative to meal frequency, adherence to dietary recommendations and reasons for not complying. An independent sample-t-test tested the differences in mean intakes of macronutrients, the percentage of macronutrients (carbohydrate, protein and fat) to total energy, average fruits and vegetable intake/day, IDDS, preventive diet scores, and food group consumption per location and A1C status (<8% and ≥8%). We utilized binary logistic regression for multivariate analysis to examine the dietary factors associated with A1C≥8% while controlling for confounding factors such as age, gender, location, monthly food expenditure per capita, physical activity, BMI, duration of diabetes, type of treatment, energy (kcal) and food insecurity status (Table 1). The chi-square test for categorical variables and one-way analysis of variance for continuous variables were used to test for differences in food security status (food security, mildly food insecure and moderately to severely food insecure) by socio-demographic and economic characteristics, food-related factors and health-related variables. This was done to assess the effects of food security in relation to dietary diversity and glycemic status. Descriptives, such as percentages and frequencies, were used to indicate the food groups participants produced for consumption and purchased from different markets. Furthermore, the chi-square test was also used to test if there were differences in the type of markets from which urban and semi-urban participants purchased the food. The independent sample t-test was used to examine the differences in HFIAS by A1C

status (<8% and ≥8%). Pearson correlation analysis was done for all the variables to be included in the linear regression model; of the variables that were highly correlated, one variable was chosen and included in the model. Multivariate linear regression was used to investigate factors associated with HFIAS. The dependent variable was HFIAS, and independent variables included: age, gender, marital status, education level, household size, monthly food expenditure per capita, monthly household income, location, IDDS, distance to the primary market, own food production for consumption, A1C, average waist circumference (Table 1).

4. *Specific Aim 3:* The FGD's were tape recorded and transcribed verbatim by the primary researcher and research assistants after listening and re-listening to the recordings and comparing with field notes. Thematic analysis was used to examine the qualitative data transcribed into themes and sub-themes. The initial codes were determined based on a thorough comparison for similarities and differences between primary researcher and research assistant transcripts. Any coding differences were discussed until a consensus was reached. The coded data was then managed by Nvivo (version 11.0, QSR International, USA) software to generate thematic inferences relative to barriers and facilitators to diet and physical activity and social support networks and triangulated with the eco-maps and quantitative data (Table 1).

Table 1: Specific aims, research questions, variables and statistical analysis

Research questions	Variables	Statistical analyses
Specific aim 1a: To assess glycemic status and associated factors		
I. What proportion of adults diagnosed with T2DM are in unacceptable vs. acceptable glycemic status in urban and semi-urban?	A1C	Chi-square test
II. What are the factors associated with unacceptable and acceptable glycemic status?	Socio-demographic characteristics Biomedical factors Perception of blood glucose	Descriptive statistics Chi-square test and Independent sample T- test Pearson correlation Multivariate linear regression (dependent variable = A1C).
Specific Aim 1b: To estimate cost of care and related expenditures for T2DM based on glycemic status		
I. What are factors associated with total expenditure in T2DM management?	Socio-demographic characteristics Cost of blood glucose monitoring Cost of care Transportation expenses Food expenditure per capita	Descriptive statistics Chi-square test and Independent sample T- test Median test Pearson correlation Multivariate linear regression (dependent variable = total expenditure).
Specific Aim 2: To assess diet quality and its association with glycemic status and factors affecting diet quality including food insecurity		
To what extent does diet quality influence glycemic status?	Socio-demographic characteristics IDDS, HFIAS score Preventive diet score Total energy (Kcal) Macronutrients: % of the total energy for CHO, protein fat, PUFA and saturated Cholesterol intake Total fruits and vegetables intake Total Sodium intake Frequency of meals Adherence to dietary recommendations Reasons for not complying to the dietary recommendations	Descriptive statistics Chi-square test and Independent sample T- test Pearson correlation Multiple logistic regression (dependent variable = A1C≥8%)

Table 1 (cont'd): Specific aims, research questions, variables and statistical analysis

Research question	Variable	Statistical analysis
II. Does food insecurity affect both diet quality and glycemic status?	Socio-demographic characteristics HFIAS score IDDS A1C Own food production for consumption Distance to the primary market Type of market Type of food purchases from the market.	Descriptive statistics Chi-square test and Independent sample T- test ANOVA Pearson correlation Multiple linear regression (dependent variable = HFIAS score).
Specific Aim 3: To qualitatively assess socio-environmental factors affecting self-management of T2DM, specifically diet and physical activity		
I. How do socio-environmental factors facilitate or hinder self-management of T2DM, especially diet and physical activity?	Socio-demographic characteristics Barriers and facilitators to appropriate diet Barriers and facilitators to physical activity Social support networks	Descriptive statistics Thematic analysis to generate themes Triangulated with eco-maps and quantitative data

F. Ethical approval

Ethical clearance (Appendix 3) was sought from the Institutional Review Board at Michigan State University (MSU). After obtaining an approval from MSU -IRB, an application was made to Ministry of Health, National Health Research Committee in Malawi. Furthermore, permission was sought from respective hospitals; KCH and Kasungu District Hospitals. Written informed consent was obtained from each participant.

CHAPTER 4- MANUSCRIPT 1

This chapter discusses the findings from the specific aim 1 a and b. The findings were divided into two manuscripts. The first manuscript examines the glycemic status and its none-dietary determinants among adults diagnosed with T2DM. The second paper provides an overview of the out-of-pocket expenditures for T2DM management in Malawi.

Title: Glycemic Status Among Adults Diagnosed with Type 2 Diabetes in Malawi: Non-Dietary Associations

Target journal: Health Education and Behavior

A. Abstract

Background: Adults diagnosed with Type 2 diabetes (T2DM), disproportionately high in Malawi, may have location specific challenges relative to disease management. Purpose: To assess glycemic status (A1C) and associations with demographic, biomedical and perceptual factors among adults diagnosed with T2DM in Malawi.

Method: A cross-sectional study (n=428 adults diagnosed with T2DM) was conducted in urban (n=288) and semi-urban (n=140) clinics. Data included: demographics, anthropometric measurements, physical activity (PA), self-reported medical information including comorbidities, and A1C. Multivariate linear regression was used to determine demographic, biomedical, and perceptual associations with A1C.

Results: A1C was above the acceptable clinical target (≥8%) for 258 (60.3%) of the participants. Hypertension was a problem overall; those with A1C≥8% had significantly ($p<0.001$) higher self-reported and diagnosed peripheral neuropathy (58.9%) and retinopathy (45%). Overall, A1C was significantly inversely associated with age and PA level, and positively with underweight

status, duration of diabetes, number of comorbidities and participant perceptions of fluctuating blood glucose. The associations differed by location. A1C was significantly inversely associated with PA and additional blood glucose monitoring (BGM) beyond that received at the government clinic in the urban area. In the semi-urban area, A1C was positively associated with duration of diabetes and weight status (under or overweight/obese).

Conclusions: A1C for the majority of participants was not acceptable. PA and BGM were beneficial among urban participants, while semi-urban participants were negatively impacted by disease duration and weight status (underweight and overweight/obesity). Therefore, location-specific interventions for diabetes management are needed to reduce serious complications in these two vulnerable populations.

B. Introduction

Type 2 diabetes mellitus (T2DM) is a non-communicable disease (NCD) and a growing problem in sub-Saharan Africa (SSA) in conjunction with infectious diseases and chronic undernutrition. In SSA, it is estimated that about 15.5 million adults aged 20–79 years have diabetes, 69.2% remain undiagnosed and 55.3% of those with diabetes live in urban/semi-urban [3]. In Malawi, diabetes mellitus is estimated at 5.6% among adults aged 25 to 64 years [13, 14] who need to be productive for the sustainable economic growth of the country. The risk factors for NCDs in Malawi are higher in urban versus rural areas: overweight (38.6% vs. 21.9%), obesity (13.6% vs. 4.4%) and physical inactivity (24.1% vs. 8.7%) [13, 14].

Educating adults with T2DM on self-management of their condition is vital for optimal glycemic status. Appropriate self-care of diabetes requires a healthy diet, physical activity, medication compliance and self-monitoring of blood glucose [17]. SSA countries have high proportion of adults with T2DM with suboptimal glycemic status due to inadequate diabetes care

[29, 75-78, 80, 164]. Factors attributed to suboptimal glycemic status were grouped into two categories: social factors and self-care behaviors [81, 82]. A recent study in Malawi showed that diabetes is poorly managed among Malawian adults even when they are on medication [15]. Lack of information on diabetes management have been stated to affect diabetes self-care practices in SSA [28, 29] even though there may be variations in economic and socio-cultural factors that could affect the management of diabetes from country to country. For instance, a study conducted in Ethiopia found that urban dwellers with T2DM had unacceptable glycemic status in comparison to their counterparts in rural areas [25]. Danquah et al., (2012) showed that urban Ghanaian adults with T2DM were overweight, had central adiposity, increased body fat and did not engage in sufficient physical activity [84]. Prolonged elevated glycemic status in T2DM is a risk for the development and progression of diabetes-related complications and aggravates public health problems [18, 22, 165] such as sight-threatening diabetes retinopathy (29.4%), retinopathy (50.1%), and proliferative retinopathy (7.3%) [22] as observed in the Blantyre area of Malawi.

Studies on factors associated with glycemic status among Malawian adults with T2DM using glycosylated hemoglobin (A1C) as an indicator of long-term glycemic exposure for over a period of two to three months [47] are lacking, hence the need to fill the knowledge gap. In a resource-limited country like Malawi, socio-demographics and economic status can affect self-management of T2DM such as blood glucose monitoring, and adherence to medication [2]. Investigating the magnitude of, and factors affecting glycemic status is the initial stage to better understanding the target population, as well as supporting formulation and planning of tailored interventions for prevention and management of T2DM.

The purpose of this study was to assess glycemic status and its association with demographic, biomedical and perceptual factors among adults diagnosed with T2DM who live in urban and semi-urban areas in Malawi. We hypothesized that over 50% of adults diagnosed with T2DM will have unacceptable level of clinical glycemic status (A1C≥8%) target, and that factors associated with glycemic status would differ by study location.

C. Methods

1. *Study design and location*: A cross-sectional study through face-face interviews was conducted from June to August 2017 in central Malawi, targeting two areas: Lilongwe (urban) at KCH and Kasungu (semi-urban) at Kasungu District Hospital. The KCH is a referral hospital for the central region of Malawi and also provides secondary care to the urban and semi-urban populations of Lilongwe [21], while Kasungu District Hospital offers services to people residing in rural and semi-urban areas of Kasungu district. Additionally, Kasungu District Hospital was the first in Malawi to pilot WHO essential package for NCD [147]. Both are public hospitals; the cost of care and prescribed diabetes medications are incurred by the government of Malawi because NCDs such as diabetes is part of the essential health package allotted to every Malawian [71].
2. *Sampling and inclusion criteria:* A convenience sample of adults diagnosed with T2DM from urban (n=288) and semi-urban (n=140) areas was targeted. Participants in the study were Malawian adults aged ≥25 years, attended out-patient diabetes clinic at the same hospital at least twice for the past year, and had a clinical appointment during the period of data collection. The primary researcher recruited the participants who met the inclusion criteria.

3. *Ethical approval:* The study received ethical approval from the Institutional Review Board at Michigan State University in the United States, and the National Health Sciences Research Committee of the Ministry of Health in Malawi. Management of the two hospitals authorized the study in their respective hospitals. Each participant provided written informed consent which was translated into the local language, *Chichewa*. All participants received an equivalent of $5 in in the local currency as compensation. To ensure confidentiality, each participant was given a unique identity number.

4. *Variables*

4.1 *Socio-demographic* information included: age, gender, educational level, marital status, monthly average household income and distance to the hospital.

4.2 Biomedical factors:

4.2.1 Self-reported diabetes-related medication information such as treatment type, duration of diabetes, comorbidities (self-reported and diagnosed), frequency of blood glucose monitoring at the government hospital and additional blood glucose monitoring at private clinic/home/diabetes peer group besides the government hospital.

4.2.2 Physical activity level. The Global Physical Activity Questionnaire by WHO was used to assess the physical activity level [151]. The total PA metabolic equivalent (MET) was calculated as a continuous variable and categorized as high PA (≥3000 MET-minutes per week) and as low-moderate PA (<3000 MET-minutes per week) [151].

4.2.3 Anthropometry. Weight and height were measured to assess body mass index (BMI) of the participants. Weight was measured using a scale (Seca 803, SECA GmbH & Co. KG, German) to the nearest 0.1 kg and height using a portable stadiometer (Seca

213, SECA GmbH & Co. KG. German) to the nearest 0.1 cm. BMI (kg/m^2) was derived and categorized according to the WHO cut-off points for classifying underweight (<18.5), normal (18.5–24.9), and overweight/obese (≥25.0) [154].

4.2.4 Self-reported perceptual factors included self-reported domain participants expressed their perceived blood glucose results as being good, always fluctuating or lower than first diagnosed.

4.2.5 Glycosylated hemoglobin (A1C). Each participant provided a venous blood sample (5 mL) drawn by a nurse and laboratory technician trained by the Ministry of Health in Malawi. The blood samples were kept in 5 mL ethylenediaminetetraacetic acid (EDTA) tubes and taken to the laboratory the same day to test for A1C using DCA Analyzer (Siemens, Tarrytown, NY, USA). The acceptable clinical cut-off of A1C <8% and unacceptable A1C≥8%, which were within recommendations of the American Diabetes Association [165] were used.

5. Statistical Analysis

We analyzed the data using IBM SPSS Statistics 24 (IBM SPSS, Armonk, New York, USA). Descriptive analyses were performed for categorical (percentages and frequencies) and continuous variables (mean ± standard deviation, SD). We compared the demographic characteristics of participants with A1C≥8% from urban and semi-urban areas using chi-square test and independent t-test. Differences in the frequencies of T2DM adults with comorbidities within A1C<8% and A1C≥8% categories were tested using chi-square tests. Correlation analysis was done to check for collinearity for all variables included in the regression model. To examine factors associated with glycemic status, multivariate linear regression was performed. The independent variables

included: demographics, biomedical and perceptual factors. All statistical analyses were considered significant at the 5% level of significance.

D. Results

1. Characteristics of the study participants

The study participants included 428 adults diagnosed with T2DM: Lilongwe-urban (n=288), Kasungu-semi-urban (n=140) (Table 2); 69.4% were women and 30.6% men, the average age was 53.9 years (range 32 to 76 years); 60.3% (n=258) had A1C≥8%; 60.5% had at least primary school education for 46.1% of the participants ranged between 30,000.34 and 122,000.17 Malawi Kwacha. Characteristics of the whole sample (n=428; n=288 for urban and n=140 semi-urban) are provided in the appendix 4.

Among participants with A1C≥8%, 174 were from the urban while 84 were from the semi-urban area (Table 2). No significant differences were noted among participants based on A1C status in both locations (60.4% of urban and 60. 0% of semi-urban participants had A1C≥8%). Semi-urban participants had significantly ($p<0.01$) higher proportion of men (42.9%) with A1C≥8% compared to urban (24.7%) participants. The proportion of underweight (11.9%) and normal weight (35.7%) status was higher among semi-urban, while overweight/obese (68.8%) was highly prevalence among urban participants. On average, the participants had known about their T2DM status for 6 years, with a significant difference ($p<0.05$) between urban (7.1 years) and semi-urban participants (5.6 years).

Table 2: Characteristics of participants with unacceptable glycemic status stratified by study location

		Participants with A1C ≥8%			
	Overall (n=428)	Total (n=258)	Urban (n=174)	Semi-urban (n=84)	p-value
Variable	n (%)	n (%)	n (%)	n (%)	
Gender					0.002
Male	131 (30.6)	79 (30.6)	43 (24.7)	36 (42.9)	
Female	297 (69.4)	179 (69.4)	131 (75.3)	48 (57.1)	
Age (mean±SD)	53.9±9.3	53.4±9.3	53.6±9.6	53.1±8.8	0.662
Marital status					0.254
Married	329 (77.4)	198 (77.7)	130 (75.6)	68 (81.9)	
Divorced/widowed	96 (22.6)	57 (22.5)	42 (24.4)	15 (18.1)	
Educational					0.253
Less or equal to primary	256 (59.8)	156 (60.5)	101 (58.1)	55 (65.5)	
Secondary and above	172 (40.2)	102 (39.5)	73 (42.0)	29 (34.5)	
Household income in 1000 MKW					0.408
≤30.33	126 (29.4)	74 (28.7)	47 (27.0)	27 (32.1)	
30.34-122.17	199 (46.5)	119 (46.1)	79 (45.4)	40 (47.6)	
≥122.18	103 (24.1)	65 (25.2)	48(27.6)	27 (20.2)	
Weight status (BMI kg/m^2)					0.001
Underweight (<18.5)	16 (3.8)	13 (5.1)	3 (1.7)	10 (11.9)	
Normal weight (18.5-24.9)	128 (30.0)	81 (31.5)	51 (29.5)	30 (35.7)	
Overweight/obese (≥25.0)	282 (66.2)	163 (63.4)	119 (68.8)	44 (52.4)	
Duration of diabetes in years (mean±SD)	6.0±4.4	6.6±4.6	7.1±4.7	5.6±4.4	0.017

MKW=Malawian Kwacha, 1$=MKW700 (June-August 2017), Mean±SD (Mean±Standard Deviation).

2. Diagnosed and self-reported diabetes-related comorbidities

Participants with A1C≥8% that reported having one or more of the following diabetes related problems: hypertension (66.3%), retinopathy (45.0%), peripheral neuropathy (58.9%), kidney (4.7%) and heart (4.2%) problems. The proportion of participants with comorbidities was significantly higher among those with A1C ≥8% than with A1C<8%. However, among participants with A1C≥8%, there were no significant differences between urban and semi-urban participants (Table 3).

Table 3: Frequencies of participants with diagnosed and self-reported diabetes-related comorbidities by glycemic status and study location

Condition	Overall (n=428)			Participants with A1C ≥8% (n=258)		
	A1C<8% n (%)	A1C≥8% n (%)	p-value	Urban n(%)	Semi-urban n (%)	p-value
Hypertension			0.769			0.452
Yes	115 (67.7)	171(66.3)		118 (68.1)	53 (64.3)	
No	55 (32.4)	87 (33.7)		56 (31.9)	31 (35.7)	
Eye problem (retinopathy			<0.001			0.388
Yes	39 (22.9)	116 (45.0)		75 (33.7)	41(41.4)	
No	131(77.1)	142 (55.0)		99 (66.3)	43 (58.6)	
Nerve problem (peripheral neuropathy)			<0.001			0.688
Yes	39 (22.9)	152 (58.9)		104 (46.2)	48 (41.4)	
No	131 (77.1)	106 (41.1)		70 (53.8)	36 (58.6)	
Kidney problem			0.017			0.490
Yes	1 (0.6)	12 (4.7)		7 (2.9)	5 (3.6)	
No	169 (99.4)	246 (95.4)		167 (97.2)	79 (96.4)	
Heart problem			0.005			0.552
Yes	2 (1.2)	18 (4.2)		11 (4.2)	7 (5.7)	
No	168 (98.8)	240 (93.0)		163 (95.8)	77 (94.3)	

3. Mean A1C of participants by demographic, biomedical and perceptual factors

Participants from semi-urban areas who were travelling <5 km to the hospital had significantly ($p<0.05$) lower mean A1C (8.1±3.0) than those who travelled ≥5 km (9.6±3.0) (Table 4). The mean A1C levels significantly ($p<0.001$) varied by weight status, being higher among underweight participants (12.2±2.9), than normal weight (9.4±2.9) and overweight/obese participants (9.1±2.7). Underweight urban participants also had higher A1C (11.9±3.7) then the normal weight (9.5±3.0) and the overweight/obese (9.0±2.5). A different trend was observed in among semi-urban participants where A1C was higher among underweight (12.2±2.8) than overweight/obese (9.2±2.9), followed by and normal weight (9.1±3.0) participants. Nearly all (92.3%; n=395) of the participants were oral hypoglycemic agents. Semi-urban participants who

were on insulin treatment had significantly ($p<0.05$) higher A1C (12.9±3.1) than on oral hypoglycemic agents (9.3±3.0) (Table 4).

Patient with T2DM were allocated specific periods for blood glucose monitoring depending on their glycemic status at the public hospital. Most participants (79.21%, mean A1C 9.3±2.8) were monitoring their blood glucose at the same hospital at least once every two to three months or more. Urban participants who were monitoring their blood glucose either at private clinics, home or diabetes peer groups in addition to the public hospital had significantly ($p<0.05$) better A1C (8.9±2.4) than those who solely depended on public hospitals (9.52±2.92) (Table 4).

Physical activity is one of the critical elements of self-management of diabetes. Participants who were vigorously active had significantly ($p<0.05$) lower A1C (8.7±2.6) than those who were low to moderately active (9.6±2.9). This was however only true in the urban area when location of residence was considered.

When asked about their perception of the blood glucose results after the nurse/doctor checked them, almost twenty-eight percent (n=121, mean A1C; 7.8±2.1) indicated that the blood glucose is always good/decreasing. Their A1C was significantly ($p<0.001$) lower than those who indicated that their blood glucose always fluctuates (9.9±2.9). This was true for both locations.

Table 4: Comparison of mean A1C by demographic, biomedical and perceptual factors

	Overall		Urban		Semi-urban	
Variable	Mean ± SD (n)	P value	Mean ± SD (n)	p-value	Mean ± SD (n)	p-value
Demographic factors						
Distance to the hospital		0.063		0.644		0.028
< 5 km	8.6±3.0 (52)		9.0±3.0 (27)		8.1±3.0 (25)	
≥5km	9.3±2.7 (364)		9.2±2.7 (261)		9.6±3.0 (103)	
Biomedical factors						
Weight status (BMI kg/m^2)		<0.001		0.042		0.003
Underweight (<18.5)	12.2±2.9 (16)		11.9±3.7 (4)		12.2±2.8 (12)	
Normal weight (18.5-24.9)	9.4±2.9 (128)		9.5±2.9 (80)		9.1±3.0 (48)	
Overweight/obese (≥25.0)	9.1±2.7 (282)		9.0±2.5 (202)		9.2±2.9 (80)	
Type of treatment		0.062		0.201		0.009
Diet only	7.3± 1.7 (6)		7.3± 1.7 (6)		-	
Insulin	10.1±3.1 (27)		9.5±3.0 (22)		12.9±2.0 (5)	
Oral hypoglycemic agents	9.2±2.8 (395)		9.2±2.7 (260)		9.3±3.0 (135)	
Frequency of blood glucose monitoring at the government hospital		0.914		0.783		0.748
Once in a month or less	9.3±2.9 (89)		9.1±2.7 (51)		9.6±3.2 (38)	
Once in every two-three month or more	9.3±2.8 (339)		9.2±2.7 (237)		9.4±3.0 (102)	
Additional blood glucose monitoring at the private clinic/home/diabetes peer groups		0.157		0.036		0.616
Yes	9.1±2.5 (198)		8.9±2.4 (142)		9.6±2.9(56)	
No	9.4±3.0 (230)		9.5±2.9 (146)		9.3±3.1 (84)	
Physical activity level		0.002		0.002		0.349
Vigorous-active	8.7±2.6 (148)		8.6±2.5 (105)		9.1±2.9 (42)	
low-moderate- active	9.6±2.9 (280)		9.6±2.7 (182)		9.6±3.1 (98)	
Perception of blood glucose		<0.001		<0.001		<0.001
Always good/decreasing	7.8±2.1 (121)		8.0±2.1 (90)		7.2±2.0 (31)	
Fluctuates always	9.9±2.8 (307)		9.7±2.7 (198)		10.2±3.0 (109)	
Blood glucose lower than first diagnosed		<0.001		<0.001		0.011
Yes	9.0±2.7 (353)		8.9±2.6 (239)		9.1±2.9 (114)	
No	10.7±2.8(72)		10.7±2.6(48)		10.9±3.2 (24)	

KM= Kilometer; mean±SD (mean± standard deviation). Comparing the mean value in the same column for each variable in overall and by location

4. Factors associated with glycemic status

Three regression models, one for the overall, urban and semi-urban samples. For every one-year increase in age of the participants, their A1C significantly ($p<0.001$) decreases by 0.09 point, suggesting that younger participants had higher A1C values. Similar significant findings were observed in the urban ($\beta=-0.09$, $p<0.001$) and semi-urban ($\beta=-0.08$, $p<0.05$) populations. The distance to the nearest hospital of ≥5 km was positive and significant ($\beta=0.92$, $p=0.05$) in increasing A1C status in the overall study population. Being underweight ($\beta=2.59$, $p<0.01$) was positively associated with A1C in the overall and semi-urban ($\beta=3.45$, $p<0.01$) populations, whereas overweight/obesity was positively associated with A1C in the semi-urban population only ($\beta=1.19$, $p<0.05$). As the duration of the diseases increased, the mean A1C also significantly increased for the overall ($\beta=0.08$, $p<0.05$) and semi-urban populations ($\beta=0.22$, $p<0.01$), but not in the urban population. Having diabetes-related comorbidities significantly and positively increased A1C irrespective of location: $\beta=0.60$ ($p<0.001$) for the overall sample, as well as the urban ($\beta=0.60$, $p<0.01$) and semi-urban ($\beta=0.61$, $p<0.05$) populations. Regular monitoring of blood glucose was inversely associated with A1C ($\beta=-0.80$, $p<0.05$) but in the urban population only. Increasing physical activity (MET-minutes per week) significantly decreased A1C in the overall ($\beta=-0.15$, $p<0.01$) and urban ($\beta=-0.15$, $p<0.05$) populations. Among participants who indicated that A1C was always fluctuating, their mean A1C significantly ($p<0.001$) increased by 1.61 points, 1.51 ($p<0.001$) and 1.71 ($p<0.05$) points in the overall, urban and semi-urban populations (Table 5).

Table 5: Multivariate linear regression models examining predictors of A1C

Variable	Overall	p-value	Urban	p-value	Semi- urban	p-value
Demographic and economic factors	Unstandardized β coefficient (SE)					
Age (years)	-0.09 (0.02)	<0.001	-0.09 (0.02)	<0.001	-0.08 (0.03)	0.011
Gender: Female	0.53 (0.36)	0.142	-0.09 (0.46)	0.857	-0.95 (0.67)	0.154
Marital status: Married	0.21 (0.36)	0.559	0.45 (0.41)	0.271	-0.52 (0.73)	0.475
Education level: Secondary and above	-0.64 (0.33)	0.057	-0.65 (0.39)	0.096	-0.75 (0.68)	0.272
Income level: ≥ 30.34 MKW (1000)	0.24 (0.31)	0.446	-0.11 (0.38)	0.782	0.81 (0.61)	0.186
Area: Semi-urban	-0.27 (0.34)	0.419	-		-	
Distance to the hospital: ≥5 km	0.85 (0.43)	0.050	0.79 (0.58)	0.180	1.19 (0.65)	0.070
Biomedical factors						
Underweight status	2.59 (0.83)	0.002	1.96 (1.49)	0.190	3.45 (1.14)	0.003
Overweight/obese status	0.02 (0.33)	0.945	-0.56 (0.42)	0.166	1.19 (0.58)	0.044
Duration of diabetes (years)	0.08 (0.04)	0.039	0.03 (0.05)	0.494	0.22 (0.07)	0.002
Number of comorbidities	0.60 (0.15)	<0.001	0.60 (0.18)	0.001	0.63 (0.29)	0.033
Type of treatment: Insulin	-0.06 (0.61)	0.916	-0.51 (0.66)	0.439	0.96 (1.62)	0.554
Frequency of blood glucose monitoring at government hospital for at least once in every two-three month and more	0.10 (0.37)	0.794	0.23 (0.46)	0.615	0.29 (0.65)	0.650
Additional blood glucose monitoring at private clinic/home/diabetes peer groups	-0.55 (0.31)	0.074	-0.80 (0.37)	0.029	0.06 (0.65)	0.920
Physical activity level (MET minutes/wk.)	-0.15 (0.05)	0.003	-0.15 (0.06)	0.012	-0.18 (0.10)	0.073
Perception of blood glucose						
Fluctuating blood glucose always	1.61 (0.34)	<0.001	1.51 (0.40)	<0.001	1.71 (0.69)	0.016
Blood glucose not lower than first diagnosed	0.66 (0.40)	0.099	0.80 (0.49)	0.101	0.08 (0.73)	0.911
Constant	11.22 (1.21) $R^{2=}0.29$		11.97 (1.47) $R^{2=}0.29$		9.36 (2.04) $R^{2=}0.45$	

MKW= Malawian Kwacha; MET=Metabolic equivalence; wk= week; km= Kilometers.

E. Discussion

This study assessed glycemic status and its predictors in adults diagnosed with T2DM in urban and semi-urban areas in Malawi. Unacceptable A1C ≥8% was present in 60.28% of the study participants. These results are within range of the previous findings within SSA: Zambia (61.3%), Ethiopia (59.4%), Sudan (85%) and South Africa (83.8%) [25, 75, 80, 164]. A recent study in Gaborone, Botswana also reported that only 36.95% of the participants had A1C>7% [78]. The proportion of unacceptable A1C in our study are comparable with findings in other regions. For instance, studies done in Malaysia and Australia reported 65.1% and 72% of T2DM patients with unacceptable glycemic status [85, 86], while in the U.S the mean A1C of black Americans was 7.8% [88] and 9.1% [91]. In both urban and semi-urban areas, about three-fifths of T2DM adults had chronic hyperglycemia, suggesting overall suboptimal glycemic status in both urban and semi-urban Malawian areas. Unacceptable glycemic status has been attributed to inadequate access to diabetes care services and non-adherence to diabetes self-care management in SSA countries [25, 82]. Our findings show that distance to the hospital provided borderline positive and significantly associated with A1C in the overall model, which may limit patients' accessibility to health services. As such, some patients may miss their doctor's appointment for blood glucose checkup, hence chronic poor glycemic status. In Malawi limited resources such as financial and human capacity have been reported to challenge the facilitation and implementation of the NCD services [16], resulting in inadequate diabetes services delivery and consequently suboptimal glycemic status among the vulnerable population.

Our findings show that young adults with T2DM were more likely to have unacceptable glycemic status in both urban and semi-urban areas, which is consistent with previous studies [76, 82, 88, 90, 166-168]. Additionally, about 77% of mortality due to diabetes in Africa is

among the adults <60 years [3]. Diabetes care is part of the essential health care package in Malawi [71], indicating that people have equal access to diabetes care services irrespective of age. Complications from early onset of elevated glycemic status have major ramifications for the individual but also for the economic development of Malawi. The leading causes of unacceptable glycemic status among young adults warrant further investigation on factors that may impact glycemic status such as diet, lifestyle factors, diabetes self-care, health-seeking behaviors and access to care.

Adult underweight (BMI<18.5) and overweight/obesity (BMI>25) are two critical factors that may aggravate unacceptable glycemic status. In Africa and Asia, it was estimated that 24-66% of patients with diabetes are either underweight or normal weight [55]. We also found that being underweight was positively associated with A1C. Similar findings were reported in previous studies, including that underweight patients with T2DM had low plasma C-peptide and decreased pancreatic β-cell function, suggesting that deficiency in insulin secretion impacted the glycemic status [92-94, 166]. In a resource-deprived country like Malawi, the importance of cases of low BMI (<18.5) cannot be underestimated due to inadequate food accessibility and availability and poor diabetes self-care. Additionally, ketosis in patients with T2DM was associated with higher AIC, and was indicated that elevated AIC does occurs with ketosis [169]. Furthermore, the findings of the present study that overweight/obese, especially in the semi-urban area, was associated with A1C are supported by the extant literature [80, 88, 90, 166, 170]. Although the high proportion of overweight/obsess T2DM were in the urban area but did not yield any significance. A recent study in Gaborone, Botswana found that BMI was not related to A1C, although the majority of the participants were overweight/obese although the high proportion of overweight/obese [78]. Indicating that chronic hyperglycemia was prevalent in

underweight and overweight/obese in a semi-urban area. Therefore, when providing diabetes education, providers should also focus on the measures of preventing both underweight and overweight/obese to achieve the recommended target of A1C.

We have corroborated previous studies [19, 76, 78, 80, 82, 87, 88, 164, 171] that the years one has lived with diabetes is significantly associated with A1C levels. The severity and longer duration of elevated A1C in T2DM adults may lead to insulin resistance due to damage of the beta cell responsible for insulin secretion [17, 171]. Duration of diabetes showed significant association with A1C in the overall model and semi-urban, but not in the urban area. Persistent A1C ≥8% increases the risk of developing diabetes related comorbidities such as retinopathy and blindness overtime [47]. Multiple diagnosed and self-reported diabetes-related comorbidities such as retinopathy and peripheral neuropathy in the present study were more common among participants with A1C≥8%. However, hypertension was a general condition affecting both participants with acceptable and unacceptable glycemic status. Similar studies in SSA countries have found hypertension is a common condition among adults with T2DM [25, 76, 82]. Having more comorbidities was significantly associated with A1C for all statistical models and aligns with previous studies conducted in the southern region of Malawi [18, 22]. Similarly, a study in Ethiopia also showed high rates of diabetes-related complications and chronic hyperglycemia in diabetes patients [25]. Although the diabetes-related comorbidities in the present study were self-reported, further research is needed to determine the quality standard of diabetes care at public t hospitals.

One of the components of self-care behaviors in the management of diabetes is monitoring of the blood glucose [17]. In our study, participants from the urban area who monitored their blood glucose through private clinics, home, diabetes peer groups in addition to

public hospital had an inverse association with A1C. It should be noted that the period for blood glucose monitoring by the majority (79.2%) of the participants in this study was once every two to three months or more. The urban participants actively participate in diabetes peer groups [21], hence increasing the frequency of blood glucose monitoring by not solely depending on the government hospital. Engaging in diabetes peer groups has been reported to improve A1C outcomes of the diabetes patients [172, 173], because patients get better understanding of their condition through education and monitoring blood glucose.

Previous findings have provided strong evidence that physical activity improves insulin sensitivity, consequently optimizing glycemic outcomes among individuals with T2DM [174-176]. In this study, physical activity was an independently associated with A1C in the overall and urban populations, but not the semi-urban. Other studies have also indicated that physical inactivity was associated with unacceptable glycemic status [19, 80, 170]. Furthermore, a high proportion of people who are physically inactive in Malawi are in urban areas [13]. Although in the semi-urban area physical activity did not give any significant findings, we are assuming that individuals in this area are always actively engaged in different activities such as farming, walking and household chores even if their A1C was above the recommended target. The ADA recommends 150 minutes of PA per week (spread across three days a week) for adults with T2DM as they are managing the condition for optimal glycemic status [17]. Therefore, future studies in Malawi should document the type of physical activity and facilitators as well as constraints to achieving PA recommendations both urban and semi-urban patients with T2DM are involved in and how they impact glycemic status.

The results indicate that participants self-reported perception of fluctuating blood glucose was associated with glycemic status. These findings mean that blood glucose of the participants

is always unstable. The suggestive reasons for fluctuating blood glucose could be multifactorial, such as inadequate understanding and management of the condition, limited access and availability of diabetes-related information and knowledge on desirable glycemic targets. Therefore, appropriate diabetes education on how an individual can achieve recommended glycemic status (A1C<8%) without having fluctuating blood glucose needs to be emphasized.

Implications to the practice: The findings provide critical information to improve the quality of standard of care for patients with diabetes in Malawi for optimal glycemic status. Age-specific interventions on intensive glycemic status in Malawian settings are required since the young adults with T2DM showed chronic hyperglycemic and are prone to diabetes-related complications with potential for early mortality. Limited accessibility to diabetes care services is one of the major factors contributing to unacceptable glycemic status. Additionally, promoting community outreach services and education on diabetes are critical to addressing the issue of access to healthcare. Underweight, overweight/obesity and physical activity were also independent factors impacting glycemic status. Thus, intensification of appropriate lifestyle behaviors including weight management and education is necessary for optimal glycemic status.

Limitations: Due to the cross-sectional nature of the study, no causal inferences can be made from the study. Because the data were collected in two areas in the central region of the country using convenience sampling, we do not claim external validity of the study results. Furthermore, the data was self-reported regarding such comorbidities and physical activity levels, with the possibility of recall bias. Finally, we did not include dietary practices in our analysis, which leaves out an essential component in understanding the determinants of glycemic status in this population.

F. Conclusions

Unacceptable glycemic status is highly prevalent among adults with T2DM in Malawi irrespective of whether they live in an urban or semi-urban area. A wide range of factors were associated with glycemic status, which may inform development of guidelines for improved management of T2DM among urban and semi-urban residents.

Title: **Determinants of Out-of-Pocket Expenditure Incurred by Adults Diagnosed with Type 2 Diabetes Mellitus in Malawi: A Cross-Sectional Study**

Target Journal: PLOS ONE

A. Abstract

Background: Type 2 diabetes mellitus (T2DM) in Malawi poses economic challenges to vulnerable populations and aggravates public health problems. Patients with T2DM incur extra costs for diabetes care services due to limited health sector resources, with potentially negative ramifications for self-care and glycemic status. The objective of the study was to determine factors associated with out-of-pocket expenditure in relation to socio-demographic and diabetes-related health factors among patients with T2DM.

Methods: A cross-sectional study was done in urban and semi-urban public hospitals in 2017 with 428 adults diagnosed with T2DM, because the government incurs the cost of care. Data included: self-reported socio-demographic and economic factors, diabetes-related information, medical and transportation expenses and glycemic status (A1C). We utilized multivariate linear regression to assess factors associated with the total out-of-pocket expenditures.

Results**:** The mean glycemic status (A1C%) of both urban (9.2±2.7) and semi-urban (9.4±3.0) participants was undesirable. Total out-of-pocket expenditure was positively associated with education, income, duration of diabetes and additional blood glucose monitoring and negatively with A1C and residing in semi-urban areas Factors associated with out-of-pocket expenditure were location specific. Out-of-pocket expenditure was negatively associated with the frequency of hospital visits for blood glucose monitoring and medication refill in the semi-urban participants and positively associated with duration of diabetes in the urban participants.

Conclusions: This study informs the health sector in Malawi that patients with T2DM patients had suboptimal glycemic status and incur high expenses despite the support from the government. Therefore, there is a need to strengthen existing health systems and improve efficiency to enhance patient services to reduce the economic burden of this vulnerable population and ultimately the nation.

B. Introduction

Non-communicable diseases (NCDs) such as Type 2 diabetes mellitus (T2DM) like any other health problem poses financial challenges to the country and stagnates economic growth [56]. Globally, the International Diabetes Federation (IDF) estimated an 8% increase in health expenditure for diabetes in 2017 (US$727 billion) compared to 2015 (US$673 billion) with a projected growth of 7% (US$776 billion) by 2045 [3]. However, Africa has the lowest spending on diabetes care with only 6% of the total health budget in 2017 [3].

T2DM is on the rise in Malawi, with the estimated prevalence of 5.6% among adults 25-64 years of age [13, 14], affecting the productive age group, which is vital for the sustainable economic growth of the country. In the Malawi, 2014-2015 fiscal year, household out-of -pocket spending on NCDs (14.7%) was the highest compared to other conditions [64]. Additionally, the estimated overall coverage for acute diabetes care is 3.3% (7% urban and 1.5% rural) and only 33% of the urban and 9% of the rural facilities were prepared to treat T2DM [64]. The Malawi Government incorporated NCDs services such as screening and treatment for hypertension and diabetes in the Malawi Health Sector Strategic Plan (MHSS) (2011 – 2016) and Essential Health Package (EHP) [71, 72]. The EHP in Malawi ensures equal access to health care, and as such, the costs of services are incurred by the government, particularly in public-operated hospitals [71, 73, 74]. However, patients also spend money on the care of their condition due to limited

resources in the health sector. Furthermore, the national health insurance scheme for Malawians is non-existent except for private health insurance benefit a small proportion of the formal sector employees [177, 178]. Inadequate resource allocation in the health sectors for diabetes compromises the quality of care and may lead to suboptimal glycemic status and associated complications, eventually increasing out-of-pocket expenditures [56, 179, 180].

The cost of care for NCDs such as T2DM is grouped into direct and indirect costs. This manuscript focusses on direct cost. Direct costs are borne by the individual patient and families, such as medications, doctor consultations, dietary expenses and travel relative to health services [96, 100]. A study done in Kenya showed that patients with diabetes incurred extra costs for transportation, consultations with doctors and medications [29]. Studies in Sudan indicated that almost 65% of family expenditure was for diabetes care, if a family member was diagnosed with the disease [101], and 52% had inadequate supply of medications, with out-of-pocket expenditure of US$175 annually [181]. Additionally, studies in India and Pakistan reported high expenditure for diabetes care among the urban and rural low socio-economic households, [99, 102]. Furthermore, the cost increased with duration of diabetes, multiple diabetes complications and treatment type [99, 102, 182]. A study done in rural areas of the southern part of Malawi showed that the people who sought NCD services spent 54.7% of their income on medical and transportation expenses [103]. The out-of-pocket expenditure on diabetes care poses challenges to the economic activities and standard of living of affected families, hence compromising general health, and contributing to the cycle of poverty and under-development [56, 99, 179, 181, 183].

Estimating the cost of diabetes care is of great importance for informing policies, families and individuals with the economic burden of the disease [96, 99] relative to planning and

implementation of interventions. It is necessary to also estimate the cost incurred by families who depend on free public services because of the potential negative implications for self-care, and the paucity of data in this respect. Therefore, the current study aimed to determine the factors associated with the out- of-pocket expenditures in relation to socio-demographics and diabetes-related health factors, especially in urban and semi-urban areas in Malawi because location of residence may provide different challenges.

C. Methods

1. Study design

A cross-sectional study was done in the central region of Malawi. Purposively, two districts were targeted: Lilongwe, the main city (urban) and Kasungu (semi-urban), because nutrition-related NCDs such as T2DM have been reported to be high in urban areas [4, 13, 58]. The study was conducted in two public hospitals: Kamuzu Central Hospital (KCH) in Lilongwe and Kasungu District Hospital in Kasungu with adults diagnosed with T2DM (≥ 25 years). As stated earlier, in public hospitals, the cost of care and prescribed diabetes medications are part of the EHP [71].

2. Study sites

Located in the main city, the KCH is a referral care center for the central region in Malawi and serves over five million people [21]. The diabetes clinic at KCH is managed by the out-patient department and is offered twice a week— Tuesdays and Fridays [21]. During the diabetes sessions, patients are provided with general information on the management of diabetes by a nurse. The only available measure of glycemic status is fasting blood glucose, and reviews are done on a quarterly basis (every three months) by the majority (over 50%) [21], depending on the first appointment of the patient.

The Kasungu District Hospital provides services for both communicable and NCDs such as T2DM [145]. The diabetes clinic at the Kasungu District Hospital is offered once a week—Wednesdays. Furthermore, in 2012, it was the first district in the country to pilot the World Health Organization (WHO) Essential Package for NCDs prevention and control (WHO PEN) designed to facilitate the implementation of prevention and management strategies in low resource settings [147]. WHO provided the district with glucometers for measuring blood glucose, blood pressure machines, weight scales and tape measures [147].

3. Ethical consideration

The study was approved by Institutional Review Board at Michigan State University in the U.S. and National Health Research Committee in the Ministry of Health in Malawi. Written consent was obtained from each selected individual. Each participant was given an equivalent of $5 in Malawian Kwacha upon completing the interviews and assessments needed for the study completion.

4. Sample size

Power Analysis and Sample Size software (PASS version 14) was used to calculate the sample size [148], taking into consideration the statistical power of 0.85 and probability level of 0.05. Therefore, the required total sample size was 428 participants. The Probability Proportional to Size (PPS) was applied to estimate with the required sample size for each study site. In the semi-urban area, the minimum sample size was 140, and for the urban area 288 participants were estimated to be sufficient.

5. Interview procedure and variables

A semi-structured questionnaire was used to obtain information on socio-demographic and economic characteristics and diabetes-related health information. Additionally, data on six months recall for out-of-pocket expenses on diabetes care such purchasing of oral hypoglycemic medications, strips, and paying for additional blood glucose monitoring besides getting free care from the government was also obtained. Furthermore, participants gave information on transportation expenses incurred per hospital visit for blood glucose monitoring (BGM) and medication refill and monthly household expenditure on food. The participants provided blood samples drawn by trained laboratory technician and nurses for glycosylated hemoglobin (A1C). We validated the price of medication, strips, and blood glucose monitoring in different private clinics and pharmacies in urban and semi-urban areas.

Monthly household income in Malawi kwacha (MKW)1000 was used as a continuous variable and categorized into three levels (1) ≤MKW30.33 (2) MKW30.34-122.17 and (3) ≥MKW122.18. To obtain food expenditure per capita, the monthly food expenses were divided by household size. The spending on medication and blood glucose monitoring including strips were combined into a cost of care variable. The BGM expenses, cost of medication, cost of care, transportation and food spending per capita were standardized to expenditures incurred per quarter a year. Therefore, in this paper, we report out-of-pocket expenditures incurred per quarter a year. The total expenditure was taken as continuous variable and categorized into three levels (MKW1000): (1) ≤MKW10.57; (2) MKW10.58-41.04 and (3) ≥MKW41.05. A1C was included as continuous variables and categorized in <8% as acceptable and ≥8% unacceptable glycemic status within the clinical target recommendation of ADA for treatment modification [165].

6. Statistical analysis

Chi-square test for categorical variables and independent sample t-tests for continuous variables were used to compare characteristics of the urban and semi-urban participants. These characteristics included socio-demographic and economic variables, diabetes-related health factors and mode of transportation. The comparison of out-of-pocket expenditures for additional BGM cost, medication, cost of care, transportation, food expenses per capita and total expenses was made using a median test due to the skew of the data and reported as median (interquartile range). The relationship of all independent variables included in the regression model was assessed using Pearson correlation. The variables that were highly correlated, only one variable was included in the final model. The multivariate linear regression was utilized to examine the influence of socio-demographics and economic variables and diabetes-related health factors on total out-of-pocket expenditure per quarter a year. All the analyses were done using SPSS version 24.

D. Results

1. Characteristics of the participants

The mean A1C% of both urban (9.2±2.7) and semi-urban (9.4±3.0) was unsatisfactory above the recommended target of A1C<8%, indicating unacceptable glycemic status (Table 6). The male participation was low in this study, but significantly higher in the semi-urban (40.0%) than urban (26.0%) areas, and the majority (74.5-83.5%) of the participants were married, and 80.5-80.6% of them travel ≥5 km to access health care services. The standard mode of transportation was public mini-buses (64.7-90.6%) or bicycle taxis (27.3%), especially in the semi-urban area (Table 6). The urban participants had significantly higher average monthly household income and longer duration of diabetes than the semi-urban (Table 6). A significant

($p<0.05$) proportion of the participants from the semi-urban area (27.1%) visited the hospital at least once a month for doctor's appointment (for BGM and medication refill), although the majority (72.9-82.3%) did so once in ≥2 months. About 66.3-67.1% of the participants ran short of oral hypoglycemic drugs sometimes before the next appointment, with 63.8-71.7% of those who ran short of medication, purchasing additional oral hypoglycemic prescribed medication. About 28.3-30.9% bought additional oral prescribed medications in anticipation that they may run short of medications. Furthermore about 40.0- 49.3% monitored blood glucose either at the private clinic/home/diabetes peer groups in addition to routine tests at the public hospital (Table 6).

Table 6: Characteristics of the participants by socio-demographic and economic factors, diabetes-related health information and mode of transportation

Variable	Urban (n=288) n (%); mean ±SD	Semi-urban (n=140) n (%); mean ±SD	p-value
Demographics and economic factors			
Age	54.3±9.5	53.0±9.0	0.171
Gender			0.003
Male	75 (26.0)	56 (40.0)	
Female	213 (74.0)	84 (60.0)	
Marital status			0.038
Married	213 (74.5)	116 (83.5)	
Divorced/widowed	73 (25.5)	23 (16.5)	
Household income per month (MKW 1000)	101.4±93.3	79.3±76.7	0.016
Number of years in school	9.1±4.1	8.5±4.4	0.167
Distance to the hospital			0.004
<5 km	27 (9.4)	25 (19.5)	
≥ 5km	261 (90.6)	103 (80.5)	
Diabetes-related health information			
A1C	9.2±2.7	9.4±3.0	0.392
Duration of diabetes	6.4±4.5	5.00±4.0	0.001
Sometimes run short of prescribed medication			0.865
Yes	191 (66.3)	94 (67.1)	
No	97 (33.7)	46 (32.9)	
Buys additional prescribed medication when sometimes run short			0.175
Yes	137 (71.7)	60 (63.8)	
No	54 (28.3)	34 (36.2)	
Buys additional prescribed medication in anticipation that they will run short of medication			0.745
Yes	30 (30.9)	13 (28.3)	
No	67 (69.1)	33 (71.7)	
Places where participants buy additional prescribed medications			<0.001
Private clinic	23 (13.8)	41 (56.2)	
Private pharmacies	144 (86.2)	32 (43.8)	
Additional BGM			0.070
Yes	142 (49.3)	56 (40.0)	
No	146 (50.7)	84 (60.0)	
Frequency of hospital visit			0.024
Once a month	51 (17.7)	38 (27.1)	
Once in ≥2 months	237 (82.3)	102 (72.9)	
Mode of transportation to the hospital			<0.001
Personal vehicle	17 (5.9)	3 (2.1)	
Public mini-bus	259 (90.6)	90 (64.7)	
Bicycle- taxi (*kabaza*)	7 (2.4)	38 (27.3)	
Walk	3 (1.1)	8 (5.8)	

2. Mean A1C of participants who run short of and purchase prescribed medications

There were no significant differences in mean A1C among participants who indicated that they sometimes ran short of prescribed medication and those who did not (Table 7). Even if participants bought additional medication, their A1C status was above the recommendation of <8%.

Table 7: Mean A1C levels of participants who sometimes run short and buy prescribed medication

Variable	A1C%; mean ± SD (n)	p-value
Sometimes run short of prescribed medications		0.680
Yes	9.3±2.7 (285)	
No	9.2±3.0 (143)	
Buy additional prescribed medication		0.367
Yes	9.2±2.7 (240)	
No	9.4±2.9 (188)	
Sometimes run short and buy additional prescribed medication		0.882
Yes	9.3±2.6 (197)	
No	9.4±2.9 (88)	
Buy prescribed medication in anticipation that they will run short		0.098
Yes	8.6±2.9 (43)	
No	9.5±2.3 (100)	

3. Out-of-pocket expenditures

The median expenditure per quarter a year was MKW24,000 or $34.29 for urban and MKW15,000 or $21.42 for semi-urban ($p<0.001$) participants. The urban participants spent a significantly ($p<0.001$) higher amount on additional BGM (MKW2,500 or $3.57) and cost of care (MKW2,000.00 or $2.85) while semi-urban participants spent more on transportation (MKW3,000 or $4.29). However, the cost of care and transportation expenses were combined, the semi-urban participants spent 26.7% of the total estimated median out-of-pocket expenditure while urban participants spent 14.1%. This result is a clear indication that the semi-urban participants spend more while seeking medical care despite their low-income status. Significant

(p<0.001) amount was spent on food in both urban (MKW20,010 or $28.59) and semi-urban (MKW15,000 or $21.43) (Table 8).

Table 8: Median (interquartile range) out-of-pocket expenditure (MKW1000) per quarter year by study location

Expenditure variables (MKW1000)	Overall (n=428)	Urban (n=288)	Semi-urban (n=140)	p-value
Additional BGM	1.50 (0.50-3.75)	2.50 (1.00-5.00)	0.32 (0.25-1.19)	<0.001
Medication	0.83 (0.50-1.50)	1.00 (0.50-1.78)	0.67 (0.33-1.25)	0.089
Cost of care	1.50 (0.67-3.74)	2.00 (0.75-5.00)	1.00 (0.45-1.75)	<0.001
Transportation	1.80 (1.00-3.00)	1.50 (1.00-2.56)	3.00 (1.50-4.80)	<0.001
Food expenses per capita	18.00 (7.50-37.50)	20.01 (9.99-39.99)	11.25 (4.04-29.25)	0.002
Total median expenses	21.74 (10.57-41.04)	24.76 (12.77-43.60)	15.00 (8.12-31.07)	<0.001

MKW (1000) =Malawian kwacha, US$=MKW700.00 (approx.)

4. Income spent per quarter a year by location, household income and A1C status

Based on the previously explained expenditure categories in the method section. A significant proportion of urban (51.4%) and semi-urban (47.1%) participants spent a moderate (MKW10,580-41,040 or $15.11-58.61) amount of money. Within the context of household income, among the urban participants, the proportion income spent significantly (p<0.001) increased with income level; for instance, 51.3% and 59.1% of the low-and middle-income category spent a moderate amount, and 57.3% of the high income spent ≥MKW41,050 or $58.64. However, in the semi-urban area, a significant (p<0.01) average expenditure was noted in 42.0%, 46.8% and 57.1% of the low-, middle-, and high-income groups respectively (Table 9). In both urban and semi-urban areas, the low-income group spent a moderate amount of money for diabetes care.

Table 9: Proportion of income spent (MKW1000) per quarter year by location, household income and A1C status

	Expenditure levels in MKW1000			
Variable	Low (≤MKW10.57) (n=106) n (%)	Moderate (MKW10.58-41.04) (n=214) n (%)	High (≥MKW41.05) (n=108) n (%)	p-value
Location (n=428)				<0.001
Urban	55 (19.1)	148 (51.4)	85 (29.5)	
Semi-urban	51 (36.4)	66 (47.1)	23 (16.4)	
Urban (n=288) Monthly household Income (MKW1000)				<0.001
≤MKW30.33	30 (39.5)	39 (51.3)	7 (9.2)	
MKW30.34-122.17	21 (15.3)	81 (59.1)	35 (25.6)	
≥MKW 122.18	4(5.3)	28 (37.3)	43 (57.3)	
A1C status				0.842
<8%	21 (18.4)	61 (53.5)	32 (28.1)	
≥8%	34 (19.5)	87 (50.0)	53 (30.5)	
Semi-urban (n=140) Monthly household Income (MKW1000)				0.002
≤MKW30.33	27 (54.0)	21 (42.0)	2 (4.0)	
MKW30.34-122.17	20 (32.3)	21 (46.7)	13 (21.0)	
≥MKW 122.18	4 (14.3)	16 (57.1)	8 (28.6)	
A1C status				0.201
<8%	18 (32.1)	25 (44.7)	13 (23.2)	
≥8%	33 (39.3)	41 (48.8)	10 (11.9)	

MKW (1000) =Malawian kwacha; US$1=MKW700.00 (approx.)

5. Factors associated with total out-of-pocket expenditure

Three multivariate linear regression models were tested, one for the overall, urban and semi-urban samples. In the overall model, the out-of-pocket expenditure was positively associated with education level ($\beta=0.69$, $p<0.05$), household income level ($\beta=0.13$, $p<0.001$), duration of diabetes ($\beta=0.95$, $p<0.01$) and additional BGM ($\beta=7.83$, $p<0.01$); and negatively with residing in the semi-urban area ($\beta=-6.37$, $p<0.05$) and A1C ($\beta=-1.00$, $p<0.05$). The factors that were positively or negatively associated with total out-of-pocket expenditure were also noted to be location specific. In the urban population, total out-of-pocket expenditure was positively

associated with household income (β=0.14, p<0.001), duration of diabetes (β=1.36, p<0.001) and additional BGM (β=7.13, p<0.05). In the semi-urban population, frequency of hospital visits for BGM or medication refill (β=-6.64, p<0.01) was negatively associated with out-of-pocket expenditure and positive associations was noted with education level (β=1.39, p<0.01), household income (β=0.07, p<0.01) and additional BGM (β=8.42, p<0.05) (Table 10). In all the three models, household income and additional BGM were the two common factors positively associated with total out-of-pocket expenditure.

Table 10: Multivariate linear regression models examining factors associated with total out-of-pocket expenditure

Variables	Overall (n=428) β(SE)	p-value	Urban (n=288) β(SE)	p-value	Semi-urban (n=140) β(SE)	p-value
Demographic and economic factors						
Age in years	-0.11 (0.16)	0.462	-0.16 (0.20)	0.422	0.00 (0.22)	0.991
Marital status: married	-3.28 (3.27)	0.316	-2.46 (4.15)	0.554	-3.34 (5.08)	0.512
Gender: female	1.17 (2.86)	0.684	0.74 (3.86)	0.848	3.60 (3.88)	0.355
Education: years in school	0.69 (0.33)	0.038	0.45 (0.44)	0.307	1.39 (0.47)	0.004
Household income	0.13 (0.02)	0.000	0.14 (0.02)	0.000	0.07 (0.02)	0.003
Location: semi-urban	-6.37 (2.85)	0.026	-	-	-	
≥5km distance to the hospital	1.67 (3.75)	0.656	10.18 (5.51)	0.066	-4.95 (4.46)	0.27
Diabetes-related health factors						
Frequency of hospital visits for BGM	-2.75 (1.49)	0.067	-1.63 (1.90)	0.393	-6.64 (2.26)	0.004
Run short of oral hypoglycemic drugs	-0.94 (2.82)	0.739	0.99 (3.65)	0.786	-4.52 (4.10)	0.272
Buying oral hypoglycemic drugs	-2.57 (2.82)	0.362	-6.68 (3.72)	0.074	3.55 (3.89)	0.364
Duration of diabetes	0.95 (0.31)	0.002	1.36 (0.41)	0.001	-0.03 (0.47)	0.951
A1C	-1.00 (0.47)	0.033	-1.06 (0.63)	0.092	-0.51 (0.63)	0.415
Additional BGM beside the government hospital	7.83 (2.72)	0.004	7.13 (3.57)	0.047	8.42 (3.80)	0.029
	R^2=0.315		R^2=0.322		R^2=0.336	

BGM=Blood Glucose Monitoring, A1C=Glycosylated Hemoglobin

E. Discussion

This study reports the findings from the direct out-of-pocket expenditure perspectives from patient receiving free diabetes care services from the public hospitals. Since the majority of Malawians live below the poverty benchmark and rates of T2DM in adults are disproportionately high, the expenses incurred in seeking medical services cannot be underestimated. In this study, almost 66-67% of the participants reported running short of prescribed medication before the

next appointment with doctors at the public hospital for BGM or medication refill due to insufficient supply of drugs. This eventually impacts medication adherence and hence glycemic status. As noted in this study, the mean A1C (9.2-9.4%) was unacceptably high above the recommended target of <8% [165]. Persistent unacceptable glycemic status could potentially cause irreversible damage such as diabetes related complications and reduce productivity of the affected individuals. Our findings are supported by a study conducted in Sudan that showed about 52% of the patients with T2DM reported inadequate drug supplies and the majority (77%) also had unacceptable glycemic status [181]. Inconsistency in medication supply forced 71.7-63.8% of those who run short of medication sometimes and 28.3-30.9% of those who were anticipating that they would run short of medication to buy additional prescribed oral hypoglycemic drugs/insulin. The commonly prescribed medications were metformin and glibenclamide (92.3% of the patients in this study) within the recommendation of the Ministry of Health in Malawi [64]. Metformin, the first-line drug for the treatment of T2DM, decreases liver glucose production and glibenclamide stimulates release of insulin by the pancreatic β cells [51]. A study conducted in Nigeria also found that metformin and glibenclamide were the mainly prescribed oral hypoglycemic drugs among patients with T2DM [184]. T2DM adults in this study purchased the medications either at the private pharmacies or a private clinic proximate to their location of residence. The prices of metformin and glibenclamide are affordable, ranging from MKW200-450 or $0.29-0.64 for 30 tablets. We found in overall, that the median expenditure for medications was MKW830 or $1.19 per quarter a year, implying that patients did not buy the complete prescribed dosage, but either one type or partial dosage to cushion them while waiting for the doctor's appointment date. The doctor's appointments varied widely among patients, ranging from once in every one to four months. Sparse doctor

appointment period prompted T2DM patients, to seek an additional BGM either at the private clinic or diabetes peer group especially in the urban area, where peer groups are operational as part of self- care management. Additional BGM significantly associated with the total out-of-pocket expenditure in both urban and semi-urban areas. A study in Sudan also indicated that high cost of care among patients with diabetes was attributed to self-monitoring of blood glucose [185]. In the semi-urban area, frequency of hospital visits was negatively associated with the total expenditures because majority of the patients were visiting the doctors once in every two or more months for BGM and medication refills. This infrequency could also be one possible explanation for the increase in cost of additional BGM beyond that conducted at the public hospitals.

The urban participants had higher total median out-of-pocket expenses than the semi-urban, due to higher expenditures on additional BGM, cost of care, and food expenses per capita, although the A1C status was the same in both locations. Residing in the semi-urban area was negatively associated with total out-of-pocket expenditures. Earlier research in India also reported high spending among the urban patients with T2DM than the rural counterparts especially for medications, as well as medical and laboratory fees [186]. We can make assumptions that the urban participants in this study had better access to medical services, though the A1C was also high. The high median expenditure with unacceptable A1C in this population needs further investigation to elucidate the factors contributing to both high spending and A1C. Overall, A1C status was negatively associated with total expenditure, implying that those with better glycemic status were less likely to spend more on diabetes care. Studies done in developed nations also found that cost of diabetes care was less in those with better glycemic status [187, 188]. The semi-urban had two times more expenses for transportation than the urban

participants. In the semi-urban areas, people are scattered and travel a long distance to the public hospital for medical services. Taking into consideration the cost of care (medication and additional BGM) and transportation expenses, the semi-urban participants spent 26.7% vs.14.1% for urban of the total median out-pocket expenses. Bringing the services closer to the communities and standardizing regular follow up would likely help to reduce the expenses of low-income population.

Socio-economic factors such as income and education status influenced the total expenditures. Household income was positively associated with out-of-pocket expenditures in both urban and semi-urban participants, indicating that people with high income were more likely to seek additional medical services despite the free support from the public hospitals. Similar observations were made by a study in Mali that among patients with diabetes, income was the independent predictor of the total expenditure on diabetes care [189]. A significant proportion of the middle-and high-income group urban participants spent moderately to high on diabetes care, while in the semi-urban area, a considerable percentage was within the low-moderate expenditure group. The differences exist due to economic status between the two locations, which could impact the quality of care. However, it should be noted that in Malawi, national health insurance is not available to the general population [177], hence increasing out-of-pocket expenditure from low-income populations. Studies in Pakistan and India found that the low-income group were spending a significant amount of their family income on diabetes care [99, 186]. Longer years in school also influenced the total expenditure in the overall model and semi-urban area. It is known that high literacy may help the individuals to understand the burden and possible complications of the disease better, and they would therefore be more likely to seek medical services. Although this may not always be the same, other studies done in Mali

and Sudan indicated that expenditure decreased with increase in education level [185, 189]. Implying that attaining a higher education does not equate to high health literacy [189], hence the need to assess the health literacy of T2DM in Malawi in terms of their knowledge and self-care behaviors especially those getting free services from the public hospitals.

T2DM is a chronic condition and if not well managed, may increase associated morbidity and premature death. The present study indicated that total out-of-pocket expenditure increased with duration of diabetes in the overall model and urban participants, indicating that with longer duration of diabetes individuals spent more money on care. Similar findings were reported by previous studies in India [99, 182, 186]. In this study, the urban participants with ≥6 years spent more on food and total median expenditure. In this urban area, individuals participate in diabetes peer groups [21]. We are hence making assumptions that these individuals may have had better awareness and understanding on the importance of diabetes management.

Limitations: This study is not without limitations. Firstly, the information collected was self-reported and biases might have occurred in estimating the cost. Secondly, we did not obtain any data on the expenses related to complications, considering that the majority may have one or more comorbidities given the unacceptable A1C levels overall. Thirdly, this study only targeted those receiving services from the public hospitals; it would have been interesting to compare with those who solely depend on private clinics and individuals with private medical insurance. Lastly, we did not collect any data on the indirect expenses such as loss of productivity, time.

F. Conclusions

Findings show that even though patients with T2DM get support from the public hospitals, a substantial amount of additional expenses are likely incurred, due to unsatisfactory

service delivery. More specifically a high proportion ran short of and purchased oral hypoglycemic drugs and had suboptimal glycemic status regardless of the location of residence. Thus, there is a need to strengthen existing health systems to enhance patient services to reduce the economic burden of this vulnerable population. Additionally, detailed cost analysis in Malawi is needed to help understand the economic implications taking into consideration indirect losses associated with the burden of T2DM and other NCD's.

CHAPTER 5- MANUSCRIPT 2

This chapter provides information on dietary intake and food insecurity of adults diagnosed with T2DM relative to glycemic status. The results of this chapter are into two parts; first (part A) describes the dietary intake and the second (part B) explains the food insecurity situation of patients with T2DM.

Title: **Dietary Associations with Glycemic Status Among Adults Diagnosed with Type 2 Diabetes Mellitus and Factors Affecting Diet Quality Including Food Insecurity**

A. Abstract

Background: Diet is a cornerstone for management of Type 2 diabetes mellitus (T2DM) to ensure optimal glycemic status but is affected by food insecurity. The objective was to assess diet and associations with glycemic status among adults diagnosed with T2DM and factors affecting diet quality including if and how food insecurity needs to be considered when trying to maximize positive outcomes in patients with T2DM.

Method: A cross-sectional study was conducted in 2017 at Kamuzu Central Hospital (urban) in Lilongwe and Kasungu District Hospital (semi-urban) in Kasungu, both in Malawi. Adults diagnosed with T2DM (n=428), in urban (n=288) and semi-urban (n=140) areas were interviewed. Demographics, anthropometrics, physical activity, dietary quality, food insecurity and glycemic status (A1C) were assessed. Quantitative twenty-four-hour and typical day recalls were used to derive individual dietary diversity scores (IDDS), preventive diet scores and macronutrient percentage of total energy based on WHO/FAO nutrition guidelines for chronic disease prevention. The Household Food Insecurity Access Scale (HFIAS) was used to assess food insecurity.

Results: Mean A1C of both males (9.5%) and females (9.2%) was above the recommended clinical glycemic target (<8%). The percent of total calories from carbohydrate was 75.4% overall, but significantly ($p<0.001$) higher than WHO/FAO recommendations among participants with A1C≥8% (79.5%) compared to those with A1C<8% (69.4%). Consumption of cereals, roots and tubers and sweet, sugary food including sweetened beverages, were significantly higher among those with A1C≥8%. Fruit and vegetable intake was disproportionately low overall. Furthermore, a significant ($p<0.001$) proportion of participants with A1C≥8% had ≤3 meals/day, while those with A1C≥8% were less likely to follow dietary recommendations compared to those with A1C<8% ($p<0.05$). Consuming a diet high in carbohydrates (OR:1.20; CI = 1.14-1.27; $p<0.001$) and having ≤3 meals per day (OR: 2.25; CI=1.17-4.30; $p<0.05$) increased the odds of not achieving the recommended A1C target of <8%. Both IDDS and preventive diet score did not show significant results in relation to A1C≥8%. Despite food insecurity status; the A1C level was ≥8% among majority of the participants, and severity was positively related to HFIAS score. The HFIAS scores was negatively associed with impacted IDD score, own food production for consumption, income status, food expenditure per capita and education level. Futhermore, residing in the of the semi-urban areas was postively associated with HFIAS score.

Conclusions: Dietary quality, especially relative to higher than recommended carbohydrate intake and meal irregularity, negatively impacts glycemic status in this target group. Additionally, food insecurity affected the diversity of the diet. Therefore, dietary interventions that focus on carbohydrate counting, total dietary quality, and meal planning are urgently needed in Malawi. Sustainable food security programs must be initiated for the

economically disadvantaged T2DM patients at risk for food insecurity for optimal health outcomes and productivity of the household and nation.

B. Introduction

Diet globally contributes to six of the eleven main factors associated with disease [1], and diet-related non-communicable diseases (NCDs) are a factor in 49.8% of disability and death in developing countries [190]. NCDs such as Type 2 diabetes mellitus (T2DM) is escalating globally, even in developing countries. In 2017, it was estimated that about 16 million adults in sub-Saharan Africa have diabetes, but the number will rise by 153% (41 million) by 2045 [3]. The prevalence of T2DM (5.6%) in Malawi is disproportionately higher in men (6.5%) than in women (4.7%) 24 to 65 years of age [13, 14]. According to a study targeting health professionals in Malawi, poor diet and inadequate knowledge of healthy eating habits were important factors reported for the increase in NCDs [16]. Therefore, promoting healthy diets and necessary changes in dietary behavior within the general population will help prevent a further rise in T2DM [10].

Diet is also a cornerstone for management of T2DM to ensure optimal glycemic status [106], however, food insecurity poses a challenge in achieving it. Patients with diabetes who are experiencing food insecurity may change their dietary patterns to unhealthy foods, skipping meals and altering meal patterns, which could negatively impact glycemic status and aggravate overall health [121-125]. Additionally, dietary advice for the management of T2DM in Malawi is based on a general food guide, which is not specific to the condition; hence, it is difficult to translate into daily nutrition counseling and education [36]. Also, nutrition labeling is voluntary and not well understood by the majority of Malawians, making informed food choices difficult [37, 38].

Therefore, these factors can lead to unhealthy dietary patterns, poor dietary compliance and meal irregularities for those diagnosed with T2DM [31, 39, 40]. Furthermore, nutrition education on dietary management of diabetes is provided by health workers, who are not trained in nutrition, and the involvement of nutritionists in NCD service provision is very low, as reported by 35% of senior health officers [16]. Therefore, knowledge of the local foods and the extent to which diet in Malawi impacts glycemic status is imperative for developing culturally appropriate nutrition education and counseling materials for management of T2DM, as well as to facilitate nutrition policy revisions to enhance the role of nutrition in NCD services.

Although previous studies have identified the dietary patterns of African adults with T2DM [31], little has been done on the impact of the Malawian diet on glycemic status in patients with T2DM. It was observed that the diet of urban and rural black South Africans with T2DM was overall high in carbohydrates and low in fiber [31]. However, the diet of patients with T2DM in urban areas was higher in animal protein with a lower polyunsaturated to saturated fat ratio compared to those in rural areas [31]. In Ghanaian and Ugandan patients who have diabetes, their diet is rich in carbohydrates, fat, and sodium, but moderate in protein and poor in fiber [84, 109]. A study conducted in Ethiopia found that the dietary practices of patients with T2DM were poor due to non-availability of fruits and vegetables, the high cost of the foods and lack of required nutrition education in the hospitals [110]. Therefore, it is appropriate to understand food consumption patterns specific to Malawians because of differences in food systems, agricultural seasons, production patterns, cultural values and economic status [31, 114]. As such, the objective was to assess diet and associations with glycemic status and factors affecting diet quality including food insecurity in adults with T2DM living in two different environments (urban and semi-urban) with potentially different challenges.

C. Methods

1. Study design, subjects, and ethics

A cross-sectional study (n=428) was conducted in 2017 in Lilongwe (urban: n=288), at Kamuzu Central Hospital and Kasungu (semi-urban: n=140) at Kasungu District Hospital. The study targeted adult's physician diagnosed with T2DM who were attending out-patient diabetes clinic in these two public hospitals. The face-to-face interviews were conducted with the participants using a structured questionnaire synthesized from validated tools. All the interviews were conducted in the local language *Chichewa* by four trained postgraduate nutrition students, including the primary researcher.

The Institutional Review Board at Michigan State University in the United States of America and the National Health Research Council in the Ministry of Health in Malawi reviewed and approved the study protocols. Additionally, respective hospitals granted permission to conduct the study. Written informed consent was obtained from each study participant by the primary researcher, and an equivalent of $5 in Malawian kwacha was given to the participants as compensation for interview and assessment data completion.

2. Socio-demographic and diabetes-related information

Demographic and economic characteristics included age, marital status, educational level, household size, employment status, location and food expenditure per month were obtained from the study participants. The average monthly food expenditure was further divided by household size to derive monthly food expenditure per capita. Furthermore, information related to diabetes such as duration of the disease in years and type of treatment was also obtained.

3. Anthropometry

Weight (kg) and height (cm) were measured to calculate body mass index (BMI) kg/m^2 and taken as a continuous variable. We measured height using a stadiometer to the nearest 0.1 cm (SECA$^{@}$ 213, SECA GmbH & Co. KG. German) and weight using the seca scale (SECA$^{@}$803, SECA GmbH & Co. KG, German) to the nearest 0.1 kg. Two measurements for waist and hip circumference were taken in cm using a non-stretchable (SECA$^{@}$201) tape and then averaged. The cut-off for waist circumference for men is >102 cm and women >88 cm and waist: hip ratio for men ≥0.90 and women ≥0.85, as an indication of central abdominal obesity or substantially increased risk of metabolic complication [154].

4. Physical activity

The global physical activity questionnaire was used, which is a WHO Stepwise approach to chronic diseases tool. It measures activity at work, travel, recreation and time spent on sedentary behaviors such as watching television on a typical day [151]. The total physical activity metabolic equivalent (MET)-minutes per week was calculated as a continuous variable and categorized into: low physical activity (<600 MET-minutes/week), moderately active (≥ 600 to <3000 MET-minutes/week) and vigorously active (≥ 3000 MET-minutes/week) [151].

5. Glycemic status

Venous blood samples drawn from the patients by a laboratory technician and nurse trained by the Ministry of Health in Malawi, were used to test for glycosylated hemoglobin (A1C) using the DCA Analyzer (Siemens, Tarrytown, NY, USA). The blood samples were kept in ethylenediaminetetraacetic acid (EDTA) tubes and transferred the same day to the laboratory for the A1C test. The A1C results were used as a continuous variable and further categorized into

two categories which were based on ADA recommendation: clinically acceptable (A1C<8%) and unacceptable (A1C≥8%) targets [165].

6. Dietary intake

In this study, diet quality was measured using two indicators, namely the individual dietary diversity score (IDDS) and preventive diet score. The two dietary recalls: 24-hour and typical day were used to assessed the dietary intake. Calibrated typically used kitchen utensils were used to guide the participants in estimating portion sizes. The preventive diet score was assessed using WHO/FAO nutrition recommendations for the prevention of chronic diseases [63]. The guidelines are based on the percent contribution to total energy specifically total fat (15-30%), saturated fatty acid (<10%), polyunsaturated fatty acids (6-10%), total carbohydrate (55-75%), protein (10-15%), cholesterol (<300 mg/day), sodium (2 g/day) and fruits and vegetable intake of ≥400 g/day [63]. The preventive diet scores ranged from 0-8. Meeting the WHO/FAO recommendation for a specific dietary factor was scored as one and zero, if not met [104, 111, 157].

Information collected from the 24-hour recalls was also used to derive a IDDS using 14 food groups: 1) cereals, 2) vitamin A rich vegetables and tubers, 3) white tubers 4) dark green leafy vegetables, 5) other vegetables, 6) vitamin A rich fruits, 7) other fruits, 8) organ meat, 9) flesh meat, 10) eggs, 11) fish, 12) legumes, nuts and seeds, 13) milk and milk product, and 14) oils and fats (including red palm oil). The response options were “consumed” (score=one) or “not consumed” (score=zero) for each specific food group. The IDDS is the sum of the scores of the 14 food groups, and the scores range from 0-14; the higher the score, the more diverse the diet [115]. The IDDS was a continuous variable (score of 0-14) and further divided into three

parts: 1) ≤3 food groups as low dietary diversity, 2) 4 to 5 food groups as medium dietary diversity and 3) ≥6 food groups as high dietary diversity[115].

7. Food security assessment

The Household Food Insecurity Access Scale (HFIAS) questionnaire developed and validated by the Food and Nutrition Technical Assistance [152] was used to assess food insecurity. The HFIAS assesses food insecurity for the past four weeks before the day of data collection. The HFIAS has nine conditions (Table 11) [152]. Each condition has a frequency of occurrence response as follows: rarely =1, sometimes = 2 and most often =3. Food security status was categorized into four groups: 1) food secure, if the household did not experience any of the nine conditions or experienced condition one (rarely); 2) mildly food insecure, if the household experienced condition one (sometimes or most often), condition two (rarely, sometimes, or often), and condition three and four (rarely); 3) moderately food insecure, if the household experienced conditions three and four (sometimes or most often), and conditions five and six (rarely or sometimes); 4) severely food insecure if the household experienced conditions five and six (most often), and conditions seven, eight and nine, (rarely, sometimes, or most often) [152]. We calculated the HFIA scores (0-27) by adding up the responses to all nine condition questions regarding the frequency of occurrence; the higher the HFIA score, the greater the food insecurity experienced by the household [152]. The HFIA scores were the primary outcome of this study.

Table 11: Household food insecurity conditions [152]

Conditions of food insecurity in the past four weeks
1) "Did you worry that your household would not have enough food?"
2) "Were you or any household member not able to eat the kinds of foods you preferred because of a lack of resources?"
3) "Did you or any household member have to eat a limited variety of foods due to a lack of resources?"
4) "Did you or any household member have to eat some foods that you did not want to eat because of a lack of resources to obtain other types of food?"
5) "Did you or any household member have to eat a smaller meal than you felt you needed because there was not enough food?"
6) "Did you or any household member have to eat fewer meals in a day because there was not enough food?"
7) "Was there ever no food to eat of any kind in your household because of lack of resources to get food?"
8) "Did you or any household member go to sleep at night hungry because there was not enough food?"
9) "Did you or any household member go a whole day and night without eating anything because there was not enough food?"

8. Market access and food sources

Participants also provided information on the type of primary and secondary food markets they used including the distance to the primary market. Additional information was also collected on type of food they purchased from each market. In this study, traditional open markets are those operated by food retailers who sell different kinds of agricultural produce either open-air or covered, and mostly found within the neighborhoods or trading centers or town/cities [191]. The small grocery store is operated at a smaller scale, located within the neighborhood and sells limited varieties of groceries such as wheat products (bread, scones,

etc.), condiments, sweets, beverages, fats, and oils, etc. Supermarkets such as Shoprite and *Chipiku* are operated at a larger scale in cities or town or trading centers and sell a variety of groceries such as meat and meat products, wheat products, fats and oils, dairy products, fruits, and vegetables etc [191]. The two primary sources of food for household consumption was also obtained from the participants. If one of the food sources was own production, we further asked the type of food they produce for household consumption. The foods purchased from the markets and produced for household consumption were classified into FAO 12 food groups that are used for assessing household dietary diversity specifically 1) cereals, 2) roots and tubers, 3) vegetables, 4) fruits, 5) meat and poultry, 6) eggs, 7) fish and other sea food, 8) pulse, legumes and nuts 9) oils and fats, 10) milk and milk products, 11) sweets and sugary foods (including sweetned beverages), and 12) spices, condiments and alcoholic beverages [115].

9. Statistical analyses

Chi-square and independent sample t-tests were used to assess the differences in the characteristics of the participants by gender. Dietary data was entered into Nutri-survey for windows copy ©2007, SEAMEO-TROPMED RCCN-University of Indonesia (www.nutrisurvey.de) computer package to derive the nutritive value of the food. For the foods that were not found in the Nutri-survey database, food composition table for Mozambique [162] and Tanzania [163] were used to determine the nutrient content of the food, and then, the values were entered into the Nutri-survey to form part of the dataset. The nutrient intake for two recalls was averaged to estimate the intake per day. Descriptive statistics were used to indicate the proportion of the participants who were meeting or not meeting the WHO/FAO nutrition guidelines for prevention of chronic diseases. Additionally, a chi-square test was used to test for difference between participants based on A1C<8% and A1C≥8% for meal frequency, adherence

to dietary recommendations and reasons for not complying. Independent sample-t-tests tested the differences in mean intakes of macronutrients, the percentage of macronutrients to total energy, average fruit and vegetable intake per day, IDDS and preventive diet scores and food group consumption per location based on A1C status (<8% and ≥8%). We utilized binary logistic regression for multivariate analysis to examine the dietary factors associated with A1C≥8% while controlling for confounding factors such as age, gender, location, monthly food expenditure per capita, physical activity, BMI, duration of diabetes, type of treatment, total energy (kcal) and food security status.

Chi-square test for categorical variables and one-way analysis of variances for continuous variables was used to test for differences in food insecurity status (food secure, mildly food insecure and moderately to severely food insecure) by socio-demographic and economic characteristics, food-related factors and health-related variables. Descriptives, such as percentages and frequencies were used to indicate the food groups participants produced for consumption and purchased from different markets. The chi-square test was also used to test if there were differences in the type of markets from which urban and semi-urban participants purchased the food. The independent sample t-test was used to examine the differences in HFIAS by A1C status (<8% and ≥8%). Multivariate linear regression was used to investigate factors associated with HFIAS. The dependent variable was HFIAS, and independent variables included: age, gender, marital status, education level, household size, monthly food expenditure per capita, monthly household income, location, IDDS, distance to the primary market, own food production for consumption, A1C, mean waist circumference. Pearson correlation analysis was done for all the variables included in the linear regression model. Of the variables that were highly correlated, only one variable was chosen and included in the model.

D. Results

Part 1 — Dietary intakes

1. Characteristics of the participants

In this study, male participants were significantly ($p<0.01$) older than the female (average age; 55.7±9.3 vs. 53.0±9.2 years respectively) (Table 12). Significant ($p<0.001$) proportions of male (93.9%) and female (70.2%) participants were married, with 29.8% of the females being either divorced/widowed. Furthermore, a significant ($p<0.01$) proportion of male (49.6%) participants had attained the secondary level of education and above, although 50.4% of males and 64.0% of females completed through the primary level of education or less. Among the male participants, 56.5% were from the urban, and 43.5% from semi-urban. Similarly, a majority (72.1%) of the female participants were from the urban area versus 28.0% from the semi-urban (Table 12).

The mean BMI of the participants was significantly higher, in females compared to males ($p<0.001$) indicating a greater likelihood of overweight/obesity (average BMI: 29.4±5.9 vs. 24.7±4.8 kg/m^2 respectively). Additionally, the average waist circumference for females was above the cut-off of >88 cm, an indication of central abdominal obesity, which was significantly ($p<0.001$) higher than in male participants. But there were no significant differences in the waist: hip ratios for both genders. Furthermore, there were no significant differences in glycemic status based on gender, but A1C values were higher than clinical target for both (mean A1C= 9.5% vs. 9.2% respectively). There were no significant differences in the duration of diabetes, treatment type and physical activity level between male and female participants (Table 12).

Table 12: Characteristics of the participants stratified by gender

	Male (n=131) mean±SD; n (%)	Female (n=297) mean±SD; n (%)	p- value
Age	55.7±9.4	53.0±9.2	0.006
Marital status			<0.001
Married	122 (93.9)	207 (70.2)	
Divorced/widowed	8 (6.2)	88 (29.8)	
Education level			0.008
≤ Primary level	66 (50.4)	190 (64.0)	
≥ Secondary level	65 (49.6)	107 (36.0)	
Food expenditure per capita			0.219
≤ 2500MKW	38 (29.0)	88 (29.6)	
2501-12000 MKW	67 (51.2)	129 (43.4)	
≥12001 MKW	26 (19.9)	80 (26.9)	
Location			0.002
Urban	74 (56.5)	214 (72.1)	
Semi-urban	57 (43.5)	83 (28.0)	
BMI (kg/m^2)	24.7±4.8	29.4±5.9	<0.001
Waist circumference (cm)	92.2±12.0	98.3±13.8	<0.001
Waist-hip ratio	1.0±0.1	0.9±0.1	0.053
Duration of diabetes	6.0±4.9	6.0±4.2	0.276
A1C%	9.5±3.0	9.2±2.7	0.970
Type of treatment			0.133
Diet only	1 (0.8)	5 (1.7)	
Insulin	4 (3.1)	23 (7.7)	
Oral hypoglycemic agents	126 (96.2)	269 (90.6)	
Physical activity			0.590
Low	33 (25.2)	64 (21.6)	
Moderate	57 (43.5)	127 (42.8)	
Vigorous	41 (31.3)	106 (35.7)	

MKW=Malawian kwacha; 1US$=MKW700.00

2. Macronutrient, fruit, vegetable and sodium intakes

The proportions of participants meeting the 55-75% of the total energy from carbohydrate (CHO) in the overallsample was low (33.9%). For the majority of semi-urban compared to urban participants (65.7% vs. 56.6% respectively) and those with A1C≥8% compared to A1C <8% (74.0% vs. 37.2% p<0.001) the CHO percent of total energy was above 75%. Furthermore,

for a significant ($p<0.01$) proportion of participants with A1C≥8% (65.2%), their protein percent of the total energy was within the recommended range of 10-15% compared to those with A1C<8% (51.5%). Although not significant by location and glycemic status, only 40.2% of all paricipants met the recommendation for contribution of percent fat to total energy (range15-30%), with 57.5% below and 2.3% above the recommendation. The polyunsaturated fatty acid intake (PUFA) for the majority (85.5%) was below 6%; 13.4% ranged between 6-10% of the recommended range and 1.2% were above 10%. Fruit and vegetable intake overall was very low, with only 11.7% of the participants meeting the WHO/FAO recommendation of 400 g/day. Sodium intake of <2000 mg/day was observed more frequently among participants with A1C<8% (75.9%), compared to 67.7% for those with A1C≥8% ($p=0.05$). Regardless of location and the glycemic status, the majority of participants met the recommendation for saturated fats, cholesterol, and dietary fiber (Table 13).

There were significant ($p<0.001$) differences in total energy intake based on glycemic status category;were energy intakes higher among participants with A1C≥8% compared to those with A1C<8% (2278.3±464.2 vs.1949.7±334.6 kcal/day) (Table 14). Likewise, significantly ($p<0.001$) higher CHO intake and percentage of CHO of the total energy were observed among participants with A1C≥8% (CHO=466.6±112.1 g/day; percentage of CHO of total energy= 79.5±7.3%).

Table 13: Macronutrient, fruit, vegetable and sodium intake based on WHO/FAO nutrition guidelines for chronic diseases

		Location			Glycemic Status		
	Overall	Urban (n=288) n (%)	Semi-urban (n=140) n (%)	p-value	A1C<8% (n=170) n (%)	A1C ≥8% (n=258) n (%)	p-value
CHO % of total energy/day				0.122			<0.001
≤54.99%	28 (6.5)	18 (6.2)	10 (7.1)		27 (15.9)	1 (0.4)	
55-75%	145 (33.9)	107 (37.2)	38 (27.1)		79 (46.5)	66 (25.6)	
≥75.01%	255 (59.6)	163 (56.6)	92 (65.7)		64 (37.7)	191 (74.0)	
Protein % of total energy/day				0.253			0.002
≤9.99	34 (8.0)	21 (7.3)	13 (9.5)		22 (13.0)	12 (4.7)	
10-15%	254 (59.8)	167 (58.0)	87 (63.5)		87 (51.5)	167 (65.2)	
>15.01%	137 (32.2)	100 (34.7)	37 (27.0)		60 (35.5)	77 (30.1)	
Fat % of total energy/day				0.176			0.413
≤14.99	246 (57.5)	157 (54.5)	89 (63.6)		97 (57.1)	149 (57.8)	
15-30%	172 (40.2)	123 (42.7)	49 (35.0)		67 (39.4)	105 (40.7)	
≥30.01%	10 (2.3)	8 (2.8)	2 (1.4)		6 (3.5)	4 (1.6)	
PUFA % of the total energy/day				0.690			0.745
≤5.99	365 (85.5)	244 (84.7)	122 (87.1)		147 (87.1)	218 (84.5)	
6-10%	57 (13.4)	41 (14.2)	16 (11.4)		20 (11.8)	37 (14.3)	
≥10.01%	5 (1.2)	3 (1.0)	2 (1.4)		2 (1.2)	3 (1.2)	
Saturated fat % of the total energy/day				0.727			0.351
<10%	423 (98.8)	285 (99.0)	138 (98.6)		167 (98.2)	256 (99.2)	
≥10.01%	5 (1.2)	3 (1.0)	2 (1.4)		3 (1.8)	2 (0.8)	
Cholesterol (mg/day)				0.038			0.155
<300 mg	414 (96.7)	275 (95.5)	139 (99.3)		167 (98.2)	247 (95.7)	
>300.01 mg	14 (3.3)	13 (4.5)	1 (0.7)		3 (1.8)	11 (4.3)	
Fruits and vegetables (g/day)				0.018			0.510
≤399.99 g	378 (88.3)	247 (85.8)	131 (93.6)		148 (87.1)	230 (89.2)	
≥400.00 g	50 (11.7)	41 (14.2)	9 (6.4)		22 (12.9)	28 (10.9)	
Total dietary fiber (g/day)				0.649			0.004
<24.99 g	18 (4.2)	13 (4.5)	5 (3.6)		13 (7.7)	5 (1.9)	
>25 g	410 (95.8)	275 (95.5)	135 (96.4)		157 (92.4)	253 (98.1)	
Sodium (mg/day)				0.687			0.050
<2000 mg	302 (70.6)	205 (71.2)	97 (69.3)		129 (75.9)	173 (67.7)	
≥2000.01 mg	126 (29.4)	83 (28.8)	43 (30.7)		41 (24.1)	85 (32.0)	

CHO= carbohydrate and PUFA=polyunsaturated fatty acids

3. Mean macronutrient, fruit and vegetable intakes and dietary quality scores

There were significant ($p<0.001$) differences in the mean protein intake relative to A1C status; higher when A1C≥8% compared to A1C<8% (79.5±7.3 vs. 69.4±11.9 g/day respectively). However, the percentage of protein of total energy was not significantly based on glycemic status. The mean fat intake was also significantly ($p<0.001$) higher among those with A1C≥8% (40.3±20.1 g/day), but there were no significant differences in the percentage contribution of fat to total energy. The mean total PUFA intake was significantly higher among participants with A1C≥8% compared to those with A1C<8% (12.6±6.8 vs. 9.1±4.2 g/day respectively), although there were no significant differences with regard to PUFA percent of the total energy. Additionally, the mean saturated fat intake was significantly ($p<0.01$) higher among those with A1C≤8% than A1C<8%, but saturated fat percent of total energy did not differ. The total dietary fiber intake was also significantly ($p<0.001$) higher among participants with A1C≥8%, even though in both glycemic status categories, the dietary fiber intake was above the recommendation of >25 g/day . Based on glycemic status category, there were no significant differences for mean intakes of cholesterol and total fruits and vegetables (Table 14).

Based on the location of residence of the participants, the CHO percent of total energy was not significant different between the urban (75.1±10.3%) and semi-urban (75.9±11.4%) participants. The contribution of protein to total energy was significantly higher in urban (14.2±3.4%) than semi-urban (13.4±3.2%). However, the mean total cholesterol (107.0±76.2 vs. 90.1±58.7 mg/day respectively; $p<0.05$) and total fruit and vegetable (265.5±144.0 vs. 233.1±108.7 g/day; ($p<0.05$) intakes were significantly higher in urban than semi-urban participants respectively (Table 14).

The mean preventive diet scores based on the WHO guidelines for prevention of chronic diseases was 5.2±1.2 in overall. There were no significant differences based on location and glycemic status (Table 14). The IDDS, overall, was 4.9±1.4, an indication of moderate dietary diversity, but significantly ($p<0.001$) higher among the urban than semi-urban (5.0±1.4 vs. 4.5±1.3) participants, even though there were no significant differences based on glycemic status. Further analysis of the IDDS categories showed that an overall 54.0% of the participants were within the average dietary diversity scores. Among the urban participants, 50.0% had moderate and 37.2% had high dietary diversity, while in the semi-urban area 62.1% were within the moderate and 19.3% in the high dietary diversity categories. The differences were significant $p<0.001$. Based on glycemic status, the majority had moderate dietary diversity; participants with A1C<8% (54.1%) and A1C≥8% (53.9%) had moderate dietary diversity, but no significant differences were observed (Table 14).

Table 14: Mean macronutrient, fruit and vegetable intakes and dietary quality scores by location and glycemic status

		Location			Glycemic status		
Variables	Overall (n=428)	Urban (n=288) Mean±SD	Semi-urban (n=140) mean±SD	p-value	A1C <8% (n=170) mean±SD	A1C ≥8% (n=258) mean±SD	p-value
Total energy (Kcal/day)	2143.1±445.8	2149.2±437.8	2130.5±463.5	0.690	1949.8±334.6	2278.3±464.2	<0.001
Total CHO (g/day)	411.8±118.3	409.2±113.3	417.2±128.2	0.510	329.1±69.2	466.6±112.1	<0.001
CHO % of energy	75.4±10.7	75.1±10.3	75.9±11.4	0.486	69.4±11.9	79.5±7.3	<0.001
Total protein (g/day)	76.7±28.9	77.2±25.5	74.5±32.6	0.292	69.6±30.2	81.3±27.0	<0.001
Protein % of energy	13.9±3.8	14.2±3.4	13.4±3.2	0.013	14.3±5.2	13.8±3.0	0.349
Total fat (g/day)	36.8±18.7	37.8±19.2	34.9±17.6	0.139	31.5±14.9	40.3±20.1	<0.001
Fat % of energy	15.1±5.7	15.4±5.8	14.3±5.4	0.065	14.9±6.4	15.1±5.4	0.719
Total PUFA (g/day)	11.2±6.1	11.3±5.8	11.0±6.8	0.654	9.1±4.2	12.6±6.8	<0.001
PUFA % of energy	4.6±1.6	4.6±1.7	4.5±1.4	0.506	4.5±1.5	4.6±1.6	0.475
Total saturated fat (g/day)	8.2±5.3	8.4±5.3	7.9±5.1	0.378	7.1±4.6	8.8±5.6	0.004
Saturated fat % of energy	3.4±1.9	3.5±1.9	3.3±1.8	0.505	3.6±2.0	3.3±1.8	0.081
Total cholesterol (mg/day)	101.6±71.5	107.0±76.2	90.1±58.7	0.038	101.0±67.3	102.1±74.5	0.889
Total dietary fiber (g/day)	37.0±7.5	37.3±7.5	36.3±7.6	0.221	34.2±7.1	39.6±7.0	<0.001
Total fruits and vegetable (g/day)	254.9±134.2	265.5±144.0	233.1±108.7	0.019	259.5±138.4	251.8±131.5	0.561
Dietary quality indicator							
Preventive diet scores	5.2±1.2	5.2±1.3	5.1±1.2	0.168	5.2±1.3	5.2±1.2	0.620
Individual dietary diversity scores (IDDS)	4.9±1.4	5.0±1.4	4.5±1.3	<0.001	5.0±1.4	4.8±1.4	0.205
Dietary diversity category				<0.001			0.655
Low dietary diversity	63 (14.7)	37 (12.9)	26 (18.6)		12 (12.9)	41 (15.9)	
Moderate dietary diversity	231 (54.0)	144 (50.0)	87 (62.1)		92 (54.1)	139 (53.9)	
High dietary diversity	134 (31.3)	107 (37.2)	27 (19.3)		56 (32.9)	78 (30.2)	

4. Meal frequency and reasons for not following dietary recommendations

Among participants with A1C≤8%, 53.1% had ≤three meals/day and 46.9% had three meals and a snack (p<0.001); 69.4% did not follow dietary recommendations (p<0.05) (Table 4). The reasons for not complying among those with A1C≥8% were: the high cost of food (67.0%), not getting an adequate education on what to eat (51.4%), food prepared at home not suitable for the conditions (41.3%), difficulty choosing food during functions/travel/work and dining out (40.8%), and seasonality of food (39.7%) (Table 15).

Table 15: Proportion of participants adhering to dietary recommendations

Variable		A1C<8% (n=170) n (%)	A1C≥8% (n=258) n (%)	p-value
Adherence to dietary recommendations				0.034
	Yes	69 (40.6)	79 (30.6)	
	No	101 (59.4)	179 (69.4)	
Number of meals per day				
	≤ 3 meals	59 (34.7)	137 (53.1)	<0.001
	3 meals and a snack	111 (65.3)	121 (46.9)	
Reasons for not following diet recommendations				
High cost of food				0.826
	Yes	69 (68.3)	120 (67.0)	
	No	32 (31.7)	59 (33.0)	
Not adequate educated on what to eat				0.058
	Yes	40 (39.6)	92 (51.4)	
	No	61 (60.3)	87 (48.6)	
Food prepared at home not suitable for disease condition				0.495
	Yes	46 (45.5)	74 (41.3)	
	No	55 (54.5)	105 (58.7)	
Difficulty to choose food during functions/work/travel & dining				0.650
	Yes	44 (43.6)	73 (40.9)	
	No	57 (56.4)	106 (59.2)	
Seasonality of fruits and vegetables				0.524
	Yes	44 (43.6)	71 (39.7)	
	No	57 (56.4)	108 (60.3)	

5. Food group consumption

The mean number of food groups consumed (Table 16) varied by location and glycemic status. Consumption of legumes and nuts ($p<0.05$) and fruits ($p<0.05$) were higher among the urban participants. Based on glycemic status, those with A1C≥8% had a significantly higher intake of cereal ($p<0.001$), roots and tubers ($p<0.05$) and sweets and sugary foods ($p<0.05$). The top six foods consumed overall in a significant amount at least above 100 g/day in ascending order were: fruits, milk and milk products, vegetables, sweets and sugary foods, roots and tubers, and cereals (Table 16).

Table 16: Mean food group consumption by location and glycemic status

		Location			Glycemic Status		
Variables	**Overall**	Urban (n=288) Mean±SD	Semi-urban (n=140) Mean±SD	p-value	A1C <8% (n=170) Mean±SD	A1C≥8% (n=258) Mean±SD	p-value
Cereals (g/day)	1568.5±505.3	1540.2±480.5	1626.8±550.1	0.096	1280.6±353.7	1758.2±501.0	<0.001
Roots and tubers (g/day)	193.5±126.6	195.8±127.5	188.7±125.2	0.667	171.6±99.3	207.2±139.5	0.023
Meat and poultry (g/day)	72.9±47.8	72.0±46.8	75.3±50.8	0.663	76.9±47.6	70.4±47.9	0.343
Eggs (g/day)	57.9±30.8	59.9±31.0	51.0±30.4	0.362	62.8±26.6	54.8±33.1	0.342
Milk and milk products (g/day)	156.2±82.3	153.0±79.2	161.4±88.5	0.679	172.2±89.0	144.8±76.2	0.165
Fish (g/day)	60.9±42.9	61.1±43.4	60.3±42.1	0.882	64.6±47.6	58.2±39.2	0.203
Legumes and nuts (g/day)	82.5±61.4	87.6±65.3	72.2±51.6	0.039	78.6±58.6	85.0±63.2	0.382
Fats and oils (g/day)	8.5±9.5	9.4±10.3	4.5±2.7	0.313	7.3±4.0	9.3±12.1	0.595
Vegetables (g/day)	177.1±100.0	177.5±100.0	176.1±100.4	0.891	174.9±94.9	178.5±103.9	0.719
Sweets, sugary foods and beverages (g/day)	181.5±123.7	184.8±126.2	172.3±112.6	0.602	152.8±76.0	204.2±147.8	0.014
Fruits (g/day)	120.4±79.6	127.0±84.9	104.8±63.5	0.047	127.6±91.3	115.2±70.1	0.233

6. Association of dietary factors with unacceptable A1C

A binary logistic regression controlled for age, gender, education status, location, monthly food expenditure per capita, treatment type, duration of diabetes, BMI, physical activity, food security status and energy intake (Table 17). The odds of having A1C≥8% significantly increased with an increase in CHO percent of total energy (OR (odds ratio)=1.20; CI: 1.14-1.27; $p<0.001$) overall, urban (OR=1.19; CI:1.11-1.23, $p<0.001$) and semi-urban (OR=1.33; CI=1.14-1.56; $p<0.001$) participants. Having ≤three meals/day in comparison with three meals and a snack/day significantly increased the risk of A1C≥8% in the overall model (OR=2.25; CI: 1.17-4.30; $p<0.05$) and among semi-urban participants (OR=5.50; CI: 1.17-25.91; $p<0.05$), but this finding was not significant for urban (OR=1.91; CI=0.88-4.12; $p=0.102$) participants. Additionally, for IDDS and the preventive diet score, the percentage of protein and fat to total energy and mean PUFA, fruit and vegetable intakes as well as following dietary recommendations did not show significant findings (Table 17).

Table 17: Dietary factors associated with unacceptable glycemic status

	Overall		Urban		Semi-urban	
	OR (95% C.I)	p-value	OR (95% CI)	p- value	OR (95% CI)	p value
Age	0.96 (0.93-1.00)	0.029	0.95 (0.91-0.99)	0.028	1.03 (0.94-1.13)	0.564
Gender						
Female	2.09 (0.99-4.41)	0.052	3.03 (1.15-7.97)	0.025	3.08 (0.57-16.49)	0.189
Male (ref)						
Education level						
≤Primary	0.92 (0.48-1.78)	0.807	1.22 (0.55-2.70)	0.619	0.18 (0.03-1.14)	0.068
≥Secondary (ref)						
Location						
Semi-urban	0.69 (0.34-1.39)	0.304	-		-	
Urban (ref)						
Monthly food						
expenditure/capita	0.94 (0.45-1.96)	0.872	0.77 (0.34-1.78)	0.542	1.25 (0.15-10.38)	0.837
≤12000MKW						
≥12001MKW (ref)						
Treatment type						
Oral hypoglycemic agent	1.86 (0.56-6.20)	0.310	2.34 (0.65-8.46)	0.196	0.0 (0.00-	0.999
Insulin (ref)						
Duration of diabetes (yrs.)	1.11 (1.02-1.21)	0.011	1.12 (1.01-1.23)	0.025	1.21 (0.98-1.47)	0.071
Physical activity level	0.78 (0.68-0.89)	<0.001	0.77 (0.65-0.92)	0.004	0.67 (0.50-0.91)	0.010
BMI	0.93 (0.88-0.98)	0.012	0.92 (0.86-0.98)	0.012	0.86 (0.74-1.01)	0.068

Table 17 (cont'd): Dietary factors associated with unacceptable glycemic status

Dietary factors	Overall OR (95% CI)	p-value	Urban OR (95% CI)	p-value	Semi-urban OR (95% CI)	p-value
IDD score	0.94 (0.75-1.17)	0.554	0.82 (0.62-1.07)	0.142	1.69 (0.92-3.11)	0.092
Preventive diet score	0.94 (0.68-1.30)	0.706	0.92 (0.63-1.36)	0.690	0.50 (0.20-1.24)	0.134
Total energy (kcal/day)	1.00 (1.00-1.00)	<0.001	1.00 (1.00-1.00)	0.002	1.01 (1.00-1.01)	0.001
CHO % of energy/day	1.20 (1.14-1.27)	<0.001	1.19 (1.11-1.27)	<0.001	1.33 (1.14-1.56)	<0.001
Protein % of energy/day	1.11 (1.00-1.24)	0.062	1.09 (0.95-1.24)	0.233	1.16 (0.93-1.44)	0.190
Fat % of energy/day	1.09 (0.99-1.21)	0.074	1.06 (0.94-1.19)	0.345	1.27 (0.99-1.63)	0.065
PUFA (g/day)	1.06 (0.94-1.20)	0.333	1.11 (0.96-1.28)	0.175	0.97 (0.72-1.30)	0.834
Amount of fruits and vegetables (g/day)	1.00 (1.00-1.00)	0.111	1.00 (0.99-1.00)	0.063	1.01 (1.00-1.01)	0.215
HFIAS score	1.12 (1.04-1.18)	0.002	1.10 (1.02-1.20)	0.019	1.21 (1.05-1.40)	0.010
Number of meals						
≤ 3 meals/day	2.25 (1.17-4.30)	0.015	1.91 (0.88-4.12)	0.102	5.50 (1.17-25.91)	0.031
3 meals and a snack (ref)						
Follow diet recommendation						
Yes	1.05 (0.54-2.00)	0.902	1.01 (0.47-2.18)	0.975	3.86 (0.60-24.79)	0.155
No (ref)						

Part 2 — Food security

About 22.7% (n=97) of the participants were food secure, 36.9% (n=158) mildly food insecure and 40.4% (n=173) moderately to severely food insecure.

1. Socio-demographic and economic characteristics by food insecurity status

Education status significantly ($p<0.001$) impacted the food security status of the participants; food secure participants spent 10.4±3.9 years in school while those who were moderately to severely food insecure had less schooling (8.0±4.3 years). A significant ($p<0.05$) proportion of participants who were moderately to severely food insecure had no occupation (44.2%) and tended to be small-scale farmers (49.6%). The majority of the participants ($p<0.001$) who were mildly and moderately to severely food insecure had a monthly income of ≤30,330.99 MKW (36.5-46.7%) and 30,340-122,170.99 MKW (36.2-42.7%) respectively. A little more than half (55.6%) of the participants from the semi-urban area were moderately-severely food insecure, and 39.2% of those from the urban area were mildly food insecure ($p<0.01$). About 55.6% of the participants who were moderately to severely food insecure had per a capita monthly food expenditure of ≤2,500MKW (Table 18).

2. Food-related factors by food insecurity status

Individual dietary diversity scores (IDDS) significantly ($p<0.05$) varied based on food security status. Food secure participants had mean IDDS of 5.2±1.3; scores for those mildly food insecure were 4.9±1.3; and scores for those moderately to severely food-insecure were 4.7±1.4. The primary market for the majority (93.9%) of the participants was the traditional open market. Additionally, distance to the primary market was not significantly different based on food security status. The secondary market varied based on food security status, 34.6-48.9% of the mildly to

moderately-severely food insecure participants, considered small-grocery shops as their secondary market, while 33.3-39.7% of food secure and mildly food insecure indicated that supermarkets were their secondary markets. Over half (54.3%) of the semi-urban participants considered small-grocery shops as the secondary market, and 33.0% of the urban participants considered, supermarkets as their secondary market. The two primary sources of food for household consumption were purchases (96.3%) and own production (79.0%). However, there were no significant differences with regard to food sources relative to food security status (Table 18).

Table 18: Characteristics of the participants by food security status

Variable	Food Secure (n=97; 22.66%)	Mildly food insecure (n=158; 36.92%)	Moderately-severely food insecure (n=173; 40.42%)	p value
	N (%);mean±SD	n (%); mean±SD	n (%); mean±SD	
Demographic and economic factors				
Age in yrs.	54.8±8.8	53.9±9.7	53.2±9.3	0.403
Gender				0.244
Male	23 (17.6)	52 (39.7)	56 (42.8)	
Female	74 (24.9)	106 (35.7)	117 (39.4)	
Marital status				0.908
Married	73 (22.2)	121 (36.8)	135 (41.0)	
Divorced/widowed	22 (22.9)	37 (38.5)	37 (38.5)	
Number of years in school	10.4±3.9	9.0±3.9	8.0±4.3	<0.001
Occupation level				0.046
No occupation	23 (26.7)	25 (29.1)	38 (44.2)	
Small-scale farming	18 (15.4)	41 (35.0)	58 (49.6)	
Small-scale business	21 (21.0)	43 (43.0)	36 (36.0)	
Professional/retired	35 (28.0)	49 (39.2)	41 (32.8)	
Household income/month				<0.001
≤30,330.99 MKW	18 (14.3)	46 (36.5)	62 (49.7)	
30,340-122,170.99 MKW	42 (21.1)	72 (36.2)	85 (42.7)	
≥122,180.00 MKW	37 (35.9)	40 (38.8)	26 (25.2)	
Location				0.001
Urban	76 (26.4)	113 (39.2)	99 (34.4)	
Semi-urban	21 (15.0)	45 (32.1)	74 (52.9)	
Monthly food expenditure/capita				<0.001
≤2,500.99MKW	15 (11.9)	41 (32.5)	70 (55.6)	
2,501-12,000.99MKW	45 (24.0)	69 (35.2)	82 (41.8)	
≥12001	37 (34.9)	48 (45.3)	21 (19.8)	
Household size	5.5±2.3	5.6±2.0	5.7±2.1	0.591
Food-related factors				
IDDS	5.2±1.3	4.9±1.3	4.7±1.4	0.011
Primary market				
Traditional open market: Yes	89 (22.1)	147 (36.6)	166 (41.3)	0.322
No	8 (30.8)	11(42.3)	7 (26.9)	
Distance to primary market <5km	76 (23.5)	120 (37.0)	128 (39.5)	
≥5km	21 (20.2)	38 (36.5)	45 (43.3)	0.722
Secondary market				
Small-grocery store: Yes	31 (16.5)	65 (34.6)	92 (48.9)	0.002
No	66 (27.5)	93 (38.8)	81 (33.8)	
Supermarkets: Yes	42 (33.3)	50 (39.7)	34 (27.0)	<0.001
No	55 (18.2)	93 (38.8)	139 (46.0)	
Food sources:				
Own production for consumption:				
Yes	75 (22.2)	131 (38.8)	132 (39.1)	0.344
No	22 (24.4)	27 (30.0)	41 (45.6)	
Purchases Yes	90 (21.8)	154 (37.8)	168 (40.8)	0.120
No	7 (43.8)	4(25.0)	5 (31.3)	
Gifts from relatives Yes	17 (34.0)	12 (24.0)	21 (42.0)	0.055
No	80 (21.2)	146 (38.6)	152 (40.2)	
Health-related factors				
Average waist circumference	98.4±12.2	97.2±13.8	94.7±13.9	0.078
Duration of diabetes in yrs.	6.3±4.6	6.1±4.4	5.7±4.3	0.501
A1C (%)	8.9±2.8	9.0±2.8	9.7±2.8	0.067

3. Food purchase from primary and secondary market and own production for consumption

Further analysis elucidated which foods were purchased from primary and secondary markets, and the foods were grouped into foods groups (Table 19). The typical foods purchased from the primary markets in descending order were vegetables (86.2%), fish (72.4%), meat (56.1%), pulses, legumes and nuts (41.1%), fruits (39.5%) and roots and tubers (33.4%). The foods purchased from the secondary markets, which were dominated by the small grocery shops were; sweets and sugary foods (sweetened beverages) (55.1%), spices/condiments/alcoholic beverages (52.8%), cereals (48.4%) especially bread, scones and rice, oils and fats (42. 3%), meat and poultry (22.7%) and milk and milk product (21.3%). Although some participants produced food for consumption, it was mainly two food groups: cereals (79.0%) especially maize, and pulses, legumes and nuts (46.5%) (Table 19).

Table 19: Food purchase from the primary and secondary markets and own production for consumption

		Primary market	Secondary market	Own food production
Food groups		n (%)	n (%)	n (%)
Cereals (maize and maize products, rice, wheat products and other grains)	Yes	138 (29.9)	**207 (48.4)**	**338 (79.0)**
	No	300 (70.1)	221 (51.6)	90 (20.0)
Vegetables (All kinds of vegetables)	Yes	**369 (86.2)**	39 (9.1)	70 (16.4)
	No	59 (13.8)	389 (93.2)	357 (83.6)
Roots and tubers (sweet potatoes, cassava potatoes, yam, etc.)	Yes	143 **(33.4)**	29 (6.8)	54 (12.6)
	No	285 (66.6)	399 (93.2)	374 (87.4)
Fruits (all kinds of fruits)	Yes	**169 (39.5)**	32 (7.5)	20 (4.7)
	No	259 (60.5)	396 (92.5)	408 (95.3)
Meat (chicken, organ meat, flesh meat)	Yes	**240 (56.1)**	97 (22.7)	44 (10.3)
	No	188 (43.9)	331 (77.3)	384 (89.7)
Eggs (chicken, ducks, guinea hen)	Yes	27 **(6.3)**	14 (3.3)	19 (4.4)
	No	401 (93.7)	414 (96.7)	409 (95.6)
Fish and seed foods (fresh or dried fish)	Yes	**310 (72.4)**	61 (14.3)	0.00
	No	118 (27.6)	367 (85.8)	0.00
Pulse, legumes and nuts (beans, nuts, cowpeas)	Yes	**176 (41.1)**	46 (10.8)	**119 (46.5)**
	No	252 (58.9)	382 (89.3)	229 (53.5)
Milk and milk product (milk, yogurt)	Yes	17 (4.0)	**91 (21.3)**	0.00
	No	411 (96.0)	337 (78.7)	0.00
Oils and fats (cooking oil, margarine, butter)	Yes	64 (15.0)	**181 (42.3)**	0.00
	No	364 (85.1)	247 (57.7)	0.00
Sweets (sugar, honey, sweetened soda or sugary foods)	Yes	71 (16.6)	**236 (55.1)**	0.00
	No	357 (83.4)	192 (44.9)	0.00
Spices/condiments/beverages (salt, sauce, tea, coffee, alcoholic beverages)	Yes	84 (19.6)	**226 (52.8)**	0.00
	No	344 (80.4)	202 (47.2)	0.00

Proportion of participants purchasing food from primary and secondary market by location

Type of market		Urban	Semi-urban	p-value
Primary market: traditional open market	Yes	272 (94.4)	130 (92.9)	0.519
	No	16 (5.6)	10 (7.1)	
Secondary market				
Small grocery shop	Yes	124 (43.1)	76 (54.3)	0.603
	No	164 (56.9)	64 (45.7)	
Supermarkets	Yes	95 (33.0)	31 (22.1)	0.021
	No	193 (67.0)	109 (77.9)	

4. Health-related factors by food security status

The average waist circumference and duration of diabetes did not differ by food security status. The mean A1C status of food secure was 8.9%, mildly food insecure (9.0%) and moderately to severely food insecure (9.7%) and all were above the recommended glycemic target A1C<8% (Table 18). In overall, the mean HFIAS was significantly ($p<0.01$) higher among participants with A1C≥8% (7.3±5.7) compared to A1C<8% (5.6±4.9) (Table 20). Similar findings were observed among urban and semi-urban participants. Moderately to severely food-insecure participants with A1C≥8% had significantly ($p<0.05$) higher HFIAS scores in the overall (Table 20).

Table 20: Household food insecurity access scale scores by A1C status and location

	Variable	A1C<8% Mean ± SD (n)	A1C≥8% Mean ± SD (n)	P value
Overall (n=428)				
	HFIA score (range 0-27)	5.6±4.9 (170)	7.3±5.7 (258)	0.002
	Mildly food insecure	4.3±1.7 (71)	4.9±1.8 (87)	0.072
	Moderately-severe food insecure	11.3±3.4 (57)	12.6±3.6 (116)	0.023
Urban (n=288)				
	HFIA score (range: 0-27)	5.2±4.6 (114)	6.5±5.3 (174)	0.027
	Mildly food insecure	4.6±1.8 (47)	4.9±1.8 (66)	0.291
	Moderately-severe food insecure	11.1±2.8 (33)	12.2±3.1 (66)	0.091
Semi-urban (n=140)				
	HFIA score (range0-27)	6.6±5.3 (56)	9.0±6.2 (84)	0.021
	Mildly food insecure	3.9±1.7 (24)	4.7±1.9 (21)	0.169
	Moderately-severe food insecure	11.6±4.0 (24)	13.1±4.1 (50)	0.127

5. Factors associated with HFIAS

Multivariate linear regression (Table 21) showed that demographic and economic characteristics such as monthly household income (β=-0.96, SE=0.40, p<0.05), monthly food expenditure per capita (β=-1.09, SE=0.43, p<0.05) and number of years in school (β=-0.16, SE=0.07, p<0.05) were negatively associated with HFIAS, whereas residing in the semi-urban area (β=1.94, SE=0.59, p<0.01) was positively associated with HFIAS. The IDD score (β=-0.48, SE=0.20, p<0.05) and own food production for consumption (β=-1.76, SE=0.65, p<0.01) were also negatively associated with HFIAS, while A1C (β=0.24, SE=0.09, p<0.05) was positively associated with HFIAS (Table 21).

Table 21: Multiple linear regression model assessing factors associated with household food insecurity access scale score

Variable	B	SE	p-value
Demographic and economic factors			
Age in yrs.	-0.03	0.03	0.380
Gender: Female	-0.50	0.60	0.403
Marital status: Married	0.66	0.67	0.328
Number of years in school	-0.16	0.07	0.019
Household size	0.24	0.13	0.073
Monthly food expenditure per capita	-1.09	0.42	0.010
Monthly household income	-0.96	0.40	0.017
Location: Semi-urban	1.94	0.59	0.001
Food-related factors			
Individual dietary diversity score (IDDS)	-0.48	0.20	0.015
Distance to the primary market >5km	-0.24	0.60	0.689
Own food production for consumption	-1.76	0.65	0.007
Health-related factors			
Glycosylated hemoglobin (A1C)	0.24	0.09	0.011
Average waist circumference	0.03	0.02	0.145
	R^2=0.202		

E. Discussion

1. Dietary intakes

The diet quality of patients with T2DM evaluated using IDDS and preventive diet score did not differ among those with A1C<8% vs. A1C≥8%. Our findings are supported by a study done in Uganda among newly diagnosed patients with T2DM, where high intake of CHO was also reported in their diets (kcal=1960/day; CHO=73%, protein=12.6% and fat =14.4% of total energy) [109]. Other studies within Africa also show a high intake of CHO intake among patients with diabetes [31, 84]. The primary sources of CHO consumed in a significant amount were cereals, roots and tubers and sweet/sugary foods, especially participants with A1C≥8%. Similarly, in South Africa and Tanzania, maize products, rice, sorghum, bread and plantains were the primary sources of CHO in diets of patients with diabetes [31, 192]. The greater the percent of CHO of the total energy (kcal)/day the lower the probability of achieving the recommended A1C<8% target, similar to other studies [193]. Therefore, a diet disproportinately high in CHO poses a risk for associated diabetes-related morbidity and mortality. High CHO in the diet may escalate A1C because of insulin resistance in T2DM [48, 194]. In systematic reviews, a diet low in CHO, even for short period of time was found to improve A1C even for short period of time [194-196]. In a two-year randomized control trial, a diet low in CHO (CHO=45%: protein=18%: fat=33% of the total energy) improved A1C of patients withT2DM [197], while in another study, A1C improved and was stable among obese patients with T2DM who followed a low CHO diet (CHO= 20%; fat=50%; and protein=30% of total energy) for 44 months [198]. Therefore, providing appropriate nutrition education that focese on a healthy balanced diet emphasizing portion size control and CHO counting without altering cultural food

preferences would be benefit patients with T2DM, because the amount of CHO intake is paramount for the glycemic outcome.

Interestingly for the majority of study participants fiber intake was in accordance with WHO/FAO nutrition recommendation for chronic disease prevention of ≥25 g/day regardless of the glycemic status. This is likely because the diet is primarly comprises of whole maize products such as whole maize thick porridge (*nsima ya mgaiwa*) served with legumes and vegetables, which are high in fiber content [163]. In countries like Malawi, Kenya and Uganda dietary fiber intake has been reported to be as high as 50 g/day [199], due to the diet composition. However, in contrast, data from other studies in Africa, showed that fiber intake was low in patients with diabetes in South Africa and Ghana [31, 84]. The differences may be attributed to the food sources, diet composition and extent of processing before consumption, e.g refined maize product.

Previous studies have indicated that dietary fatty acids such as saturated fats may contribute to the progression of insulin resistance which may in turn impact clinical glycemic target outcomes [200, 201]. In the current study, most of the participants met the WHO/FAO requirement for saturated fatty acids (<10% of total energy/day) and cholesterol (<300 mg/day) similar to other studies [31, 109, 202]. However, only few met PUFA requirements. In general, the fat content of the diet was low to moderate, providing an average 15.4% of the total energy. Therefore, consuming locally available food low in saturated fat and high in polyunsaturated fats should be promoted and encouraged for T2DM in Malawi.

Vegetables and fruit are important components of a healthy diet, and have been reported in meta-analyses and systematic reviews to positively influence have health effects on the prevention and management of T2DM [203-205]. For example, increased vegetable and fruit

intake/day had beneficial effects on the A1C [206-208] and cardiovascular risks in T2DM [206]. However, fruit and vegetable intake was below the required target of >400 g/day in all participants regardless of A1C status. A study conducted the WHO and Ministry of Health also indicated that fruit intake was very low among all Malawians [13]. A previous study in Ireland also found that among patients with T2DM, intake of fruit and vegetables was below the recommendation by WHO/FAO of >400 g/day [157]. Data from the Prospective Urban Rural Epidemiology (PURE) study also found that consumption of fruit and vegetables was low in low-income countries globally [209]. In the current study, participants consumed green leafy vegetables and fruit, but quantities were insufficient to meet requirements. The availability and accessibility of fruits and vegetables in Malawi depends on the seasonality, which would therefore impact intake. Therefore, when providing nutrition education this target population, emphasis should be on increasing quantity and variety of low-CHO fruit and vegetables.

Small and frequent meals including snacks are part of the nutrition recommendations for management of T2DM [165]. Participants who had ≤three meals/day were at increased risk of having elevated A1C≥8%, and the majority did not comply with the dietary recommendations. The reasons for not following dieatry recommedations in the current study included: cost of food, inadquate education on what to eat and seasonality of the fruits and vegetables. Similar findings were also reported by studies in Ethiopia and South Africa that dietary recommendation compliance in patients with T2DM was impacted by food cost and availability and nutrition knowledge of the patients and the health workers [31, 110, 210]. Meal irregularities have been reported to impact cardiometabolic health outcomes such as insulin sensitivity and fasting blood glucose [211-213]. Previous studies found that skipping meals especially breakfast and late evening meals in T2DM patients was associated with high A1C [214], postprandial

hyperglycemia and impaired insulin response [215]. Therefore, regularity and distrubution of meals and snacks over the course of the day is an important consideration. Additionally, further study is warranted to enhance our understand of how specific meal patterns are associated with A1C in Malawi, because the likelihood of disorderly meal patterns is high in low income population due to limited resources coupled with food insecurity.

2. Food security

Although not much emphasis has been placed on food insecurity concerning NCDs such as T2DM in Malawi, we found that food insecurity was mild in 36.9% of the participants and moderate to severe in 40.4%. The urban participants experienced food insecurity mildly, and the moderate to severe of food insecurity was more prevalent in the semi-urban area, clearly indicating that food insecurity exists in patients with T2DM in both urban and semi-urban areas. A possible explanation for the high food insecurity in this study is the season when the data was collected, considering season impact on food availability, accessibility, and affordability in Malawi. Our data was collected during the beginning of dry season when food availability and variety is typically limited. Furthermore, the majority of the participants were from urban/semi-urban low-income families, which also affected affordability. Our findings are supported by a study in Kenya, which reported that food insecurity was prevalent in 32% patients with diabetes [216]. Furthermore, studies conducted in the U.S among low-income population also found that food insecurity was common in T2DM patients [121, 125, 126, 217-219].

The education level of the participants was associated with HFIAS scores, indicating that participants who had more years of formal education were more economically stable and had greater food purchasing power. Moreover, 44.2% of those who had no occupation and 49.6% of small-scale farmers were moderately to severely food insecure compared to those who were

engaged in small-scale business or employed. This implies that type of employment among patients with T2DM may help to alleviate food insecurity problems in both urban and semi-urban low-income populations. Furthermore, household income and food expenditure per capita also impacted the HFIAS score among patients with T2DM, which could also potentially affect the diversity of the diet. Considering that for over 90% of the participants in the current study, food purchase was the predominant source of food acquisition for the household. Therefore, income level may influence the kind of food purchased (especially cheap unhealthy food), and compromise the quality of the diet, and food expenditure per capita in food insecure households [9]. Our findings are congruent with previous studies which showed that demographic and economic characteristics are predictors of household food insecurity [121, 126, 127, 129, 220].

Food insecurity status of the patients affected the diversity of the diet, as noted that HFIAS score was negatively associated with the IDDS. Other studies also found that food insecurity was associated with low dietary diversity [9, 129, 218, 221]. Low dietary diversity compromises the nutrition quality of the diet and ultimately to undesirable health outcomes. The possible explanation for the low diversity among food insecure patients with T2DM is the food source, although a significant number indicated that they produce food for household consumption, the predominate food crops were maize and groundnuts, which may not provide enough for the total nutritional quality of the diet. As such, food access would play an essential role in diversifying the diets. The majority of the participants purchased foods such as vegetables, meat, fish and pulses, legumes and nuts from the traditional open markets, which are very common in Malawi. However, mild and moderate to severe food-insecure participants purchased from the secondary markets, which were predominately by the small grocery shops, equivalent to convenience store in the U.S. The foods purchased from the secondary markets

included sugary foods, processed wheat products, fat, and oils, etc. A study done in Malawi indicated that food insecure Malawians especially those in urban areas had inadequate access to healthy foods, and hence, a compromised diet quality [9]. It is therefore necessary to provide nutrition education in this population on healthy food choices within the context of food accessibility, purchasing power, and nutritional knowledge shortcomings. Additionally, in Malawi seasonality plays an essential role on the availability of food and since this study was done at the beginning of the dry season, food choices were likely limited. Promotion of home/community gardens to increase variety of vegetables and fruit is helpful for dietary complementation. Only 16.4% and 4.7% of the participants produced vegetables and fruit respectively for household consumption. Studies that have promoted home/community gardening in developed and developing countries have shown dietary benefits, lower expenditure on food and positive health outcomes relative to both undernutrition and diet-related chronic diseases across the lifespan [222-226].

While little has been reported on food insecurity status in relation to A1C in Malawi, our findings show food insecurity negatively impacted glycemic status. These findings suggest that, among patients with T2DM in Malawi, food insecurity may contribute to suboptimal glycemic status and consequently diabetes-related complications. The A1C of the participants was above the recommended target of <8% [165] in the majority of both food secure and food insecure participants. Our results are consistent with prior studies done in developed nations which demonstrated that food insecurity negatively impacted glycemic status [122, 217, 219, 227], although the food insecurity situations may differ from that of the developing countries. Another study in Jordan also observed that moderate to severe food insecurity worsened glycemic status in diabetes patients [126]. In low income populations such as those in the current study, glycemic

status may be further compromised due to competing priorities of the food expenses, self-management and health care costs [120].

F. Conclusions

The findings of this study indicate that diet quality assessed using IDDS and preventive diet score was not associated with A1C. However, the diet was high in CHO and consumption of CHO rich foods such as cereals, roots and tubers and sweet, sugary food, including sweetened beverages, were significantly high among those with A1C≥8%, and disproportionately low daily intakes of fruit and vegetables. Additionally, meal irregularities, especially ≤ three meals/day also negatively impacted A1C. Moreover, food insecurity is a concern in patient with T2DM both in urban and semi-urban areas and impacted and glycemic status the dietary diversity. Therefore, there is an urgent need for dietary approaches to reduce consumption of food disproportionately high in CHO. CHO counting, portion size control, meal planning and increasing in fruit and vegetables consumption are all important. Periodic food insecurity assessments should be part and parcel of diabetes education in the hospitals and clinics to better determine a patient's food challenges. Furthermore, a longitudinal study should be done across different regions in the country and seasons to examine changes in food insecurity based on location in relation to glycemic status over time. Additionally, since food purchase was the primary source of food for household consumption, a detailed study is needed to adequately address concerns of the food purchase environment such as markets and diets, and how they impact NCDs in urban, semi-urban and rural areas in Malawi.

CHAPTER 6- MANUSCRIPT 3

This chapter provides insight into the barriers and facilitators to diet and physical activity including social support as perceived by adults diagnosed with T2DM in Malawi. The results of this chapter have been summarized based on the social ecological model as it pertains to self-management of diabetes, which was the theoretical framework for this dissertation.

Title: **Perceived Barriers and Facilitators to Diet and Physical Activity Among Adults Diagnosed with Type 2 Diabetes Mellitus in Malawi**

Target journal: Health and Social Care in the Community

A. Abstract

Background: Diet and physical activity are crucial to Type 2 diabetes mellitus (T2DM) self-care management. However, socio-environmental and cultural factors can impede lifestyle behaviors, and hence T2DM management, especially in low income populations. Therefore, we aimed to qualitatively identify barriers, facilitators and support for diet and physical activity among low-income adults diagnosed with T2DM in Malawi.

Method: We purposively sampled adults (n=39; 21 females and 18 males) diagnosed with T2DM (≥40 years), from a larger clinical assessment study, conducted in urban and semi-urban public hospitals in Malawi. Four focus group discussions (female=2 and male =2) were conducted, two in each study location. The data were audio-recorded, transcribed verbatim, coded, then organized and analyzed with NVivo software to generate thematic findings.

Results: Family, friends, and health worker ties were the emergent themes that facilitated both diet and physical activity and were reported as socio-support systems. However, diabetes peer groups were noted more in urban than in semi-urban areas. Barriers to diet appropriate for T2DM included: cost and access to food; lack of knowledge on what and how much to eat;

challenges of separate preparation and purchase of food; dilemmas of what to eat during functions and travel; and, conflicting dietary information from different sources. Comorbidities and fear of public ridicule were barriers to participants being physically active.

Conclusions: Barriers, in particular, food cost and accessibility, inadequate nutrition knowledge and inconsistent dietary information influenced dietary quality and likely subsequent glycemic management. Physical activity engagement was hindered by diabetes-related comorbidities, which may have emanated from chronic hyperglycemia. Therefore, social and environmental factors should be prioritized by nutritionists, dietitians, and health workers when developing and providing nutrition and physical activity education to adults with T2DM in Malawi. This will enhance optimal glycemic status delay, ameliorate or prevent serious complications.

B. Introduction

Diabetes is a serious problem associated with morbidity, premature death, and economic challenges in both developed and developing nations. Globally, the number of adults with diabetes is expected to reach 629 million by 2045 [228]. Furthermore, a predicted 153% increase in the number of people with diabetes in Africa by 2045 (from 16 million adults in 2017 to 45 million by 2045) [228] will pose serious challenges in meeting the demand for diabetes services. Malawi is one of the countries impacted with a triple burden of malnutrition, specifically protein and calorie undernourishment, micronutrient deficiencies, and non-communicable diseases such as diabetes. The estimated prevalence of diabetes in Malawi is a concerning, 5.6% among adults aged 25-64 years [13, 14] compared to 4.4% in Africa overall [3].

Self-management of T2DM including a healthy lifestyle, especially dietary behavior and physical activity, is critical for an optimal glycemic outcome [56, 66]. Self-management encompasses the ability of the person to manage disease-related symptoms and complications, lifestyle changes, physical and psychological consequences which occur in conjunction with living with the disease [229, 230]. Optimal care of diabetes is hence a primary responsibility of the patient and family. Yet, different social and environmental factors might pose specific challenges to the management of diabetes, such as income, availability and access to healthy foods, and physical activity limitations. As such, patients with T2DM require support from family members, the communities in which they live and health system e.g. the availability of dietary and physical activity guidelines [27, 43, 46, 131]. Studies have reported seasonal food variations, income and unwillingness of family members to change eating patterns as barriers to following a diet [132-136]. Comorbidities such as loss of sight and amputations were some of the factors reported to have impacted physical activity due to suboptimal glycemia [138]. There is dearth of data in Malawi on barriers and facilitators to diet and physical activity in T2DM management as perceived by patients themselves. Qualitative assessment of issues affecting diabetes management in Malawi, especially regarding diet and physical activity as well as if and how social support is a factor, was deemed important. More specifically, understanding these culturally specific factors will help health and nutrition professionals develop interventions and education materials [136, 139] appropriate for Malawians, which can easily be rolled out at the community level. Therefore, the objective was to qualitatively assess patient/client specific barriers and facilitators to achieving dietary and physical activity needs to elucidate these issues in the target population.

C. Methods

1. Data collection

Simple descriptive characteristics such as age distribution was done to identify which age group was mostly represented from a larger clinical assessment study, conducted in urban (Kamuzu Central Hospital in Lilongwe) and semi-urban (Kasungu District Hospital in Kasungu) public hospitals in Malawi. We hence purposively sampled adults (n=39; 21 females and 18 males) diagnosed with T2DM ≥40 years, the group which was predominantly reflected among those with T2DM in the clinical study sample. Four focus group discussions (FGDs) of at least 10 participants per group (female=2 and male =2) were conducted, two in each study location. The FGDs were conducted by the primary researcher and two trained research assistants. The interview was guided by a set of questions with key elements of the socio-ecological model. All the discussions were held in the local language: *Chichewa*. The FGDs were voice recorded and field notes were taken. After each focus group, the primary researcher and two research assistants shared the notes to check the consistency of information captured. Audit trails were documented and kept by the primary researcher.

In order to clearly understand the importance of support-networks, which may act as barriers or facilitators to diet and physical activity within their socio-environment, eco-maps were developed during FGDs with the participants. These eco-maps portrayed visual/graphical representation of social support networks that patients with diabetes were exposed to through their families and communities [158-161]. The primary researcher first demonstrated how the eco-maps should be drawn and explained the use of symbols. The commonly used symbols were: strong/positive support (─), tenuous/weak support (------), stressful support (~~~~), energy flows in both direction (↔), energy flows in one direction (→) [159-161]. The symbols show the

strength of support patients with diabetes received in relation to self-management of their disease. The participants were given papers to draw their own eco-maps depending on where they perceived diet and physical activity support and resources for diabetes management.

2. Ethical approval

The Institutional Review Board at Michigan State University and National Health Research Council in the Ministry of Health in Malawi granted approval of the study. Permission to conduct research in two hospitals was also obtained. Written informed consent was obtained from each participant after explaining the aim of the study. As a way of ensuring confidentiality, each participant was assigned a unique identifier. All participants received an equivalent of $5 in in the local currency as compensation.

3. Data analysis

The discussions were tape recorded and transcribed verbatim by the researcher and research assistants after listening and re-listening to the recordings and comparing with field notes. Thematic analysis was used to examine the qualitative data transcribed and categorized into themes and sub-themes [231]. The initial codes were determined based on a thorough comparison for similarities and differences between the primary researcher and research assistant transcripts. Any coding differences were discussed until an agreement was reached. NVivo (version 11.0, QSR International, USA) software was then used to generate thematic inferences relative to barriers and facilitators to diet and physical activity and social support networks and triangulated with the eco-maps and quantitative data especially demographic characteristics and biomedical information such as clinical glycemic target (glycosylated hemoglobin/A1C) , co-morbidities and body mass index (BMI) (Appendix 5).

4. Thematic Analysis

Thematic analysis is a method in qualitative research that involves identifying, analyzing and reporting themes from experiences and echoes participant perceived reality based on the data collected and previously identified in the literature [231]. It also describes themes related to the research questions and has been reported to be suitable for health and well-being research [232]. The advantages of thematic analysis are that it can also be used in a small or large data set and is applicable in data or theory-based analysis [233]. In this study, deductive, semantic and latent approaches were used for thematic analysis [231]. The deductive approach provides detailed aspects of the data based on the researcher area of interest [in this study barriers and facilitators]. Semantic analysis provided the descriptive interpretation of the data [231]. Furthermore, the latent approach supported the analysis, by identifying the fundamental ideas, assumptions, and conceptualization [231].

5. Trustworthiness

Trustworthiness of qualitative research can be established through credibility, transferability, dependability and conformability [234-237]. Credibility in this study was established through data triangulation (focus group discussions, eco-maps, individual interviews and the literature search) as well as peer debriefing after each focus group discussion and when translating the FGDs verbatim (from *Chichew*a to English) [234, 235]. Transferability is defined as the application of the results to other settings [237] and was attained through the purposive sampling used in the study. Dependability addresses the subject of reliability, and was achieved through research design and its implementation and detailed explanation of procedures followed for field data collection [234]. Conformability was established through audit trail, which ensured proper documentation of the procedure followed during data collection and analysis

[keeping records of the raw data, field notes, transcripts etc.] [234, 235]. Additionally, direct verbatim quotation from the participants was also used to provide a better explanation of the results.

D. Results

1. Characteristics of the participants

A total of 39 adults diagnosed with T2DM participated in the FGDs, of which 21 were from the urban location (47.6% male and 52.4% female) with the mean age of 57.6±8.3 years (mean ± SD). About 85.7% of the urban and 77.8% of the semi-urban participants were married (Table 22). Additionally, 72.8% of the semi-urban participants attained less or equal to the primary level of education, and 52.4% of the urban participants were secondary school educated. The majority of the participants from both the urban (71.4%) or semi-urban (66.7%) areas were overweight/obese. The mean duration of diabetes was 8.1±5.5 years for the urban and 5.4±3.9 years for the semi-urban participants. Glycemic status of the participants regardless of the location of residence was above the clinical glycemic target (A1C<8%), with a mean of 8.7±2.5% for the urban and 9.7±3.4% for the semi-urban participants. The majority of the participants were treated on oral hypoglycemic agents; 76.2% of the urban and 94.4% of the semi-urban participants.

Table 22: Characteristics of the participants stratified by location

Variable	Urban (n=21)	Semi-urban (n=18)
	n (%) or mean±SD	n (%) or mean±SD
Demographic factors		
Mean age (yrs.)	57.6±8.3	53.1±7.5
Gender		
Male	10 (47.6)	8 (44.4)
Female	11 (52.4)	10 (55.6)
Marital Status		
Married	18 (85.7)	14 (77.8)
Divorced/widowed	3 (14.3)	4 (22.2)
Education level		
≤primary level	10 (47.6)	13 (72.2)
≥Secondary level	11 (52.4)	5 (27.8)
Occupation status		
Small-scale farming	1 (4.8)	8 (44.4)
Professional/retired	6 (28.6)	5 (27.8)
Small-scale business	12 (57.1)	3 (16.7)
No occupation	2 (9.5)	2 (11.1)
Health-related factors		
BMI (kg/m^2)		
Normal weight	6 (28.6)	6 (33.3)
Overweight/obese	15 (71.4)	12 (66.7)
Mean duration of diabetes (yrs.)	8.1±5.5	5.4±3.9
Mean A1C (%)	8.7±2.5	9.7±3.4
Treatment type		
Diet alone	4 (19.0)	0 (0.0)
Insulin	1 (4.8)	1 (5.6)
Oral Hypoglycemic Agents	16 (76.2)	17 (94.4)

2. Emergent themes

The emergent themes were facilitators to appropriate diet and physical activity, barriers to appropriate diet and physical activity and support network for diabetes management (Table 23). The facilitators to diet, physical activity and supports networks were similar which included: support from family/friends, diabetes peer groups, emphasis from health workers, workplace/workmate support, and religious groups. Barriers for diet included: cost and access to

food, household/family size, lack of knowledge on what and how much to eat, challenges of separate preparation and purchase of food, dilemmas of what to eat during functions and travel, inconsistent dietary information from different sources and difficulties in changing dietary habits. The barriers to physical activity were fear of public ridicule and comorbidities.

Table 23:Themes and subthemes stratified by location as perceived by adults diagnosed with T2DM

Themes	Sub-themes	Urban	Semi-urban
Facilitators to appropriate diet			
	Family support	√	√
	Diabetes peer group	√	X
	Emphasis from health workers	√	√
	Elimination of certain foods	√	√
Barriers to appropriate diet			
	Cost and access to food	√	√
	Household/family size	X	√
	Lack of knowledge on what and how much to eat	√	√
	Separate preparation and purchase of food	√	√
	Dilemmas of what to eat during functions and travel	√	√
	Inconsistent dietary information from different sources	√	X
	Difficulty in changing dietary habits	√	√
Facilitators to physical activity			
	Family support	√	√
	Emphasis from the health worker	√	√
	Household chores and type of work	√	√
Barriers to physical activity			
	Fear of public ridicule	√	X
	Comorbidities	√	√
Support networks/system			
	Family members/friends	√	√
	Diabetes support group	√	X
	Health workers	√	√
	Religious groups	√	√
	Workplace/workmates	X	√

√= mentioned and X = not mentioned

The barriers and facilitators including social support are presented in accordance with the components of the socio-ecological model (Fig 4). The components include; policy systems (macrosystem), institutional and community (ecosystem), interpersonal (mesosystem) and intrapersonal (microsystem). The barriers, facilitators and social support networks are complemented with direct quotations from participants with the following variables, age, gender, weight status, A1C% and location.

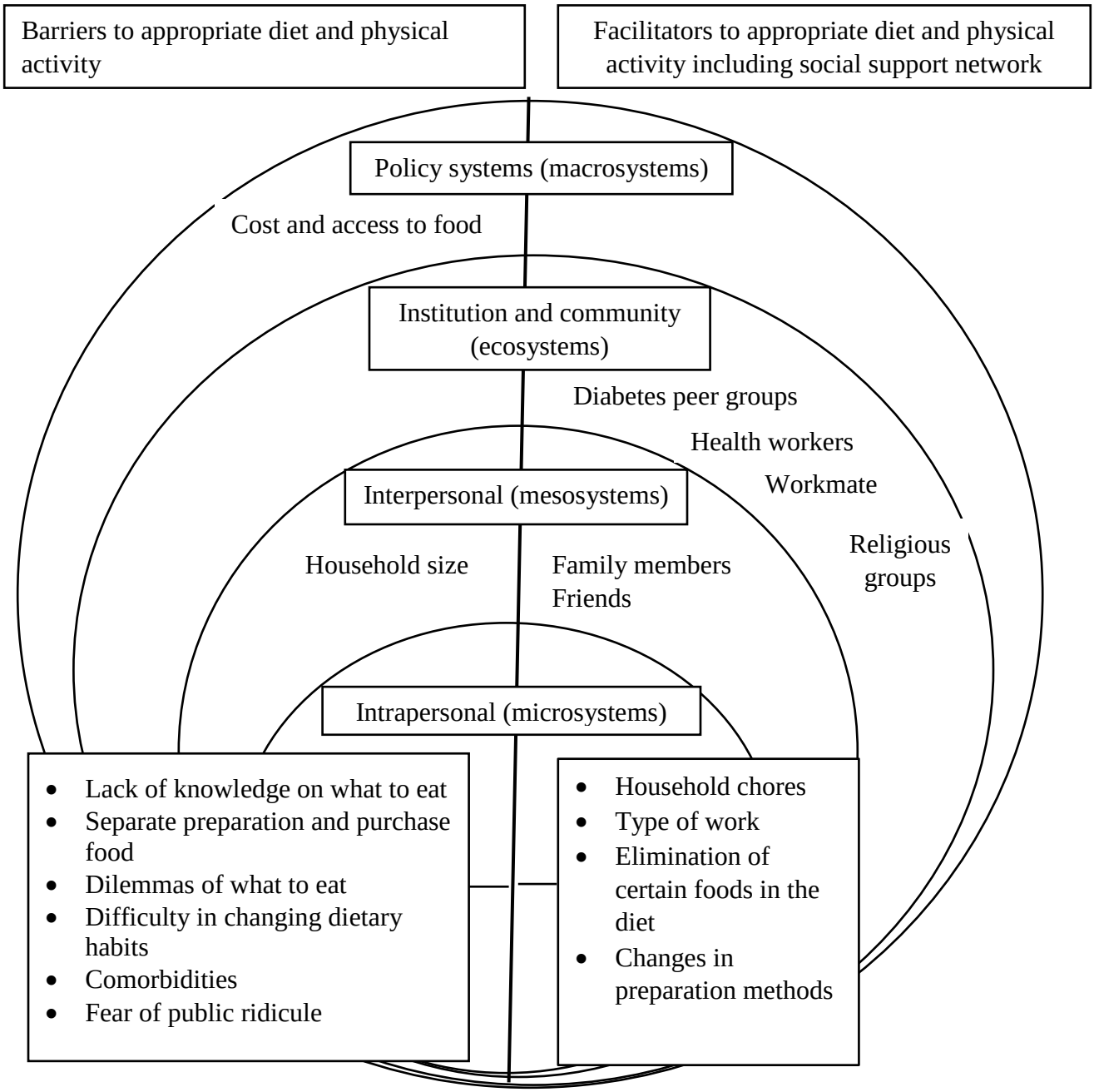


Figure 4: Barriers and facilitators including social support for diet and physical activity in the management of T2DM according to the socio-ecological model

2.1: Theme 1: Facilitators to appropriate diet

Family members

The participants from both urban and semi-urban FGDs reported family member support by spouses and children acted as facilitators to diet by providing resources to purchase food and help in food preparation. One of the participants from the urban FGDs indicated that the wife always tries to reinforce appropriate dietary behaviors. One of the participants said *"I will tell you a story from my experience. One day my wife, two children and I were traveling, going to a funeral in the village. Then on our way, we decided to stop at Mzuzu to have some breakfast at the restaurant. When the waiter came, I whispered in his ears to bring me (a) full breakfast (eggs, sausage, full cream milk and plate full of potato chips-french fries) but saw him bringing the whole maize porridge which he said that my wife had prepared for me and gave it to him to warm. Indeed, my wife supports me"* ***FGD#3, gender=male, age=69 years, BMI=overweight, A1C=8.1%, location=urban.*** In some instances where both spouses were diagnosed with T2DM, they reminded each other on the kind of food to eat. One female participant said "*I get support on what to eat from my husband. We remind each other what to eat because both of us have diabetes and hypertension. We always eat together. I cook relish (side dishes) recommended for diabetes without adding salt and oil. He always reminds me not to add oil to the food. We know each other well"* ***FGD#1, gender=female, age=63 years, BMI=obese, A1C=7.6%, location=urban.***

Diabetes peer groups

In the urban areas, diabetes peer groups are well established and functioning with the support from a retired nurse at Kamuzu Central Hospital. The TD2M patients teach and remind each other how much and what type of foods are suitable or not suitable for T2DM patients. One of the female participants indicated that; "*In our diabetes group we remind each other on what to*

eat and ways of preparing food. For instance, when eating chicken, we should remove the skin because it has a lot of oil. We also remind each other not to drink soft drinks [sweetened beverages] and even reduce the quantity when eating whole maize thick porridge" ***FGD#1, gender=female, age=63 years, BMI=obese, A1C=7.6%, location= urban.***

Emphasis from health workers

Health workers especially the nurses and clinicians provided nutrition education and reinforced appropriate dietary behaviors to patients with T2DM at the hospital level. One of the male participants from the urban area explained this relative to portion control and appropriate eating pattern. "*The retired nurse emphasizes that with diabetes we can eat anything but there should be limits as to how much we can consume. Like for cassava, the portion size should match a box of matches, only two pieces per day. For whole maize thick porridge only two scoops should be given depending on the size of the scoop and our eating patterns should be stable, not constantly varying. For instance, today you eat lots of foods and the next day just a little, because your blood sugar will always be high"* ***FGD#3, gender=male, age=63 years, BMI=normal weight, A1C=10.4%, location= urban.*** One of the participants from the semi-urban area indicated that the support from the health workers is not only at the hospital but also in their communities/public places. *"The clinician always teaches us to eat a lot of fruits and vegetables. Even when I meet him in the community, he always reminds me. For instance, one day we met at the market place, and I was having soft drinks [sweetened beverages]. Unfortunately, he saw me and told me to stop taking soft drinks"* ***FGD#4, gender=male, age=52 years, BMI=normal weight, A1C=8.8%, location= semi-urban.***

Eliminate certain foods in the diet

Many participants indicated that they have eliminated refined maize, sweetened beverages and too much oil in their diet and changed the food preparation methods. A female participant from the urban area explained how she has changed her eating pattern since she was diagnosed with the condition. "*When I was diagnosed with diabetes, here at the hospital I was told to eat whole maize flour thick porridge and not to eat margarine and sugar. I usually have roasted fish or boiled or roasted meat with no oil added [I don't fry my food]. I don't eat rice because I was told it has a lot of starch".* ***FGD#1, gender= female, age=63 years, BMI=obese, A1C=7.6%, location=urban.*** Another female participant from the semi-urban area also echoed how he changed his eating pattern by not eating sweetened beverages, reducing the quantity of food he consumed and learning different healthy preparation methods; *"I used to eat anything, meat, fanta and coke, but since my diagnosis I stopped, and have become too selective on what I eat. What has really changed is the kind of food and preparation methods, including reducing the quantity".* ***FGD#2, gender= female, age=48 years, BMI=obese, A1C=14%, location=semi-urban.***

2.2: Theme 2: Barriers to appropriate diet

Cost and access to food

Food cost, availability and accessibility appeared to be the main barrier to diet regardless of location. Additionally, resource restraint such as income also hindered participants from purchasing foods recommended for diabetes by the health workers such as fruits. Many participants from the semi-urban area expressed concerns about the availability of food on the local market. *"Here in Kasungu [semi-urban] food is not available and scarce in the market such as fruits, coke lite, brown bread, and skimmed milk. I always take full cream milk because it is the only milk available at the market. Sometimes I really wish to take coke lite, but I always*

substitute with sweetened beverages to quench my thirst". ***FGD#4, gender=male, age=43 years, BMI=overweight, A1C=12.9%, location=semi-urban.*** Some participants from the urban areas indicated that having an adequate budget for food was challenging*;* "*I do not have proper budget to eat food recommended for diabetes, I buy what is available on the market and according to the money I have. For fruits, I buy bananas because they are cheap and always available compared to apples"* ***FGD#3, gender= male, age=45 years, BMI=overweight, A1C=9.5%, location= urban.*** Additionally, the foods recommended for T2DM patients by the health workers were not always available at the local market, as stated by a female participant; "*Diabetes can be managed using locally available food, but in the villages, we live, the foods are not available, and the only cheap food available is maize. At the hospital the emphasis is to buy expensive fruits such as apples, which I can't afford, even if I work. We have been advised to use artificial sweetener instead of normal sugar which is also expensive here in Kasungu [semi-urban]. That is why most of the times we mostly just eat what is available at that time. Most of the times my blood sugar levels are elevated, because I really do not have the resources to buy expensive foods such as fruits and artificial sweeteners"* ***FGD#2, gender=female, age=42 years, BMI=obese, A1C=10%, location= semi-urban.***

Household/family size and other responsibilities

Household size as barrier to diet was reported especially by the participants from the semi-urban areas. Due to limited resources, patients with T2DM compromise their needs [purchasing food recommended for diabetes management] and prioritize the family needs and preferences. *"As for me, money is the big issue. For example, I may want to buy food for my condition, but considering that my children and other relatives want to be fed and have fees for school, I always prioritize these school fees and eat what is available on that day without even*

thinking about my condition". ***FGD#4, gender=male, age=53 years, BMI=normal, A1C=14%, location= semi-urban.*** Due to inadequate finances, participants found it difficult to allocate sufficient money for purchasing food needs in the larger families; *"I have difficulties dividing money between my family and food. It is difficult to buy recommended foods with the little money I get. I always prioritize my family more than food"* ***FGD#4, gender= male, age=52, BMI=normal, A1C=8.8%, location=semi-urban.***

Lack of knowledge on what and how much to eat

Participants from both urban and semi-urban areas expressed concern regarding how dietary information is provided by the health workers. Not much emphasis was given to portion size control, and specific foods that are appropriate and not appropriate for T2DM patients, hence posing challenges in the dietary management of T2DM. One female participant expressed that *"We have been advised to reduce the quantity of food, but the problem is that we don't know how much we should reduce it by, and it is not clear which foods to reduce except changing from refined to whole maize thick porridge. If they showed us the quantities that would be good"* ***FGD#1, gender=female, age=45 years, BMI=obese,*** **A1C=11.3%, location=*urban*.** Additionally, participants have been told to stop eating certain food in their diets, but not how to balance food groups as is clearly evident in the following quote *"We have been advised to stop eating meat, rice [rich in starch], beans, sugar and eggs [high cholesterol]. But how can one eat only maize thick porridge with vegetables. I feel like we are being punished."* ***FGD#4, gender=female, Age=57, BMI=overweight, A1C=14%, location= semi-urban.***

Separate preparation and purchase of food

Food preparation and purchase for individuals with T2DM is done separately from the rest of the family members. Considering family resources and size, separate food preparation and

purchase were perceived as barriers to appropriate food choices. One female participant from the urban area expressed that food preparation for her, as a person with T2DM is done separately considering that some family members may not want to eat the food recommended for someone with T2DM. "*My children cook food for me separately from the rest of the family, because they don't like the food recommended for diabetes. But sometimes, they get tired and I just eat what is available on that day".* ***FGD#1, gender= female, age=61 years, BMI=overweight, A1C=14%, location=urban.*** In some instances, where food was also purchased separately for T2DM, limited financial resources were sometimes a barrier. "*I buy food recommended for diabetes, for myself first, then for the rest of the family. But sometimes I am limited, and I just buy what is cheap on the market for the whole family, although it is very difficult to be buying food separately, considering that food in Malawi are expensive and not as available compared to Zambia and South Africa"* ***FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%, location=urban.***

Inconsistent dietary information from different sources

Patients with T2DM reported receiving different information on dietary management from health workers in both public and private hospitals and social media, which was confusing. The conflicting information hindered patients from making appropriate dietary choices. There are some participants who go to both private and public hospitals for diabetes services; *"When I go to the private clinic the doctors advise me to stop taking meat, salt, sweet beverages, and not to use cooking fat/oil, but without telling me the reasons. When I come at the government hospital the nurse explains that I should take food in moderation, so I don't know who to believe"* ***FGD#3, gender=male, age =58 years, BMI overweight, A1C=6.3%, location= urban.*** Other participants indicated that the dietary information from newly recruited nurses and those

who were experienced was different; "*The newly recruited nurses they teach us differently from the old nurse. I feel like there is conflicting information especially on what to eat and how much. The new nurses the emphasis is on to stop eating this and that, while the old nurse sometimes will explain and demonstrate. The problem is that we are counselled by different people each time" **FGD#3, gender=male, age=45 years, BMI=overweight, A1C=9.5%, location=urban.***

Dilemmas of what to eat during functions and travel

During social events such as weddings and when travelling, participants expressed concern that they cannot find recommended foods. As such, they improvise or eat what is available at that moment and reduce the amount to be consumed. "*Sometimes, it's really a burden when I travel to church functions, even if they communicate that we have diabetes, but they still cook refined maize flour thick porridge. Sometimes they bring fanta [sweetened beverage] for me to drink, it is so tempting I sometimes do drink it, because I have no other option. I thank God my blood sugar is not always high." **FGD#1, gender=female, age=52 years, BMI=obese, A1C=5.5%, location= urban.*** Some participants indicated that the food served during special events such as weddings and parties is considered delicious and difficult to resist. *"At parties, I do eat the foods that are there because the foods are usually delicious. On Christmas day, I neglected my condition and I ate delicious foods with my children, and my blood sugar is always high" **FGD#2, gender=female, age=42 years, BMI=obese, A1C=10%, location= semi-urban.*** Additionally, when travelling to different areas within the country, participants found it difficult to find appropriate food to purchase because most of the food sold along the way [street foods] are not recommended for T2DM management. "*When travelling, going to my home village in Chitipa [rural area in Malawi], for example, it is hard to eat foods*

because all the foods sold on the way have a lot of oil, are fried or are sweetened beverages. ***FGD #4, gender=male, age=52 years, BMI=normal weight, A1C=8.8%, location= semi-urban.***

Difficulty in changing dietary habits

Some participants indicated that it is challenging to reduce the quantities of food and to eliminate certain foods that they enjoyed prior to diagnosis of T2DM. One female participant expressed that she doesn't follow recommendations from the hospital; "*It is not easy to change especially for me. I still do not follow what I have been told at the hospital, especially when I am alone. I assume that no one is watching me, so I eat a lot of fried potatoes, sugary foods and soft drinks. Most times large quantity of thick maize porridge at once. Thus, when I come to the hospital my blood sugar is always high*" ***FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%, location =urban.*** Some indicated that reducing the quantity of thick maize porridge was challenging; *"It is very difficult to change, even now I still eat large quantities of whole maize thick porridge during one meal. I use a lot of sugar in my tea and still take fatty meat and full cream milk. I find it a burden to stop. I hope with time I will change"****. FGD#4, gender= male, age=53 years, BMI=normal, A1C=14%, location= semi-urban.*** Other participants stated that the food recommended for the management of diabetes does not taste good. "*I sometimes eat what the nurse advises us to eat, though it's not my desire because the food is not delicious, but with time, I will get used to it. What has really changed is switching from refined to whole maize thick porridge. And sometimes I really crave coke [sweetened beverage]. I was really enjoying food before getting diagnosed with diabetes".* ***FGD# 3, gender=male, age=58 years, BMI=overweight, A1C=6.3%, location= urban.***

2.3: Theme 3: Facilitators to physical activity

Support from family and friends

Motivation and reinforcement to do physical activities as part of diabetes self-management was provided by friends and family members such as children. *"I exercise at home. Sometimes, I walk distances to the field and help my children do household chores. I also play netball with my grandchildren every now and then"* ***FGD#2, gender=female, age=48 years, BMI=obese, A1C=14%, location=semi-urban.*** Another participant indicated that friends provided support for physical activity; *"I have a friend who pick me up in the morning to go for a run before work. Sometimes I play football with my younger children at home as part of exercise, we really enjoy it"* ***FGD #4, gender=male, age=52 years, BMI=normal weight, A1C=8.8%, location= semi-urban.***

Type of work/household chores

Household chores was the predominate means of engaging in physical activity by both male and female participants. These household chores included: washing clothes by hand, sweeping and mopping. For instance, one of the male participants from the urban area indicated that *"I briskly walk as part of my exercise. I also go to Lilongwe river to wash my clothes either two or three times a week and I wash for over 40 minutes. I even wash my wife clothes which I also consider as part of my exercise and it's really helping me****. FGD#3, gender=male, age=61 years, BMI=normal weight, A1C=8.7%, location=urban.*** Most of the female participants in both study locations expressed that they did a lot of household chores, which acts as means of physical activity; *"For me I don't get any help, so I do house work alone until I sweat even though others say I am old fashioned because I don't have a housemaid to help with household chores, but I am healthy. I sweep the outside and clean my big house alone without problems as*

part of my exercise each day" ***FGD#1, gender=female, age=52 years, BMI=obese, A1C=5.5%, location= urban.*** Likewise, mainly male participants indicated that involvement in manual work such as farming, carpentry and welding acted as part of their routine physical activity. *"I do farm a lot and my work involves carrying heavy metals, because I am a welder. So, I do physical activity through work".* ***FGD#3, gender=male, age=63 years, A1C=10.4%, location=urban.*** Another male participant from the semi-urban area also indicated that "*My work is manual, I am a carpenter, so I carry heavy and chop wood a lot each day"****. FGD#4, gender= male, age=52, BMI=normal, A1C=8.3%, location= semi-urban.***

Emphasis from the health worker

Health workers appeared to be instrumental in emphasizing emphasize the importance of physical activity as part of T2DM self-management through diabetes education at the hospital. *"I get support to do physical activity from the hospital. We are encouraged to engage ourselves in several activities at home such as washing cloth and walking for long distance as exercise, of which I always do. I even help my wife some of the household chores such as sweeping"* ***FGD#4, gender=male, age=55 years, BMI=overweight, A1C=6.4%, location= semi-urban.***

2.4: Theme 4: Barriers to physical activity

Fear of public ridicule

Although involvement in physical activity is required for diabetes management, fear of the potential negative connotations from society acted as a setback to freely participate in the different forms of activities. "*I sometimes [once in a while] dance in my bedroom as part of exercise, because my children and other family members including the neighbors laugh at me when I dance as exercise outside the house"* ***FGD#1, gender=female, age=61 years, BMI=obese, A1C=9.3%, location= urban.*** "Indeed, neighbors disappoint us. One day a neighbor

said, "*Why do you do all the household chores as if you don't have children?" But for me this is part of my exercise".* ***FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%, location=urban.***

Comorbidities

Diabetes-related comorbidities and other conditions may hinder patients from engaging in physical activity. Comorbidities such as stroke, leg and sight problems inhibited patients from involvement in physical activity. Comorbidities as a hindrance to physical activity was mentioned by both male and female participants, especially from the urban area. One female participant explained; *"In terms of physical activity, I don't run, but I dance sometimes but not always because of my leg problem and minor stroke I had."* ***FDG#1, gender=female, age=61 years, BMI=obese, A1C=9.3%, location=urban.*** Another male participant echoed by saying; "*I don't do a lot of exercise; at times I try my best to exercise in the morning despite having leg problems and I can't see far especially when I feel like my blood sugar is high".* ***FGD#3, gender=male, age=69 years, BMI=overweight, A1C=8.1%, location= urban.***

2.5: Theme 5: Social support networks

Family members/friends

Family and friend provided social support especially as mentioned with regard to medication adherence. "*As for me my grandchild is the one that reminds me to take my medicine. I have raised that grandchild alone so most of the times the grandchild reminds me to take the medicine and sometimes I even send him to get the medicine for me. Most of the times, my wife and I forget about the medicine, but my grandchild never does, he is always there to remind me to take my medications. When I take a bath before eating, he always reminds me to take my medications"* ***FGD#3, gender=male, age=61 years, BMI=normal weight, A1C=8.7%,***

location= urban. Other participants also indicated that they were supported by both family members and friends. *"I get support from my 7-year-old boy. When I am going to work, he always reminds me "daddy, have you taken your medicine today". My wife is also involved, and her friends also encourage me, and remind me of the condition I have"* ***FGD#=4, gender=male, age=53 years, BMI=normal weight, A1C=14%, location=semi-urban.***

Diabetes peer group participation

Participating in diabetes peer groups among the urban participants provided the opportunity to share information on weight loss and enforced good eating habits. "*In our groups with fellow diabetes patients we encourage each other to lose weight. And tell each other not to eat the skin of chicken because it has a lot of oil".* ***FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%, location=urban.*** Additionally, within the diabetes peer groups everyone acted as a messenger *"At the diabetes groups everyone is the messenger of the other, we advise each other to live well and not to eat too much just because there is food, and we need to control ourselves".* ***FGD#1, gender=female, age=63 years, BMI=obese, A1C=7.6%, location=urban.***

Workplace/workmate

Semi-urban participants who worked in different institutions stated that co-workers provided support by ensuring that the food served to T2DM patients was appropriate, especially during official events. "*My workmates as well take part. I previously used to like fanta but now they bring me water, and they tell other coworkers that I can't have fanta. Even at teacher training college (TTC) where I work, the women there say that I should take care of myself because I have a little child who needs my help".* ***FGD# 3, gender=male, age =52 years, BMI=normal, A1C=8.8%, location=semi-urban.*** Additionally, some participants disclosed to

their supervisors that they had diabetes, so that they could be easily accommodated "*At the workplace, I told my boss of my condition, so he allows me to leave whenever I don't feel well. We are protected at work because I told my boss who allows me to go home when I do not feel well to rest".* ***FGD# 2, gender= female, age=42 years, BMI=obese, A1C=10%, location=semi-urban.***

Religious groups

Female participants, predominantly from both urban and semi-urban FGDs, were involved in religious groups and strongly believed and prayed to God for support. "*I am supported at church because I keep praying and they say God will heal us. However, I still take medication as needed and follow the advice given on food, like eating mustard without oil added to it, although I have to force myself to eat it".* ***FGD#2, gender=female, age=42 years, BMI=obese, A1C=10%, location= semi-urban.*** While other participants used the religious platform to inform/teach members on the symptoms of T2DM. "*At my church people understand that I have diabetes and as such they prepare foods suitable for me. Other people ask me the symptoms that I felt before I was diagnosed with the condition and I explain to them e.g. fever, excessive thirst or frequent urination but for malaria I have spent four years now without suffering from it. Sometimes even some church members call me on my phone to ask for the symptoms of diabetes".* ***FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%, location= urban.***

3. Eco-maps

The interactive drawing of the eco-maps by the study participants enhanced the understanding of the social support networks for the management of T2DM (Fig 4). Critical sources of support for diabetes self-management included family, friends, diabetes peer groups,

health workers, religious groups, and workmates. The strength and type of support varied based on the sources. There were strong ties between patients with T2DM and their family members (spouses, children, and grandchildren), which provided support for diabetes management such as reminding them to take medication, preparing food and reinforcing appropriate dietary habits. On the other hand, health workers also provided a supportive environment for patients with diabetes through diabetes education at the hospital. The existence of diabetes peer groups was a platform to interact and share information of self-management of diabetes, especially among the urban participants. Working participants [those who were employed], were supported by knowledgeable coworkers especially regarding food choices. Female participants reported that they sometimes receive support from religious groups and through prayers.

Symbols

(─) Positive support

(---) Weak support

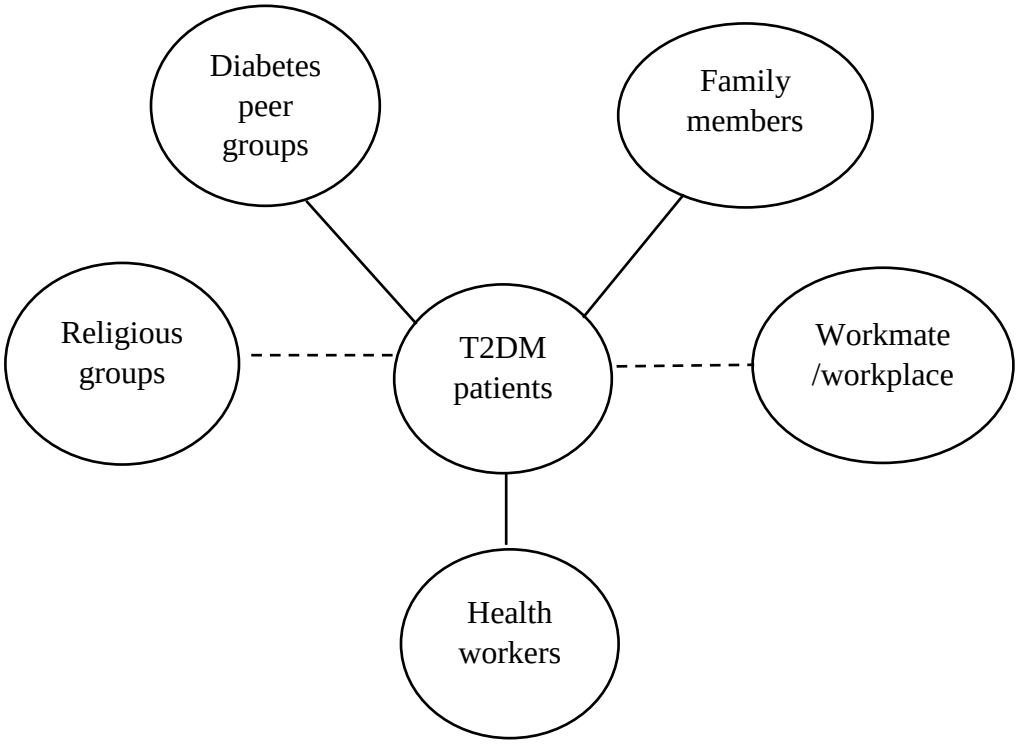


Figure 5: Eco-map illustrating areas of social support as perceived by study adults diagnosed with T2DM

E. Discussion

It was imperative to gather information about perceived barriers and facilitators to diet and physical activity including social support systems in T2DM self-care management to ensure optimal glycemic status. The results from this study indicated that there were several factors impacting healthy diet and physical activity behaviors.

Food cost and access were commonly mentioned among both urban and semi-urban participants as barriers to healthy eating. This study was conducted toward the beginning of the dry season (August 2017). As such, food availability, accessibility and prices on the market

especially for fruits and vegetables may have been impacted and, hence, consumption. In both urban and rural areas, the consumption of green leafy vegetables has declined with increases in price [238]. Our findings are consistent with previous findings that financial constraints and food seasonality impacted the diet of T2DM individuals due to an increase in cost and limited availability on the market [110, 132]. Additionally, large family sizes and other priorities compromised the quality of the diet. These findings are similar to studies in Ghana and South Africa where inadequate money, food insecurity and family size affected the purchase of appropriate food for management of diabetes [132]. Food insecurity is a serious problem in Malawi [119] and it could have in one way or the other affected the healthy eating of the T2DM due to limited food availability and access.

We noted that food items for T2DM individuals are bought and prepared separately, because of family members not willing to change dietary habits that negatively influenced healthy eating. Even patients with T2DM alluded to the fact that it was difficult to change dietary habits and eliminate certain foods from the diet because they still craved food items they enjoyed before being diagnosed with the condition. Mayega et al., (2014) indicated that although patients with diabetes may experience difficulty achieving a healthy diet due to poverty and family size and challenges in the modification of dietary behavior [136]. Muchiri et al., (2014) indicated that some individuals with T2DM may not be in charge of meal planning as such separate food preparation and purchasing acted as a barrier to healthy eating in South Africa [239]. This sentiment was expressed by participants as a definite limitation. Not knowing what and how much to eat during social events and travel and control of portion sizes, in addition to the conflicting information from different sources, also hindered the intake of a healthy diet among diabetes patients in Malawi. Unavailability of appropriate guidelines for the management of

T2DM in Malawi and the fact that there are few to no registered dietitians in the country especially the hospitals could have contributed to health care professionals who are not nutrition experts providing general and sometimes confusing information to patients. It was specifically noted that the dietary information provided to patients was in general terms such as stop eating oily foods, reduce the quantity of food consumed, and change from eating refined to whole maize porridge, without in-depth explanations. Doherty et al., (2014) stated that the portion size information given to individuals with T2DM in Ghana was insufficient and arbitrary thus affecting adherence to dietary recommendations [132]. Additionally, Laranjo et al., (2015) also found that portion size control, craving for certain food items, cost of healthy foods and maintaining a healthy diet during social functions and holidays were barriers to healthy diet among patients withT2DM [139]. Furthermore, inadequate diabetes education, lack of support from communities and conflicting information on diets were also reported as barriers to appropriate diet [27, 135, 137].

Physical activity is one of the components of self-management of diabetes. Engaging in household chores and other jobs such as farming, and welding were some of the activities T2DM individuals were involved in. However, diabetes-related comorbidities such as stroke hindered the engagement in physical activity. Loss of vision and amputation due to uncontrolled hyperglycemia were also reported to negatively impact the engagement in physical activity in Kenya [138]. Lack of proper guidelines on physical activity as the case of Malawi, has been reported also to hinder adherence to physical activity among patients with T2DM [240], and may indeed also be the case in Malawi. For example, inadequate emphasis when providing diabetes education on what type and intensity of physical activity has been shown to be beneficial [135, 240]. Fear of public ridicule appeared was a barrier to physical activity especially from the

participants in urban areas. This was also evident in a study by Kiawi et al., (2006) in Cameroon where in some urban areas, walking was associated with poverty [133].

The eco-maps helped in visualizing which areas and type of support T2DM individuals received from society. Support from health workers and family members such as spouses and children were facilitators to both diet and physical activity. The support provided included food preparation, medication reminders and encouragement to engage in physical activity. Frequent interaction with family members and friends was also reported in other studies as both a motivator and facilitator to diabetes self-care and promoted health behaviors such as physical activity and well- being among patients with T2DM in India and Denmark [240, 241]. Similarly, support for food preparation and keeping an eye on what kind of food individuals with T2DM should consume [27, 135, 139, 160, 242] also acted as facilitators to healthy eating in several other studies. Diabetes peer groups acted as a social support network and facilitators to diet and physical activity especially in urban areas. Participating in diabetes peer support groups provided a platform for individuals with T2DM to interact and promote lifestyle changes such as sharing information on what to eat and exercise. Evidence has shown that peer support in self-management of diabetes in South Africa, Uganda, Cameroon, and Thailand improved glycemic status, dietary intake, blood pressure, and weight status [243]. A meta-analysis of randomized controlled trials showed that frequent contact with peers with diabetes significantly improved glycemic outcomes [244]. Furthermore, self-care behaviors such as diet, exercise, foot care and blood glucose monitoring improved after peer support in Cameroon [245]. Therefore, there is need to strengthen and use existing platforms such as religious groups and work places to help individuals with T2DM to share knowledge and promote access to resources to improve glycemic status and prevent diabetes-related complications.

F. Conclusions

Our findings revealed that the barriers such as inadequate nutrition knowledge on what and how much to eat and inconsistent dietary information provided by health workers could be possibly emanating from the unavailability of diabetes specific dietary guidelines to provide standardized information. In addition, the paucity of experts trained in medical nutrition therapy for conditions such as T2DM in Malawi, makes it imperative that such training be a national focus with the rising prevalence of NCDs. Diabetes-related comorbidities due to chronic hyperglycemia hindered engagement in physical activities. Social support from families, health workers, and diabetes peer groups acted as facilitators for both healthy eating and physical activity. Therefore, a focus on socio-environmental factors should be prioritized by nutritionists, dietitians, and health workers when developing and providing nutrition and physical activity education in Malawi. Additionally, more in-depth research is needed to elucidate the possibility of using social networks such as religious groups and work places for providing nutrition information for the prevention and management of diabetes.

CHAPTER 7- SUMMARY AND CONCLUSIONS

A. Summary of the findings

Diabetes is an increasing public health problem, globally affecting about 425 million people in 2017, of which low- and middle-income countries bear almost 80% of the diabetes burden [3]. Unfortunately, in the sub-Saharan Africa (SSA) region, the number of people with diabetes is estimated to increase by 154% by 2045, even though the region does not have the resources and capacity to curb the rising epidemic [3]. Of greater concern is the fact that about 69.2% of those with diabetes in SSA are undiagnosed, hence the prevalence could be even higher than currently estimated [3]. In Malawi, about 5.6% of adult (25 to 64 years) have been diagnosed with T2DM [13]. The prevalence of diabetes is higher in urban (3.0%) than rural (1.7%) areas and that about 41% of those with diabetes in Malawi are undiagnosed [15]. Furthermore, the risk factors for NCDs in Malawi are higher in urban than rural areas as evidenced by the following urban vs. rural rates respectively: overweight (38.6% vs. 21.9%), obesity (13.6% vs. 4.4%) and physical inactivity (24.1% vs. 8.7%) [13].

Self-management of diabetes requires eating a healthy diet, engaging in regular physical activity, medication compliance, foot care and self-monitoring of blood glucose [66]. Adequate diabetes education is necessary for optimal glycemic status; however, unavailability of diet and physical activity guidelines and economic and socio-cultural factors negatively impact diabetes self-care practices [27-29]. Provision of nutrition education in diabetes management by health workers not trained on nutrition could also contribute to patients with T2DM not being cognizant of appropriate recommendations [16]. Furthermore, nutrition labeling is voluntary and not well understood by the majority of Malawians, making informed food choices difficult

[37, 38]. This leads to unhealthy dietary patterns and poor dietary compliance, including for those diagnosed with diabetes [31, 39, 40].

There is currently a paucity of data in Malawi on the factors associated with acceptable and unacceptable levels of glycemic status, because A1C tests are not done in most hospitals [18, 21], even though it is the gold standard recommended because it reflects long-term glycemic exposure for over a period of two to three months [23-26]. Additionally, assessing diet quality in patients with T2DM is important because little is known about the contribution of local Malawian's diets to their glycemic status. It is also imperative to understand the relationship of eating habits to disease management based on location of residence (urban and semi-urban) to identify challenges and guide strategies for dietary counselling.

The overall aim of this study was to assess the extent to which clinically targeted glycemic status is achieved and associated factors among Malawian adults with T2DM and the implication of diet quality, food insecurity and socio-environmental factors. Findings provide helpful insight into the development of nutrition education and extension materials for prevention and management of T2DM in Malawi as well as inform nutrition policy revisions to enhance the role of nutrition in NCD services, especially T2DM in Malawi.

A cross-sectional mixed method study was conducted in two phases. The first phase was quantitative in nature, with a convenience sample of 428 adults diagnosed with T2DM in Lilongwe (urban; Kamuzu Central Hospital; n=280) and Kasungu (semi-urban; Kasungu District Hospital; n=144) districts. The data were obtained through face -to-face individual interviews, and parameters collected included: socio-demographics, self-reported medical information, anthropometrics, dietary intakes, and blood samples for A1C testing. Data were used to estimate the proportion of adults with acceptable (A1C<8%) and unacceptable (A1C≥8%) clinical

targeted glycemic status [165] and to determine associated factors associated. Additionally, dietary and other factors associated with unacceptable glycemic status were assessed. The second phase qualitatively assessed barriers and facilitators to diet and physical activity, two key aspects of self-management in diabetes, as well as social support systems. Four focus group discussion were conducted two in each study location for each gender category.

The results showed that overall, glycemic status was suboptimal in both urban and semi-urban areas in Malawi. A little over 60% of adults diagnosed with T2DM had unacceptable (A1C≥8%) glycemic status and the findings are comparable to previously published findings within the SSA region [25, 75, 80, 164]. Young adults were more likely to have suboptimal glycemic status, consistent with previous findings in Senegal, Cameroon, Guinea, Singapore, Iran and Germany [76, 82, 166-168]. Nutritional status of adults diagnosed with T2DM was also associated with glycemic status. Being underweight interestingly increased the likelihood of a higher than acceptable A1C in the overall and semi-urban population, similar to that found in previous studies in China and Singapore [92-94, 166]. Additionally, as would be expected, overweight/obesity especially among those from the semi-urban area, was associated with higher than acceptable A1C levels, similar to the previously published findings in South Africa, Singapore and Saudi Arabia [80, 166, 170].

The longer the duration of T2DM, the more likely the A1C was to be unacceptable among semi-urban participants. In this study, both diagnosed and self-reported diabetes-related comorbidities were common, especially hypertension with a greater likelihood of multiple comorbidities when the A1C was unacceptable in both urban and semi-urban participants. This is to be expected and supported in the literature [18, 22, 25]. One way of ensuring that the blood glucose is within the recommended target, is frequent monitoring, which is a component self-

management of diabetes. Frequent blood glucose monitoring in addition to that done at the public hospital, either at diabetes peer group meeting/home/private clinic resulted in participants more likely to have acceptable A1C levels, especially in the urban areas. Active participation in diabetes peer groups has been reported to improve A1C outcomes of the diabetes patients [172, 173], which could provide a platform for blood glucose monitoring and diabetes education, especially in the urban area, but may need to be encouraged in the semi-urban area as well. Being physically active also improved A1C levels in the overall and urban area participants. Physical activity is also one of the components of diabetes self-management that has been shown to improve insulin sensitivity among patients with T2DM [174-176]. In previously published studies, physical inactivity was associated with unacceptable glycemic status [19, 80, 170]. Participants who self- reported perceptions that their blood glucose was unstable were less likely to have acceptable A1C levels, suggesting that they were inherently aware that there was a problem, but it is unclear if they understood the magnitude of the situation. Therefore, when providing diabetes education emphasis on all components of diabetes self-management should be a requirement to increase the likelihood of an optimal glycemic status.

Participants with acceptable glycemic status were less likely to spend more income on diabetes care; a similar association was seen in previously reported studies in developed nations [187, 188]. More comprehensive diabetes services in Malawi are more likely to be available in urban than semi-urban and rural areas [64]. As such, the urban participants had higher total median out-of-pocket expenses than the semi-urban, due to additional BGM, cost of care overall, and food expenses per capita, similar to another study in India [186]. Income was an independent factor positively associated with total out of pocket expenditure, implying that participants with T2DM participants with a higher income were more likely to seek additional

diabetes services. Similar observations were made by researchers who conducted a study in Mali [189]. Supporting previous findings [99, 182, 186], the current study also showed that total expenditure on diabetes was associated with duration of diabetes in the overall study group and specifically in the urban area, demonstrating that with a longer duration of diabetes, individuals spent more money on diabetes care. The number of years spent in school was also significantly associated with a greater total out of pocket expenditure, particularly in the overall model and semi-urban areas, contrary to findings reported in Sudan and Mali where the uneducated patients with T2DM spent more on diabetes care [185, 189] and attaining a higher education did not equate to high health literacy [189]. There is a need to assess the health literacy of patients with T2DM in Malawi in terms of their disease knowledge and self-care behaviors.

The diet quality of patients with T2DM regardless of glycemic status did not differ using IDDS and the preventive diet score. However, the quality of the diet was generally poor, high in CHO and low to moderate in protein and fat, with an average energy intake of 2143.1 kcal/day with 75.4% CHO, 13.9% protein and 15.1% fat, in line with other studies in South Africa, Ghana and Uganda [31, 84, 109]. It was not surprising that consumption of cereals, roots and tubers and sweet/sugary foods was significantly high among participants with A1C≥8%. In Malawi, maize is staple food that was commonly consumed by the majority of the participants regardless of glycemic status. Similarly, in South Africa and Tanzania; maize products, rice, sorghum and bread and plantains were the primary sources of CHO in diets of patients with diabetes [31, 192]. The dietary fiber intake in this study was above the recommendation of WHO/FAO of >25 g/day, contrary to the findings by previous studies within SSA [31, 109]. The differences could probably be due to composition of the diet. Because the diet overall was problematic especially with regard to CHO intake, which was disproportionately high in this study, in conjunction with

unacceptable A1C levels, it is therefore appropriate to prioritize nutrition. Similar to diabetes counseling recommendations advocated by the Academy of Nutrition and Dietetics in the USA, developing culturally relevant Malawi food exchange lists (CHO counting materials) would likely be advantageous for this vulnerable population and improve outcomes.

The diet of Malawian patients with T2DM was found to be within the nutrition recommendation of WHO/FAO chronic diseases for saturated fatty acids (<10% of total energy/day), cholesterol (300 mg/day) and less for polyunsaturated fatty acids (6-10% of total energy/day). But, only 15.4% of the total energy was from fat, well within the total fat recommendation. The fruit and vegetable intakes were found to be below the recommendation of >400 g/day, similar to the prevously published studies in Malawi and Ireland [13, 157]. Generally, food availability and accessibility especially for fruit and vegetables in Malawi varies with seasonality, and since this study was done in the beginning of the dry season, intake may have been impacted due to limited availability or higher costs.

Meal irregularities of ≤three meals/day increased the probability of the A1C ≥8%. Previous findings associated meal irregularities with decreased insulin sensitivity, elevated fasting blood glucose, higher A1C, postprandial hyperglycemia and impaired insulin response [211-215]. The majority of the participants indicated that they did not comply with dietary recommendations due to cost of food, inadquate education on what to eat and seasonality of the fruits and vegetables, similar to the findings in Ethiopia and South Africa [31, 110, 210]. Considering that meal irregularities were associated with unacceptable A1C in this study, providing adequate education on the importance of meal planning and timing of meals using locally available resources is urgently needed.

Additionally, food insecurity is a serious problem in Malawi [41] that likely also impacted the meal patterns. Only 22.7% were food secure, 36.9% mildly food insecure and 40.4% were moderately to severely food insecure, supporting the literature from developed nations among the low-income patients with diabetes [121, 125, 126, 217-219]. The HFIAS score was significantly negatively associated with IDD score, indicating that the diet quality is compromised in line with the previously published studies [9, 129, 218, 221]. Additionally, an increase in HFIA score as an indicator of food insecurity significantly increased the A1C levels, congruent with the available evidence in developed nations [122, 217, 219, 227]. However, socio-demographic characteristics such as education status, household income and food expenditure per capita were also associated with the HFIA score, consistent with the already existing literature [121, 126, 127, 129, 220].

For over 90% of the participants, the main source of food for household consumption was through purchasing, especially from the traditional open markets and small grocery shops. Mildly and moderately to severely food-insecure participants bought food from the secondary markets, which were dominated by small grocery shops. The food that participants purchased from the secondary markets were sugary foods, processed wheat products, fat, and oils, in line with early published research in Malawi [9]. Although a small percentage of participants indicated that they produced food for household consumption, it was mainly maize and groundnuts which may not provide adequate nutrients for a total healthy diet. Considering that food purchasing was the predominant source of food at the household level, nutrition education that focuses on making healthy food choices on a budget, as well as perhaps educating food store owners in increasing availability of affordable healthy choices might be beneficial.

Food cost and access were the major barriers to healthy eating mentioned by the participants. It was indicated that the prices of food such as fruit and vegetables were high and affected their daily consumption, supporting the recently published findings by the International Food Policy Research Institute (IFPRI) [238] and other studies [110, 132] which examined fruit and vegetable cost versus consumption Ethiopia and Ghana. Additionally, family size and other priorities, separate food purchases and meal preparation for patients with T2DM were also perceived as barriers to eating healthy, similar to studies in Ghana and South Africa [132, 239] also conducted with patients with T2DM. Several participants felt that it was difficult to change eating habits and eliminate certain foods in their diet because they still craved food items they enjoyed prior to diagnosis with T2DM similar to that reported in Uganda [136]. It was also noted that patients with T2DM experienced dilemmas with regard to what to eat during social events and travel, which also hindered healthy eating. Additionally, participants expressed concerns about conflicting dietary information from different sources, which was also too general. Unavailability of appropriate guidelines for the management of T2DM in Malawi and the lack of trained registered dietitian nutritionists should be a priority moving forward in order to address this problem. More specifically providing more in-depth evidence based appropriate nutrition education on a healthy balanced diet fr T2DM that emphasizes portion size control, meal regularity, how to deal with food insecurity issues, and CHO counting, without altering cultural food preferences is recommended.

The barriers to physical activity included diabetes-related comorbidities such as stroke, similar to previously published findings in Kenya and India [138, 240]. Furthermore, the urban participants mentioned that fear of public ridicule was a barrier to physical activity, consistent with a study done in urban Cameroon [133]. However, some of the facilitators for physical

activity engagement included; engaging in household chores, especially women, and labor-intensive jobs for men as farming.

Social support networks identified via the eco-maps were in agreement with other similar studies that showed that individuals with T2DM individuals had strong ties to health workers and family members [27, 135, 139, 160, 242]. But, for those residing in the urban area, diabetes peer groups were also deemed valuable for support. Evidence has shown that peer support in self-management of diabetes, yields positive health outcomes [243-245].

The A1C, which is the primary outcome of this study, was influenced by multiple factors. Based on the components of the socio-ecological model, primary findings are grouped within the components: intrapersonal (individual level or microsystem), interpersonal (family and friends or mesosystem), institutional and community settings (workplace and homes or ecosystem) and policy environments (macrosystem) (See Figure 6 which follows).

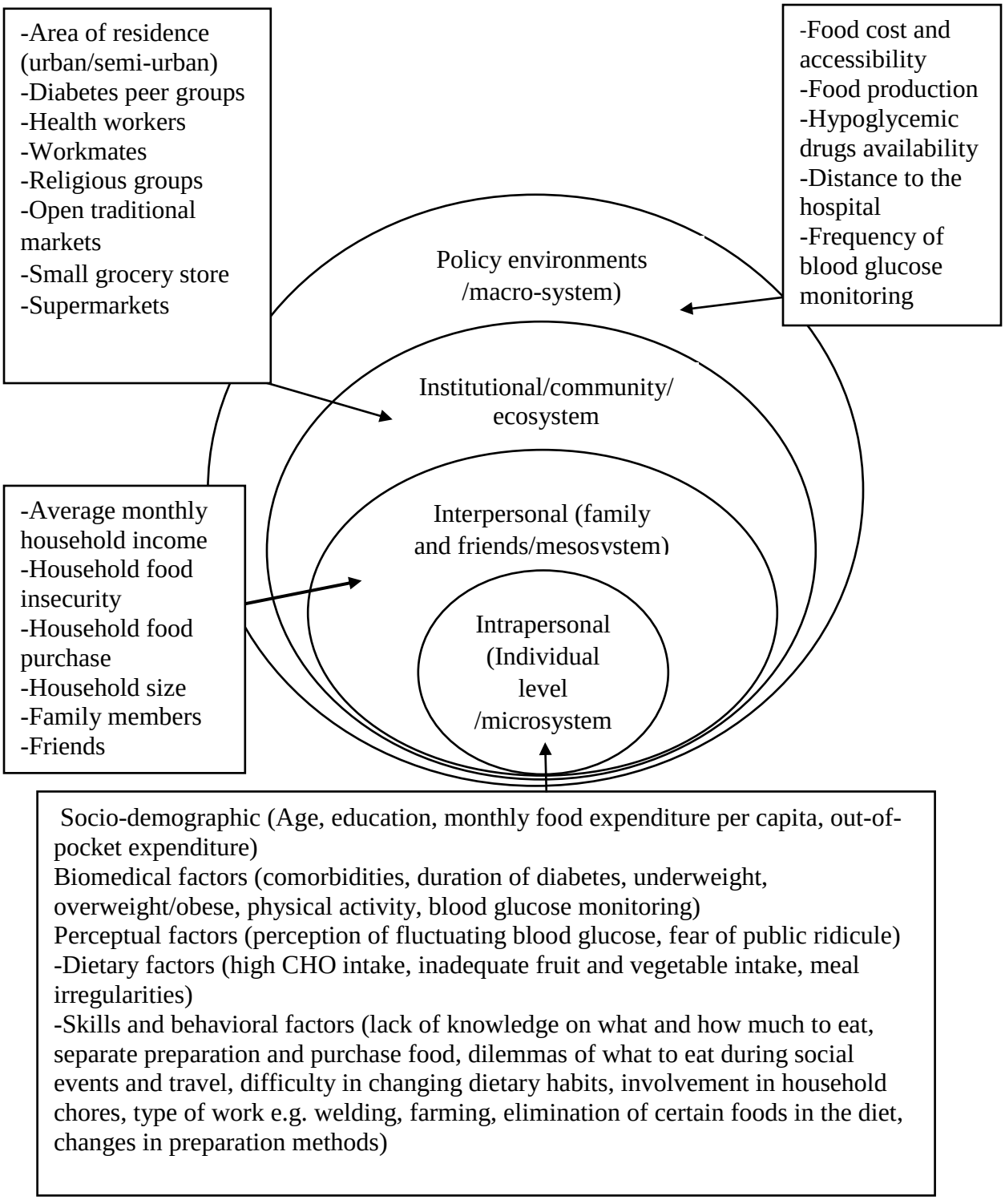


Figure 6: Summary of results based on the components of the socio-ecological model

B. Policy and practice recommendations

Glycemic status of adults diagnosed with T2DM in Malawi was influenced by multiple factors, which could help in health policy revisions relative to diabetes services to improve the standards of care for optimal glycemic status. The Ministry of Health in Malawi is currently implementing essential health care packages for different conditions including diabetes services. Limited accessibility to resources and services led to infrequent monitoring of blood glucose, running short of medication, out-of-pocket expenditures and a longer distance to the hospitals. It is therefore necessary to maximize the diabetes services through community outreach programs, especially to reach those far away from the hospital, and particularly in the semi-urban area where people are spread out. Additionally, the Ministry of Health should advocate and lobby for availability of a wider variety of oral hypoglycemic drugs since only two were mentioned. In developed countries, there is a plethora of drug choices, which enhances treatment in conjunction with self-management practices to achieve better metabolic outcomes.

Underweight, overweight/obese and physical activity were independent factors related to elevated glycemic status. Therefore, when providing diabetes education, health workers should continue to enforce strategies for appropriate lifestyle behaviors such as weight management by addressing both underweight and overweight/obesity and being physically active. To optimize glycemic status.

Dietary quality was generally inadequate in both urban and semi-urban adults diagnosed with T2DM in Malawi, high in CHO, and insufficient fruit, and vegetables. In addition, meals were also irregular and associated with chronic hyperglycemia. Inadequate knowledge on what and how much to eat for optimal blood glucose coupled with the provision of nutrition education by health workers who were not trained in nutrition and the non-availability of general dietary

guidelines for T2DM prevention and management were notable findings that need to be addressed. There is an urgent need for Malawi to develop dietary guidelines specific for T2DM prevention and management. These dietary guidelines will help in the development of nutrition education materials such as food exchange list, carbohydrate counting tools, portion control and meal planning. The nutrition education materials can subsequently be used for providing training to nutritionists, dietitians, and health workers to increase accuracy of information for individuals with T2DM. Additionally, even if nutritionists in the hospitals are overwhelmed with cases of undernutrition, it is imperative to support the implementation of NCD services especially in providing nutrition education and counseling to patients with T2DM.

Food insecurity in Malawi has been linked to undernutrition and rural areas for a long time. Our findings show that there is also an NCD link specifically with regard to compromised dietary diversity and poorer unacceptable glycemic status. Therefore, it is suggested that food insecurity topics should be incorporated in nutrition education and assessments/screening periodically to identify the groups at risk at the clinical/hospital level. Additionally, the Ministry of Health and Agriculture should lobby for the implementation of food security programs targeting families with NCDs regardless of location of residence. Food cost and accessibility, especially of fruit and vegetables, were barriers to healthy eating due in part to seasonality. Previous studies that promoted home/community gardening in developed and developing countries have shown improved dietary intakes, less expenditure on food and positive health outcomes [222-226]. Therefore, promoting vegetable and fruit gardening either at home or in the community (e.g. with diabetes peer groups) would be a potentially sustainable way of combating food accessibility and availability among patients with T2DM and others in both urban and semi-urban areas.

Strong support systems were identified for diabetes management from health workers, families and diabetes peer groups (in urban areas). Not much was mentioned about churches and workmates. Initiating workplace healthy food choices and eating programs to prevent and manage NCDs including T2DM in Malawi might be helpful especially in urban areas where the majority of the people with NCDs are residing and working. Additionally, engaging churches as the platform for dissemination and teaching people about NCDs would be paramount as most people from both urban and semi-urban areas are active in church activities.

C. Future research recommendations

The present study provides important information on the factors associated with glycemic status such as socio-demographic, biomedical, perceptual, out-pocket expenditure, dietary, and food security. In addition, barriers and facilitators to healthy eating and physical activity including social support systems were identified.

The factors associated with unacceptable glycemic status among young adults especially warrants further investigation especially with regard to diet, lifestyle factors, access to care, diabetes self-care and health-seeking behaviors. Developing culturally appropriate and sustainable programs and testing the feasibility of other platforms such as religious groups and workplaces in both urban and semi-urban areas will provide insight into best approaches to use for this vulnerable population for which the disease ramifications if not diagnosed or controlled are devastating. Furthermore, this study targeted adults diagnosed with T2DM receiving diabetes services at public hospitals and the majority were low-income. It is therefore suggested that a similar study be done targeting those receiving diabetes care from the private hospitals and religious hospitals under the Christian Health Association of Malawi, which covers almost 29% of all health services in Malawi [69, 70], to examine if there are different determinants of

glycemic status. Also, there is need for a national long-term study to determine the factors contributing to suboptimal glycemic status over time with data collected from patients, health providers and policy makers.

The fact that food availability in Malawi depends with the season warrants a longitudinal study targeting patients with T2DM to establish changes in food patterns, diet quality and food security in relation to different biomarkers such as lipid profile and A1C over time across different regions and seasonality in Malawi. Previous studies have shown that seasonality and geographical regions plays a significant impact on clinical glycemic status of patients with T2DM, A1C tend to be unacceptably higher in cold/winter than hot/summer season, because of the physiological changes in glucose metabolism [246-249] Meal irregularities also impacted the glycemic status. As such, further study is necessary to understand meal pattern, skipping and snacking in relation to A1C in Malawi, because the likelihood of disorderly meal patterns is high due to limited resources coupled with food insecurity. Meal irregularities such as skipping breakfast and late evening meals have been reported to impact cardiometabolic health outcomes such as A1C, postprandial hyperglycemia, insulin sensitivity/response and fasting blood glucose [211-215]. Additionally, food purchase was the primary source of food for household consumption. A detailed study is needed to adequately address concerns of the food environment such as markets and diets and how they impact NCDs in urban, semi-urban and rural areas in Malawi.

Some of the barriers to healthy eating included difficulties in changing dietary habits, not knowing what and how much to eat and separate food purchase and preparation for adults diagnosed with T2DM. It is therefore suggested that an intervention study be done on nutrition education and counseling for dietary behavior change using the trans-theoretical model [250] to

be able to examine the stages of change such pre-contemplation, contemplation, preparation, action, maintenance, and termination. The study should target adults with T2DM and their family members because socio-environmental factors also contributed to suboptimal glycemic status.

D. Strengths of the study

The strength of this study includes the following. 1) The study was a mixed method— both quantitative and qualitative—and was conducted in two locations in two phases. The first was quantitative in nature with the sample of 428 adults diagnosed with T2DM and the second phase was qualitative with four focus group discussions (two for each gender— male and female) in urban and semi-urban hospitals. 2) The major outcome of the study was the gold standard biomarker of glycemic status (A1C), which is not commonly done in Malawi. Additionally, the study had several aspects such as socio-demographics, biomedical, perceptual, out-of-pocket expenditure on diabetes care, dietary intakes, food insecurity, barrier and facilitators to healthy eating and physical activity and social support systems including the eco-maps. The results of the study are addressed different issues within the socio-ecological model.

E. Limitations of the study

The cross-sectional design of the study does not allow for causality, only associations. Additionally, self-reported data such as the comorbidities, cost of diabetes care, and dietary recalls may have been biased because of the potential for subjectivity with self-reports. The study participants were those receiving diabetes services from the public hospitals in two areas of the central region namely; Lilongwe (urban) and Kasungu (semi-urban), which do not represent all patients with T2DM in Malawi. Therefore, the results may not be generalizable. Food availability and accessibility in Malawi depends on the season, but this study was done at the

beginning of the dry season (June-August 2017). Therefore, the dietary and food insecurity data is applicable only to that particular period.

F. Conclusions

In summary, glycemic status of adults diagnosed with T2DM in Malawi is suboptimal, regardless of the location of residence. The determinants of unacceptable glycemic status included: younger age, distance travelled to the hospital, physical activity level, underweight, overweight/obese status, number of comorbidities, duration of diabetes, need for additional blood glucose monitoring beside the government hospital and participant perceptions of fluctuating blood glucose. Additionally, hypertension was the common comorbidity, although peripheral neuropathy and retinopathy were also high among those with A1C≥8%. Out-of-pocket expenditure for diabetes care was higher in urban than semi-urban areas. But the expenditure increased with a decrease in A1C levels. Diet quality was generally poor, high in CHO, low-moderate in fat and protein and inadequate fruits and vegetable intakes. High CHO intake and meal irregularities increased the likelihood of having A1C≥8%. Food insecurity decreased diversity of the diet and increased the A1C in both urban and semi-urban participants. Social and environmental factors also played a role as barriers, facilitators to healthy eating and physical activity, as well as social support systems for diabetes self-management behaviors. Family and health worker ties acted as facilitators to healthy eating and physical activity, as well as a social support system. T2DM definitely warrants more in-depth attention in Malawi in order to decrease the persistence of unacceptable glycemic status and inevitable associated complications. Population productivity and long-term benefits for the nation cannot be ignored.

APPENDICES

APPENDIX A: Individual interviews questionnaire

MICHIGAN STATE
UNIVERSITY

DIETARY AND ASSOCIATED DETERMINANTS OF GLYCEMIC CONTROL AND TYPE 2 DIABETES SELF-MANAGEMENT AMONG ADULTS IN MALAWI

INDIVIDUAL INTERVIEW QUESTIONNAIRE

JUNE 2017

SECTION 1: SOCIO-DEMOGRAPHIC AND ECONOMIC INFORMATION

General instruction: Circle responses from the respondents where appropriate.

Q1. Gender of respondent
- Male----------1
- Female----------2

Q2. Age of respondent (years):----------

Q3. District of residence
- Lilongwe ----------1
- Kasungu----------2

Q4. Area of residence (*Lilongwe participants only*) ----------

Q5. Name of Group Village Head (*Kasungu participants only*) ----------

Q6. How long have you lived in the main city/town (years) ----------

Q7. Just before you moved here, did you live in a city, in a town, or in the rural area?
- City, specify---------- 1
- Town, specify ---------- 2
- Rural Area, specify---------- 3
- Outside Malawi----------4
- None----------88

Q8. What is your religion?
- Christianity----------1
- Islam----------2
- Others (specify)---------- 77

Q9. What is your marital status?
- Married----------1
- Divorced----------2
- Widowed----------3
- Single ----------4
- Separated/cohabit----------5

Q10: Are you the head of the household
- Yes----------1
- No----------2

Q11. What is the highest level of education you have completed*??*
- Standard 1-4----------1
- Standard 5-8----------2
- Form 1-2----------3
- Form 3-4----------4
- Non-university with certificate/diploma----------5
- University with diploma/Degree -------6
- Other (*specify*)----------77
- None----------88

Q12. How many years have you been in school----------

Q13. What is your tribe?
- Tumbuka----------1
- Ngonde----------2
- Chewa----------3
- Yao----------4
- Ngoni----------5
- Sena----------6
- Lomwe----------7
- Other (*specify*)----------77

Q14. Respondent's main occupation?
- Farmer----------1
- Full time formal employment ----------2
- Self employed *(specify*)---------- 3
- Casual employment----------4
- Business, (*specify)*---------- 5
- Domestic/housework---------- 6
- Retired----------7
- Other (*specify*)---------- 77
- None----------88

Q15. How many people including yourself, live in your household?
- No. of children under 18 years ---------
- No. of adults----------

	Q16. Can you tell me what is the average income of the household per month? MK ---------- Q17. Can you tell me what is your average income per month (respondents income) MK----------

SECTION 2: DIABETES-RELATED INFORMATION: Diabetes history, treatment and blood glucose monitoring

Q18. How long has it been since the doctor or nurse told you that you have sugar disease (years)? ---------- Q19. How did you find out you have sugar disease? Routine checkup----------1 Sick ----------2 Community event where they checked our blood ----------3 Other (*specify*)----------77 Q20. If Q 19 is 2, ask how he/she was feeling (symptoms) and for how long (months)? Weight loss----------1 Frequent urination----------2 Excessive thirst----------3 Other (*specify*)----------77 Q21. How many people in your household (*living in the same house*) have diabetes? ---------- Q22. Other than your immediate household, in your family, who else has/had diabetes? (*multiple responses are allowed*). Father----------1 Mother ----------2 Grandparents----------3 Sisters/brother----------4 Uncle/aunt----------5 Children ----------6 None----------88 Other *(specify*)----------77 Q23. How often do you go to the hospital/clinic to check your blood sugar? Once a month----------1 Once in two months----------2 Every three months---------- 3 Other (*specify*)----------77	Q24. After the nurse/doctor has checked your blood sugar, what are your results like? Always good (normal levels)----------1 Sometimes good (fluctuating)----------2 Not good always (above normal levels)----------3 Changes (reducing)----------4 Changes (increasing)----------5 Other *(specify*)----------77 *Confirm and record most recent fasting blood glucose from health passport* ---------- Q25. Is your blood sugar levels lower now than first found with sugar disease? Yes----------1 No----------2 Don't Know----------99 Q26. Apart from the government hospital/clinic, do you sometimes go to private clinic to check your blood sugar? Yes----------1 No----------2 Q27. How much does it cost to check your blood sugar at private clinic? MK ---------- Q28. Do you sometimes check blood sugar levels at home? Yes----------1 No----------2 Q29. If yes to Q28, what is the cost of test strips? MK ----------(Approx.) Q30.What type of diabetes treatment do you use? Diet alone----------1 Tablets----------2 Insulin injections ---------- 3 Diet+ Tablets----------4 Diet + insulin injections----------5 Diet + exercise----------6 Other (*specify*)----------77

Q31. If you take diabetes tablets, do you take as recommended by the nurse/doctor?

Yes----------1
No----------2

Q32. What is the name of diabetes tablets (sugar lowering drug) you are currently taking ----------

Q 33: How frequent do you take diabetes tablets (sugar lowering drugs)----------

Q34. Do you sometimes run short of the diabetes medications you get from the government hospital/clinic before the next visit?

Yes----------1
No----------2

Q35. Do you sometimes buy diabetes medications, in addition to the ones you get from the government hospital/clinic?

Yes----------1
No----------2

Q36. If yes to Q35, where do you buy medication?

Private hospitals----------1
Private pharmacies----------2
Other(specify)----------77

Q37. How much does it cost for the medication, (MK) ----------(Approx.)?

Q38. Apart from the diabetes tablets (sugar lowering drugs), do you take any other drugs?

Yes----------1
No----------2

Q39. If yes to Q 38, what is the name of drug and for what purpose?----------

Diabetes related - problems and other conditions

Q40. Have you ever been hospitalized because of problems related to sugar disease?

Yes----------1
No----------2

Q48. Do you smoke? And how often in a month?

Q41. Have you been told by the doctor or nurse if you have any of the following conditions since you have had sugar disease?

1 = Yes 2=No

High blood pressure----------
Eye problems----------
Nerve problems----------
Kidney problems----------
Heart problems----------

Q42. Over the past three months, did you have malaria?

Yes----------1
No----------2

Diabetes education and lifestyle

Q43. Have you received any nutrition education (teaching) on diabetes management at the hospital/clinic?

Yes----------1
No----------2

Q44. If yes to Q43, who provided the teaching?

Doctor---------- 1
Nurse----------2
Nutritionist/Dietitian----------3
Other (*specify*)----------77

Q45. How was the teaching done at the hospital/clinic?

Group session----------1
Individual counseling----------2
Both 1&2----------3
Other (*specify*)----------77

Q46. Apart from the hospital/clinic, where else do you get information on sugar disease?

Church----------1
Radio/TV----------2
Diabetes Association of Malawi------3
Diabetes groups----------4
None----------88
Other (*specify*)----------77

Q47. Do you think you get the same message from everyone on sugar disease?

Yes----------1
No----------2

Yes----------1
No----------2

Q49. Do you drink alcohol? And how often in a month?
Yes----------1
No----------2

Access to diabetes hospital/clinic

Q50. Is diabetes hospital/clinic easy to get to from where you live?
Yes----------1
No----------2

Q51.What is the distance to the nearest diabetes hospital/clinic?
< 5 km----------1
5-10 km----------2
≥10 km----------3
Don't know----------99

Q52. What means of transport do you use when going to the hospital/clinic?
Personal vehicle----------1
Personal bicycle----------2
Private (taxi-car)---------- 3
Public transport ----------4
Walk----------5
Bicycle taxi (*kabaza*)----------6
Other (*specify)* ----------77

Q53. How much does it cost on transport per hospital/clinic visit? MK----------(Approx)

SECTION 3: PHYSICAL ACTIVITY LEVELS

Q54. Global Physical Activity Questionnaire (GPAQ)

Question	**Response**	**Code**
Activity at work		
P1. Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like [carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously?	Yes----------1 No----------2 If No, go to P 4	P1
P2. In a typical week, on how many days do you do vigorous intensity activities as part of your work?	Number of days----------	P2
P3. How much time do you spend doing vigorous-intensity activities at work on a typical day?	Hours---- Minutes----	P3 a-b
P4. Does your work involve moderate-intensity activity that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously?	Yes----------1 No----------2 If No, go to P 7	P4
P5. In a typical week, on how many days do you do moderate intensity activities as part of your work?	Number of days----------	P5
P6. How much time do you spend doing moderate-intensity activities at work on a typical day?	Hours---- Min-----	P6 a-b
Travel to and from places		
The next questions exclude the physical activities at work that you have already mentioned. Now I would like to ask you about the usual way you travel to and from places. For example, to work, for shopping, to market, to place of worship.		
P7. Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places?	Yes----------1 No----------2 If No, go to P 10	P7

P8. In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days----------	P8
P9. How much time do you spend walking or bicycling for travel on a typical day?	Hours---------- Min----------	P9 a-b
Recreational activities		
The next questions exclude the work and transport activities that you have already mentioned. Now I would like to ask you about sports, fitness and during your free time.		
P 10. Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate like [running or football,] for at least 10 minutes continuously?	Yes----------1 No----------2 If No, go to P 13	P10
P11. In a typical week, on how many days do you do vigorous intensity sports, fitness or recreational (leisure) activities?	Number of days----------	P11
P12. How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?	Hours---------- Min----------	P12
P13. Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate such as brisk walking,(cycling, swimming, volleyball, netball, football)for at least 10 minutes continuously?	Yes----------1 No----------2 If No, go to P 16	P13
P14. In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (leisure) activities?	Number of days----	P14
P15. How much time do you spend doing moderate-intensity sports, fitness or recreational (leisure) activities on a typical day?	Hours---------- Min----------	P15
Sedentary behavior		
The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent [sitting at a desk, sitting with friends, travelling in car, bus, reading, playing cards or watching television], but do not include time spent sleeping.		
How much time do you usually spend sitting or leaning back & relaxing on a typical day?	Hours---------- Min----------	P16 (a-b)

SECTION 4: DIETARY AND FOOD SECURITY ASSESSMENT

Now, I would like to ask you some questions about how you eat.

Q 55. Has the way you eat changed since you were told you have sugar disease? Yes----------1 No----------2 Q56. Has the eating pattern of the family changed since you were told you have sugar disease? Yes----------1 No----------2 Q57.Do you eat the same meal prepared for the family? Yes----------1 No, prepare separately sometimes-----2 No, prepare separately always----------3 Q58. How many meals do you take per day?	Q60. If No to Q59, what could be the reasons of not following eating plan? **Yes—1, No—2** High cost of foods for healthy eating---------- Seasonality of fruits and vegetables ---------- Difficulty in choosing appropriate and recommended foods---------- Foods prepared at home not based on my disease condition---------- Not getting required/adequate nutrition education on healthy eating---------- Other reasons

---------- Q59. Do you always follow your recommended eating plan /diet plan in trying to control blood sugar? Yes----------1 No----------2	Q61. Was yesterday a special day where special kinds of foods were eaten? Yes----------1 No----------2 Q62. Did you eat anything (meal or snack) OUTSIDE the home yesterday? Yes----------1 No----------2

Q63. Please describe the foods (meals and snacks) that you ate or drank yesterday during the day and night, whether at home or outside the home. Start with the first food or drink of the morning.

If yesterday **was** a special day, then ask the respondent to describe the foods (meals and snacks) consumed the **day before yesterday.**

Subject ID:	Day of the week:	Date:	
Time/meal	Description of the food or drink	Amount eaten	Place eaten

Q64. Based on response from Q63, fill in the food groups based on the information recorded. For any food groups not mentioned, ask the respondent if a food item from this group was eaten. ***Remember to ask Q65***

Dietary diversity measuring tool by FANTA

	Food group	Examples	Yes= 1 No=0	**Q65**. What foods did you like eating "most" frequently on weekly basis before you were told you have sugar disease? *(if she/he still remember)*
1	CEREALS	Corn/maize, rice, wheat, sorghum, millet or any other grains or foods made from these (e.g. *nsima*, bread, noodles, porridge or other grain products		
2	VITAMIN A RICH VEGETABLES AND TUBERS	pumpkin, carrots, squash, or sweet potatoes that are orange inside + *other locally available vitamin-A rich vegetables (e.g. red sweet pepper)*		
3	WHITE TUBERS AND ROOTS	white potatoes, white yams, white cassava, or other foods made from roots		
4	DARK GREEN LEAFY VEGETABLES	dark green/leafy vegetables, including wild ones + *locally available vitamin-A rich leaves such as amaranth, cassava leaves, kale, spinach etc*.		
5	OTHER VEGETABLES	Other vegetables (e.g. tomato, onion, eggplant), including wild vegetables		
6	VITAMIN A RICH FRUITS	ripe mangoes, cantaloupe, apricots (fresh or dried), ripe papaya, dried peaches + *other locally available vitamin A-rich fruits*		
7	OTHER FRUITS	other fruits, including wild fruits		
8	ORGAN MEAT (IRONRICH)	liver, kidney, heart or other organ meats or blood-based foods		
9	FLESH MEATS	beef, pork, lamb, goat, rabbit, wild game, chicken, duck, or other birds		
10	EGGS	Chicken, duck, guinea hen or any other egg		

11	FISH	fresh or dried fish or shellfish		
12	LEGUMES, NUTS AND SEEDS	beans, peas, lentils, nuts, seeds or foods made from these		
13	MILK AND MILK PRODUCTS	milk, cheese, yogurt or other milk products		
14	OILS AND FATS	oil, fats or butter added to food or used for cooking		
15	RED PALM PRODUCTS	Red palm oil, palm nut or palm nut pulp sauce		
16	SWEETS	sugar, honey, sweetened soda or sugary foods such as chocolates, candies, cookies and cakes		
17	SPICES, CONDIMENTS, BEVERAGES	spices(black pepper, salt), condiments (soy sauce, hot sauce), coffee, tea, alcoholic beverages		

Q66. Please describe the foods (meals and snacks) that you ate or drank any other typical day (apart from previous 24 hours) during the day and night, whether at home or outside the home. Start with the first food or drink of the morning.

Subject ID:	Day of the week:	Date:	
Time/meal	Description of the food or drink	Amount eaten	Place eaten

Q67. Apart from the diet, list any other foods or herbs or supplements that you use to manage blood sugar?

Access to food markets

Q68. What type of food market do you most frequently go to buy foods?

Open local markets----------1
Small grocery stores----------2
Super markets (Shoprite, Chipiku, People's Choice, SANA etc)----------3
Farm shop/gate----------4
Convenient stores (gas store)----------5
Street vending----------6
Other (*specify*)----------77

Q69.What is the distance to the daily market where you buy food?

< 5 km----------1
5-10 km----------2
≥10 km----------3

Q70. What kind of foods do you buy from the daily food market you go to? *(list down all the foods mentioned)*

Q70. What is the second type of food market that you frequently go to buy foods? (*multiple response)*

Open local markets----------1
Small grocery stores----------2
Super markets (Shoprite, *Chipiku*, People's Choice, *SANA* etc)----------3
Farm shop/gate----------4
Convenient stores (gas store)----------5
Street vending----------6
Other (*specify*)----------77

Q71. What kind of foods do you buy from the second food market you go to? *(list the foods)*

Q72. On average per month, how much money is used to buy food for your household? (MK)
……Approx

Q73. If you changed your diet, are you using more money now to buy food than before you had sugar disease?

Yes----------1
No----------2

Q74. What are the two main sources of food in your household? (multiple responses are allowed)

Source	Type of food

Own production----------1
Purchased----------2
Borrowed, bartered, exchanged for labour, gift from friends or relatives------3
Food aid----------4
Other (Specify) ----------77

Q75. I would like to ask you some questions regarding food access at your household

Household Food Insecurity Access Scale (HFIAS) Measurement Tool by FANTA

INSTRUCTION: For each of question, consider what has happened in the <u>past 4 weeks</u>. *Read out each condition and ask if respondent or any household member experienced it in the past 4 weeks focusing on the words in* ***bold.*** *If response to the occurrence question is* ***yes,*** *ask how often it happened in the past four weeks (probing to get correct code). If no, move to next question until all 9 questions are completed. Note that the reason for experiencing a specific condition should be lack of* ***food/resources*** *as per question and not other reasons such as travel, sickness e.t.c,* ***And remember that food is not only maize.***

No.	QUESTION	RESPONSE OPTIONS: 0 = No 1=Yes	**How often did this happen?** 1 = Rarely (1-2 times) 2 = Sometimes (3-10 times) 3 = Often (more than 10 times)
1	In the past four weeks, did you **worry** that your household would not have enough food?		
2	In the past four weeks, were you or any household member **not able to eat the kinds of foods you preferred** because of a lack of resources?		
3	In the past four weeks, did you or any household member have **to eat a limited variety of foods** due to a lack of resources?		
4	In the past four weeks, did you or any household member have to **eat some foods that you really did not want to eat** because of a lack of resources to obtain other types of food?		
5	In the past four weeks, did you or any household member have to **eat a smaller meal than you felt you needed** because there was not enough food?		
6	In the past four weeks, did you or any other household member have **to eat fewer meals in a day** because there was not enough food?		
7	In the past four weeks, **was there ever no food to eat of any kind** in your household because of lack of resources to get food?		
8	In the past four weeks, did you or any household member go to **sleep at night hungry** because there was not enough food?		

9	In the past four weeks, did you or any household member go **a whole day and night without eating** anything because there was not enough food?		

Section 5: ANTHROPOMETRIC MEASUREMENTS

Q76: Now, I would like to take simple measurements.

Weight: _____ kg Height: _____ cm

Waist: _____ cm Hip: _____ cm

Section 6: GLYCOSYLATED HEMOGLOBIN (A1C)

Q77: Now, I would like to request you provide us with few drops of blood so that we can check to see your blood sugar levels for the past three months.

A1C results: _____

THANK YOU!

END OF INTERVIEW

APPENDIX B: Focus group discussions questionnaire

MICHIGAN STATE
UNIVERSITY

DIETARY AND ASSOCIATED DETERMINANTS OF GLYCEMIC CONTROL AND TYPE 2 DIABETES SELF-MANAGEMENT AMONG ADULTS IN MALAWI

FOCUS GROUP DISCUSSION GUIDE

JUNE 2017

Instructions: *Administer section one to each individual respondent while section two to the group.*

Section 1: Demographic and economic characteristics

ID code: ……../……/……../

Q1. Gender of the respondent
- Male----------1
- Female----------2

Q2. Age of the respondent (years):----------

Q3. District of residence
- Lilongwe ----------1
- Kasungu----------2

Q4. Area of residence (*Lilongwe participants only*) ----------

Q5. Name of Group Village Head (*Kasungu participants only*) ----------

Q6. How long have you lived in the main city/town (years) ----------

Q7. Just before you moved here, did you live in a city, in a town, or in the rural area?
- City, specify---------- 1
- Town, specify ---------- 2
- Rural Area, specify----------3
- Outside Malawi----------4
- None----------88

Q8. What is your religion?
- Christianity----------1
- Muslim----------2
- Others specify---------- 77

Q9. What is your marital status?
- Married----------1
- Divorced----------2
- Widowed----------3
- Single ----------4
- Separated/cohabit----------5

Q10. What is the highest level of education you have completed*?*
- Standard 1-4----------1
- Standard 5-8----------2
- Form 1-2---------- 3
- Form 3-4---------- 4
- Non-university with certificate/diploma---------- ----------5
- University with diploma/Degree -------6
- Other (*specify*)----------77
- None----------88

Q11. What is your tribe?
- Tumbuka----------1
- Ngonde----------2
- Chewa----------3
- Yao----------4
- Ngoni----------5
- Sena----------6
- Lomwe----------7
- Other (*specify*)----------77

Q12. Respondent's main occupation?
- Farmer----------1
- Full time formal employment ---------- 2
- Self-employed *(specify*)---------- ----3
- Casual employment---------- 4
- Business, (*specify)*---------- ---5
- Domestic/housework---------- 6
- Retired----------7
- Other (*specify*)----------77
- None----------88

	Q13. How many people including yourself, live in your household? No. of children under 18 years --------- No. of adults---------- Q14. Can you tell me what is the average income of the household per month? ---------- ---------- --------MK

Section 2: Focus group discussion questions

Intrapersonal (individual level)

1. Tell me about your routine with diabetes?
2. How has it changed your eating pattern?
3. How about physical activity level?
4. How do personal factors help you to manage well your diabetes, especially on diet and physical activity? (*Probe: income, knowledge, cultural beliefs and religious restrictions)*
5. From your experience, how do personal factors hinder management of diabetes, especially on diet and physical activity? (*Probe: income, knowledge, cultural beliefs and religious restrictions)*
6. Are there any specific foods or other things that you believe/know help in reducing blood sugar? (*Probe: foods or herbs or supplements and how they help)*
7. How do you manage diabetes on special occasions such as weddings or Christmas and parties? *(Probe: diet)*

Interpersonal

8. How does the family members, friends, neighbors, colleagues and fellow diabetes patients support you as you manage diabetes? *(Probe: diet and physical activity)*
9. Does the eating practices of your household affects managing your diabetes? *(probe: eating/meal pattern, cooking practices, eating away from home, food shopping, food availability)*

Institutional and community level

10. What information do you get from hospitals on management of diabetes regarding diet and physical activity?
11. From your experience, how do you follow the advice given by nurse/doctors at the hospital? (*Probe: diet and physical activity*)
12. How do the church members, work colleagues support you as you manage diabetes? (*Probe*: *diet and physical activity)*
13. How are the foods that you eat outside your home different from what you eat at home? (*Probe: workplace, church, travelling etc)*
14. Does where you live/stay affect managing your diabetes? (*Probe: food availability and accessibility, access to market (market place, types of foods available), and physical activity places).*
15. How does media/information/ads affects your diet and physical activity as managing diabetes?
16. Do you want to say anything else about your diet and physical activity?

APPENDIX C: Ethical approval and consent form

Institutional Review Board at Michigan State University

MICHIGAN STATE
UNIVERSITY

Modification and Continuing Review APPROVAL

April 12, 2018

To: Lorraine Weatherspoon

Re: **MSU Study ID:** LEGACY17-060
IRB: BIRB
Principal Investigator: Lorraine Weatherspoon
Category: Expedited 2, 6, 7
Submission: Modification and Continuing Review MODCR00000175
Submission Approval Date: 4/12/2018
Effective Date: 4/12/2018
Project Expiration Date: 4/11/2019

Title: Dietary and Associated Determinants of glycemic Control and Type 2 Diabetes Self-Management Among Adults in Malawi

This submission has been approved by the Michigan State University (MSU) BIRB. The submission was reviewed by the Institutional Review Board (IRB) through the Non-Committee Review procedure. The IRB has found that this research project protects the rights and welfare of human subjects and meets the requirements of MSU's Federal Wide Assurance (FWA00004556) and the federal regulations for the protection of human subjects in research (e.g., 45 CFR 46, 21 CFR 50, 56, other applicable regulations).

Documents Included:
• HRP-510 - Template - Legacy Protocol.mphwanthe (1).docx, Category: IRB Protocol;

Continuing Review: IRB approval is valid until the expiration date listed above. If the research continues to involve human subjects, you must submit a Continuing Review request at least one month before expiration.

Modifications: Any proposed change or modification with certain limited exceptions discussed below must be reviewed and approved by the IRB prior to implementation of the change. Please submit a Modification request to have the changes reviewed. If changes are made at the time of continuing review, please submit a Modification and Continuing Review request.

Immediate Change to Eliminate a Hazard: When an immediate change in a research protocol is necessary to eliminate a hazard to subjects, the proposed change need not be reviewed by the IRB prior to its implementation. In such situations, however, investigators must report the change in protocol to the IRB immediately thereafter.

Office of Regulatory Affairs
Human Research Protection Program

4000 Collins Road
Suite 136
Lansing, MI 48910

517-355-2180
Fax: 517-432-4503
Email: irb@msu.edu
www.hrpp.msu.edu

MICHIGAN STATE UNIVERSITY

Initial IRB Application Approval

March 7, 2017

To: Lorraine Weatherspoon
334 Trout FSHN Bldg
MSU

Re: **IRB#** 17-060 Category: EXPEDITED
Approval Date: March 7, 2017
Expiration Date: March 6, 2018

Title: Dietary and Associated Determinants of glycemic Control and Type 2 Diabetes Self-Management Among Adults in Malawi

The Institutional Review Board has completed their review of your project. I am pleased to advise you that **your project has been approved**.

Please send Kamuzu Central Hospital and Kasungu district hospital ethics committee approval letters and approved consent forms to the MSU IRB upon receipt. Note if the consent forms approved by the MSU IRB are revised by Kamuzu Central Hospital and Kasungu district hospital ethics the revised forms must be submitted to the MSU IRB via a revision before implementation.

The committee has found that your research project is appropriate in design, protects the rights and welfare of human subjects, and meets the requirements of MSU's Federal Wide Assurance and the Federal Guidelines (45 CFR 46 and 21 CFR Part 50). The protection of human subjects in research is a partnership between the IRB and the investigators. We look forward to working with you as we both fulfill our responsibilities.

Renewals: IRB approval is valid until the expiration date listed above. If you are continuing your project, you must submit an ***Application for Renewal*** application at least one month before expiration. If the project is completed, please submit an ***Application for Permanent Closure***.

Revisions: The IRB must review any changes in the project, prior to initiation of the change. Please submit an ***Application for Revision*** to have your changes reviewed. If changes are made at the time of renewal, please include an ***Application for Revision*** with the renewal application.

Problems: If issues should arise during the conduct of the research, such as unanticipated problems, adverse events, or any problem that may increase the risk to the human subjects, notify the IRB office promptly. Forms are available to report these issues.

Please use the IRB number listed above on any forms submitted which relate to this project, or on any correspondence with the IRB office.

If we can be of further assistance, please contact us at 517-355-2180 or via email at IRB@msu.edu. Thank you for your cooperation.

c: Getrude Mphwanthe

Office of Regulatory Affairs
Human Research Protection Programs

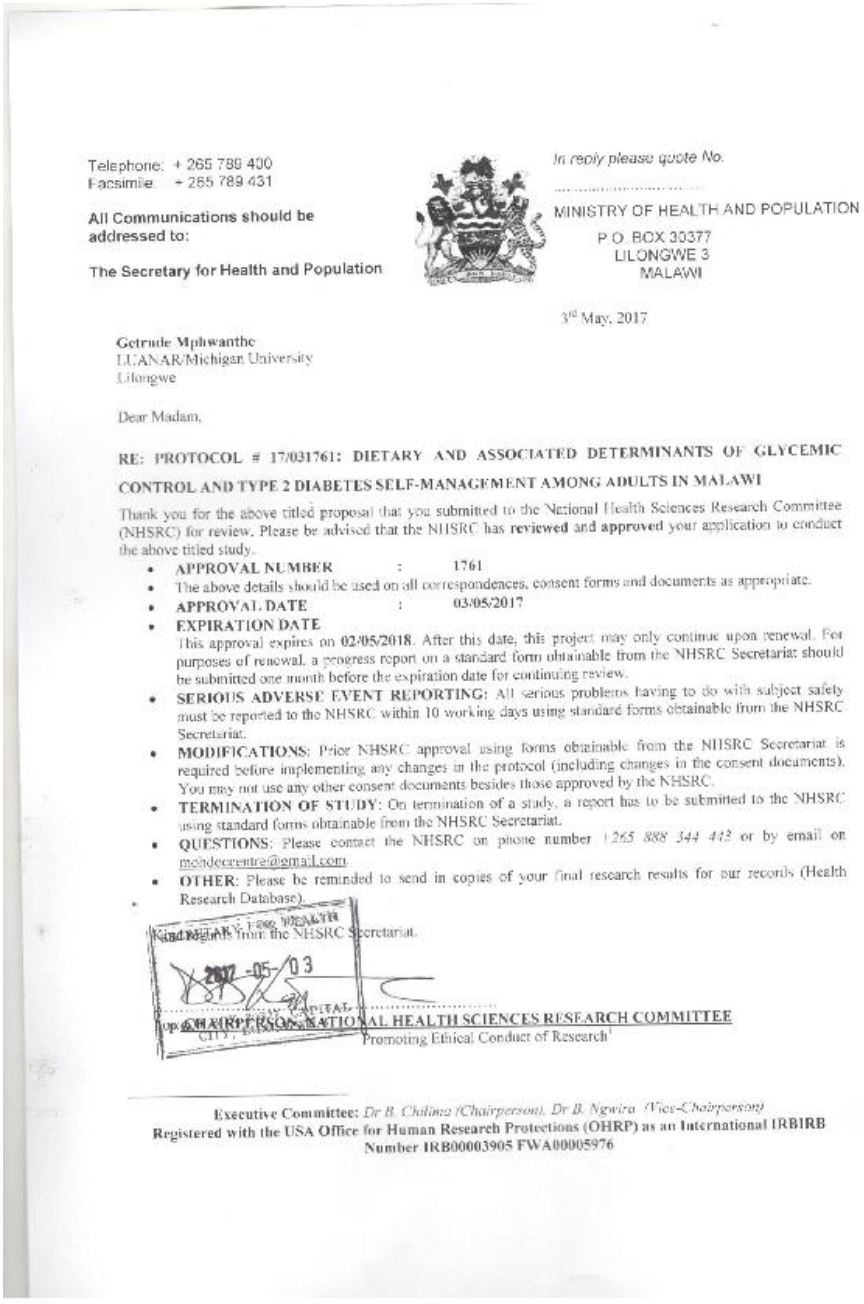
Biomedical & Health Institutional Review Board (BIRB)

Community Research Institutional Review Board (CRIRB)

Social Science Behavioral/Education Institutional Review Board (SIRB)

Olds Hall
408 West Circle Drive, #207
East Lansing, MI 48824
(517) 355-2180
Fax: (517) 432-4503
Email: irb@msu.edu
www.hrpp.msu.edu

National Health Research Committee in the Ministry of Health in Malawi



Telephone: + 265 789 400
Facsimile: + 265 789 431

All Communications should be addressed to:

The Secretary for Health and Population

In reply please quote No.

.....

MINISTRY OF HEALTH AND POPULATION
P O BOX 30377
LILONGWE 3
MALAWI

3rd May, 2017

Getrude Mphwanthe
LUANAR/Michigan University
Lilongwe

Dear Madam,

RE: PROTOCOL # 17/031761: DIETARY AND ASSOCIATED DETERMINANTS OF GLYCEMIC CONTROL AND TYPE 2 DIABETES SELF-MANAGEMENT AMONG ADULTS IN MALAWI

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review. Please be advised that the NHSRC has **reviewed** and **approved** your application to conduct the above titled study.

- **APPROVAL NUMBER** : 1761
- The above details should be used on all correspondences, consent forms and documents as appropriate.
- **APPROVAL DATE** : 03/05/2017
- **EXPIRATION DATE**
  This approval expires on **02/05/2018**. After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the NHSRC Secretariat should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING:** All serious problems having to do with subject safety must be reported to the NHSRC within 10 working days using standard forms obtainable from the NHSRC Secretariat.
- **MODIFICATIONS**: Prior NHSRC approval using forms obtainable from the NHSRC Secretariat is required before implementing any changes in the protocol (including changes in the consent documents). You may not use any other consent documents besides those approved by the NHSRC.
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the NHSRC using standard forms obtainable from the NHSRC Secretariat.
- **QUESTIONS**: Please contact the NHSRC on phone number *+265 888 344 443* or by email on mohdecentre@gmail.com.
- **OTHER**: Please be reminded to send in copies of your final research results for our records (Health Research Database).

Kind Regards from the NHSRC Secretariat.

SECRETARY FOR HEALTH
2017 -05- 03
CAPITAL CITY

Dr. CHAIRPERSON, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE
Promoting Ethical Conduct of Research[1]

Executive Committee: *Dr B. Chilima (Chairperson), Dr B. Ngwira (Vice-Chairperson)*
Registered with the USA Office for Human Research Protections (OHRP) as an International IRB/IRB Number IRB00003905 FWA00005976

Telephone: + 265 253 400
Fax: + 265 253 630

All Communications should be addressed to:

The District Health Officer

In reply please quote No.
Ref. No. KDH/PF/635
MINISTRY OF HEALTH
KASUNGU DISTRICT HOSPITAL
P. O. BOX 19,
KASUNGU
15th February, 2017

TO WHOM IT MAY CONCERN

LETTER OF SUPPORT

This is letter of support, as required by the National health Sciences Research Committee in Malawi, for ***Getrude Mphwanthe,*** a graduate student at Michigan State University in the United States, currently, studying for the Doctor of Philosophy in Human Nutrition. She intends to conduct a research at Kasungu district hospital, which is titled ***"Dietary and associated determinants of glycemic control and type 2 diabetes self-management among adults in Malawi***". The study is aimed at elucidating the extent to which local Malawians diets influence glycemic control.

The student has approached us and is permitted to conduct her study at Kasungu district hospital.

Yours Sincerely,

Dr Ireen Kamwaza,
Acting District Health Officer

1

Consent form in English

Research Participant Information and Consent Form

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation, and to empower you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Study Title: Dietary and associated determinants of glycemic control and Type 2 diabetes (T2DM) self-management among adults in Malawi

Researcher and Title: Lorraine Weatherspoon, Professor of Human Nutrition

Department and Institution: Food Science and Human Nutrition, Michigan State University

Contact information: Phone; +1 (517) 353-3328; Email: weathe43@anr.msu.edu OR Getrude Mphwanthe +265 999044481

PURPOSE OF RESEARCH

You are being asked to participate in a research study to assess diet quality and socio-environmental factors affecting glycemic control in adults diagnosed with T2DM in Malawi

You have been selected as a possible participant in this study because are a Malawian adult aged 24 years and above diagnosed with T2DM and coming for glucose checkup at this hospital.

From this study, the researchers hope to learn the extent to which local Malawian diets influence glycemic control in adults diagnosed with T2DM. The results shall also be used to write a dissertation to meet requirements of Doctor of philosophy (PhD) study at Michigan State University.

Your participation in this study will take about one hour.

WHAT YOU WILL DO

You will be asked questions on general diabetes care, dietary intakes, food security and physical activity. We will also take anthropometric measures such as weight, height, waist and hip circumference. We will also take blood sample drawn by laboratory technician during your routine blood glucose checkup to assess your glycated hemoglobin levels (A1C). We will also conduct focus group discussions to learn more of the socio-environmental factors affecting diabetes management, especially on diet and physical activity. If you choose not to participate in the study your care will not change, your fasting blood glucose will still be checked by the nurse and you will attend nutrition and diabetes talks.

POTENTIAL BENEFITS

The potential benefits for taking part in this study is that you will be able to know how local Malawian diets affects glycated hemoglobin levels (A1C). However, your participation in this study may influence direct policies and help in developing culturally specific and appropriate dietary interventions on the management and prevention of diabetes.

POTENTIAL RISKS

There are no risks to you for participating in the study. However, researchers may want to repeat some anthropometric measurements such as height, weight, waist and hip circumference if not taken correctly.

PRIVACY AND CONFIDENTIALITY

The data for this study will be collected confidentially. The Information collected will be kept confidential to the maximum extent allowable by law. Only the research team, and the Michigan State University Human Research Protection Program shall have access to the data. The data shall be stored at Dr. Lorraine Weatherspoon lab in the department of Food Science and Human Nutrition at Michigan State University for a minimum of 3 years after the project closes. The finding of this study shall be published in reputable journals and shall be presented at conferences but identities of participants will remain strictly confidential.

YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

Your participation in this study is on voluntary basis. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

You have the right to say no.

You may change your mind at any time and withdraw from the study.

You may choose not to answer specific questions or to stop participating at any time.

Choosing not to participate in this study will not make any difference in the quality of diabetes care you receive at this hospital.

If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact Dr. Weatherspoon at 355-8474, ext. 136 or Getrude Mphwanthe at +265 999044481 with any questions or to report an injury.

COSTS AND COMPENSATION FOR BEING IN THE STUDY

There are no out of pocket costs on your side for taking part in the study. You will get a compensation of $5 for participating in the study.

CONTACT INFORMATION

If you have concerns or any questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher: Dr. Lorraine Weatherspoon, G.M. Trout FSHN building, 469 Wilson Rd. Room 140, Michigan State University, East Lansing, MI 48824, or email weathe43@anr.msu.edu or Phone; +1(517) 353-3328 or Getrude Mphwanthe +265 999044481

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 408 West Circle Drive, Olds Hall Room 207, MSU, East Lansing, MI 48824.

DOCUMENTATION OF INFORMED CONSENT

Your signature line below means that you voluntarily agree to participate in this study. You will be given a copy of this form to keep.

_____ _____

Signature Date

If you agree to be audio taped during the focus group, please indicate "yes" in the space below.

Yes_____ No _____

If you agree to be photographed, please indicate "yes" in the space below.

Yes____ No ____

Consent form in *Chichewa*

Kalata wa chivomelezo/chilolezo chotenga nawo gawo pakafukufuku

Muli kupephedwa kutenga nawo gawo pa kafukukuku.Ochita kafukufuku amayenera kupereka chikalata ichi chofotokoza za ubwino ndi kuipa kotangapo gawo pa kafukufuku kuonenetsetsa kuti kutengapo gawo kwanu ndi chiganizo chomwe mwapanga mosakakamizidwa koma mwaufulu wanu. Choncho ndinu omasuka kufunsa funso lililonse lomwe mungakhale nalo kwa ochita kafukufuku.

Mutu wa kafukufuku: Chakudya ndi kadyedwe koyera posamalira matenda a shuga m'Malawi.

Mwini wakafukufuku ndi udindo wake: Lorraine Weatherspoon, pulofesa ndinso mphunzitsi wa ukachenjede pa nkhani ya zakudya ndi kadyedwe koyenera.

Komwe akuchokera: Food Science and Human Nutrition, Michigan State University

Keyala ndi nambala ya lamnya: Phone; +1 (517) 353-3328; Email: weathe43@anr.msu.edu Kapena Getrude Mphwanthe pa +265 999044481

CHOLINGA CHA KAFUKUFUKU

Muli kupephedwa kutengapo pali pa kafukufuku ofuna kuona momwe zakudya zaku Malawi zimathandizira kuti shuga mthupi akhale mumulingo wake.

Mwasakhidwa kutengapo mbali pa kafukufukuyi chifukwa muli ndi matenda a shuga ndinso mudakwanitsa zaka makhumi awiri ndi zinayi ndinso kuposera/kupyolera apo

Ochita kafukufuku akufuna kudziwa ngati chakudya ndi kadyedwe koyera ku Malawi kutha kuthandiza kuti shuga mthupi asamakwelere makamaka kwa anthu amene ali ndi matenda a shuga. Zosatili za kafukufukuyi zigwiritsidwa ntchito pokwaniritsa zofunikira pa maphunziro aukadaulo kusukulo yawu kachenjede ya Michigan State University

Kafukufuku adzatenga pafupifupi ola imodzi

ZOMWE TIDZACHITE

Mudzafunsidwa mafunso okhuzana momwe mumasamalira matenda a shuga, za kadyedwa, kapezedwe ka chakudya chokwanira ndinso masewero olimbitsa thupi. Tizakupephaninso kuti tikuyezeni kulemenra kwanu, tsikhu, kukula kwa chiuno ndi hipi. Tazakupephani kuti a zachipatala (laboratory technician) akutengeniko magazi pang'ono kuti tikayeze mulingo wa shuga magazi anu kwa miyezi itatu yapitawo. Tizakhalanos ndi zokambirana pa gulu zokhuzana ndi mene masamalira matenda a shuga, koma zokambira zathu makamaka zizakhala zokhuzana ndi kadyedwe koyenera ndi masewero olimbitsa thupi. If you choose not to participate in the study your care will not change, your fasting blood glucose will still be checked by the nurse and you will attend nutrition and diabetes talks. Dziwani kuti ngati mutasankha kusatengapo gawo pakafukufuku uyu, thandizo lomwe a Namwino kapena adokotala adzapereke kwa inu pa kasamalidwe ka matenda a shuga silidzasintha chifukwa simunalowe mkafukufuku.

PHINDU LOTENGA NAWO GAWO MU KAFUKUFUKU

Phindu lotengapo gawo pa kafukufukuyi ndi lakuti mudzadziwa mene zakudya zomwe timadya ku Malawi kuno mowe zimathandizithara ku matenda a shuga. Komabe dziwani kuti kutengapo gawo kwanu mukafukufuku uyu kudzathandiza ngakhale boma lithe kupanga ndondomeko ya chakudya ndi kadyedwe

koyenera makamaka pa matenda a shuga molingana ndi zakudya zomwe anthu amadya. Pothandiza kupewa ndi kasamalidwa ka matenda a shuga.

KUIPA KOLOWA MUKAFUKUFUKU

Palibe vuto lilonse lomwe lingaoneke kwa inu chifukwa mwalowa mukafukufuku ameneyu. Koma nthawi zina tizafuna kuti mwina tikuyezeninso sikelo, msikhu, mchiuno ndi hipi ngati sitinayeze bwino poyambirira

KUKUSUNGIRANI CHINSINSI PA KAFUKUFUKU

Kafukufuku ndi wa chinsinsi. Wochita kafukufuku sadzapanga zoti zomwe inu mwanena ziululike monga mwamalamulo a dziko. Amene adzadziwa za zomwe inu mwatiuza ndi ochita kafukufuku okha ndi omwe anapereka chilolezo kuti kafukufufku achitike. Zotsatira zidzasungidwa ku laboratare ya Dr. Lorraine Weatherspoon, gawo la sayansi ya zakudya ndi madyedwe oyenera ku sukulu ya ukachenede ya Michigan State University ku America. Dziwaninso kuti zotsatira zitha kudzaulutsidwa mmisonkhano ya akatswiri aza manyedwe oyenera, koma dzina lanu silidzatchulidwa kapena kulumizidwa ndi zotsatira zanu kuti mudziwike ayi.

UFULU OLOWA, KUKANA NDI KUTULUKA MKAFUKUFUKU

Kulowa mkafuufuku uyu ndu ufulu wanu. Simudzalandira chilango chifukwa chokana kutengapo gawo pakafukufuku, kapena kutaya mwayi uliwonse. Mutha kusiya popanda kukakamizidwa.

Dziwani kuti muli ndi ufulu okana.

Dziwani kuti muli ndi ufulu otuluka.

Mutha kusankha kusayankha mafunso ena kapenanso kusiya kuyankha mafunso nthawi iliyonse

Thandizo lanu silidzatengera kulowa kapena kukana kulowa kafukufuku ayi.

Ngati mutavulale chifukwa chotengepo mbali pa kafukufukuyi, sukulu ya ukachenjede ya Michigan State izakutandizani kuti mulandi chitandizo mwasanga. Ngati muli pa inshuwalansi ili yonse, a inshuwalansi azatumizilidwa kalata. A inshuwalansi azalipila ndalama malingana ndi ndondomeko yake, ngati ndalama zolipila zizapitilire, uzakhala udindo wanu kulipila ndalama zoonjezera. A sukula ya ukachenjede ya Michigan State sizapeleka chiongola dzanja chilichonse kamba ka ululu kapena kupweteka, pokhapokha malamulo atatero. Izi sizikuthandauza kuti mukuphwanya ufulu uliwonse muli nawo. Ngati muli ndi mafunso kapena mukufuna kupeleka uthenga kulingana ndi kuvulala kwanu utha kuyimba lamya kwa Dr. Weatherspoon +1(517) 353-3328, kapena Getrude Mphwanthe pa +265 999044481

MALIPIRO KAPENA CHIPEPESO MKAFUKUFUKU

Simudzagwiritsa ntchito kapena kuwononga ndalama yanu kapena kanthu kalikonse (ngati malipiro) chifukwa mwalowa mkafukufuku ayi. Komanso tidzafuna kupereka ka mphatso kangachepe kokwanira Mk 3,500.00 ($5) chifukwa chotengapo mbali pa kafukufukuyi.

KEYALA NDI MLAMNYA ZA WAMKULU WA KAFUKUFUKU

Ngati mutakhala ndi mafunso kapena nkhawa zili zonse pa kafukufuku ameneyu, chonde lumikizanani ndi mkulu wakafukufuku yemwe ali Mphunzitsi wanga pa keyala ndi lamnya izi: Dr.Lorraine Weatherspoon, G.M. Trout FSHN building, 469 Wilson Rd. Room 140, Michigan State University, East Lansing, MI 48824, or email weathe43@anr.msu.edu or Phone; +1(517) 353-3328 kapena Getrude Mphwanthe +265 999044481

Ngati mutankala ndimafunso kapena nkhawa zina zokhudzana ndi gawo kapena ufulu wanu mukafukufukuyu ndipo mukufuna kumva zambiri kapena kuthandizapo, ngakhale kupereka dandaulo pa kafukufuku ameneyu, mukhoza kulemba kalata kapena kuchita lamnya pa keyala ndi nambala ya lamnya zili mmusimu; Michigan State University's Human Research Protection Program pa 517-355-2180, Fax 517-432-4503, kapena email irb@msu.edu or regular mail at 408 West Circle Drive, Olds Hall Room 207, MSU, East Lansing, MI 48824.

UMBONI WA CHIVOMELEZO

kusainila kwanu mmusimu zitanthauza kuti mwavomereza mwaufulu popanda kukakamizidwa kuti inu ndi mwana wanu mulowe mkafukufuku. Mudzalandira kalata iyi kuti inunso musunge.

_____ _____

Tikitilani Tsiku Tsiku

Ngati mwavomela kuti zokamibilana pa gulupa zijambulidwe, sindikizani eya musimo.

Eya _____ Ayi _____

Ngati mwavomela kuti mujambulidwe chithuzi, sindikizani eya musimo.

Eya ____ Ayi ____

APPENDIX D: Demographic characteristics of the whole sample stratified by study location

	Overall (n=428)	**Urban (n=288)**	**Semi-urban (n=140)**		
Variable	n (%)	n (%)	n (%)	X^2	p-value
Gender				10.00	0.007
Male	131 (30.6)	74 (25.7)	57 (40.7)		
Female	297 (69.4)	214 (74.3)	83 (59.3)		
Age (mean±SD)	53.9±9.3	54.9±9.5	53.0±9.0		0.171
Marital status				4.31	0.038
Married	329 (77.4)	213 (74.5)	116 (83.4)		
Divorced/widowed	96 (22.6)	73 (25.5)	23 (16.6)		
Educational				2.329	0.127
Less or equal to primary	256 (59.8)	165 (57.3)	91 (65.0)		
Secondary and above	172 (40.2)	123 (42.7)	49 (35.0)		
Household income in 1000 MKW				4.430	0.109
≤30.33	126 (29.4)	76 (26.4)	50 (35.7)		
30.34-122.17	199 (46.5)	137 (47.6)	62 (44.3)		
≥122.18	103 (24.1)	75 (26.0)	28 (20.0)		
Weight status (BMI kg/m^2)				16.705	<0.001
Underweight (<18.5)	16 (3.8)	4 (1.4)	12 (8.57)		
Normal weight (18.5-24.9)	128 (30.0)	80 (28.0)	48 (34.3)		
Overweight/obese (≥25.0)	282 (66.2)	202 (70.6)	80 (57.1)		
Duration of diabetes in years (mean±SD)	6.0±4.43	6.4±4.5	5.0±4.0		0.001

APPENDIX E: Themes, subthemes and direct quotes

Themes	Sub-theme	Direct quote
Facilitators to diet	Family support	"My relatives know that I have diabetes, and they always prepare whole maize porridge (*nsima ya mgaiwa*) with relish added groundnut powder to it—instead of cooking fat" **FGD #4, gender=male, age=52 years, BMI=normal weight, A1C=8.8%, location=semi-urban** "I will tell you a story from my experience. One day my wife, two children and I were traveling, going to a funeral in the village in Rumphi. Then on our way, we decided to stop at Mzuzu to have some breakfast. I was seated with my son at another table and my wife and daughter sat at theirs too, I sat far from my wife because I wanted to order some food that I don't get to eat at home. I didn't know that my wife had prepared whole maize porridge for me from home and put it in a food warmer/container. When the waiter came, I whispered in his ears to bring me (a) full breakfast (eggs, sausage, full cream milk and plate full of potato chips-french fries) but saw him bringing the whole maize porridge which he said that my wife had prepared for me and gave it to him to warm. Indeed, my wife supports me" **FGD#3, gender=male age=69 years, BMI=overweight, A1C=8.1%, location=urban** "When diagnosed with sugar disease [diabetes], the doctor asked me to bring my spouse and she was given charts with foods to prepare at home based on the condition" **FGD#3, gender=male, age=69 years, BMI=overweight, A1C=8.1%, location=urban** "My children understand my condition and they prepare foods recommended for diabetes, and my husband always makes sure that when he gets his salary, he should buy food for me as a person with diabetes" **FGD2#, gender=female, age=48 years, BMI=obese, A1C=14%, location=semi-urban** "When my children are home, they prepare delicious meals for the family, for instance fried Irish potatoes (French fries), but food that is not recommended for diabetes. Sometimes I really wish I ate it, but with my condition, doing so is putting myself at risk. So, my children hide or sometimes snatch the food away from me. But I always persuade them to let me eat two pieces" **FGD#2, gender=female, age=42 years, BMI=obese, A1C=10%, location=semi-urban** "I get support on what to eat from my husband. We remind each other what to eat because both of us have diabetes and hypertension. We always eat together. I cook relish (side dishes) recommended for diabetes without adding salt and oil. He always reminds me not to

		add oil to the food. We know each other well" **FGD#1, gender=Female, age=63 years, BMI=obese, A1C=7.6%, location=urban**
	Diabetes support group	In our diabetes group we remind each other on what to eat and ways of preparing food. For instance, when eating chicken, we should remove the skin because it has a lot of oil. We also remind each other not to drink soft drinks and even reduce the quantity when eating whole maize thick porridge. **FGD#1, gender=female, age=63 years, BMI=obese, A1C=7.6%, location=urban** "In our diabetes groups we remind each other of what kinds of food to eat, how much and when. Even for exercises we tell each other to check our feet and we teach each other how to remove stress". **FGD#1, gender=female, age=44 years, BMI=normal, A1C=7.0%, location=urban**
	Emphasis from the health worker	"The retired nurse emphasizes that with diabetes we can eat anything but there should be limits as to how much we can consume. Like for cassava, the portion size should match a box of matches, only two pieces per day. For whole maize thick porridge (*nsima ya mgaiwa*) only two scoops should be given depending on the size of the scoop and our eating patterns should be stable, not constantly varying. For instance, today you eat lots of foods and the next day just a little, because your blood sugar will always be high" **FGD#3, gender=male, age=63 years, BMI= normal, A1C=10.4%. location= urban** "The clinician always teaches us to eat a lot of fruits and vegetables. Even when I meet him in the community, he always reminds me. For instance, one day we met at the market place, and I was having soft drinks. Unfortunately, he saw me and told me to stop taking soft drinks" **FGD#4, gender=male, age=52 years, BMI=normal, A1C=8.8%, location=semi-urban**
Barriers to healthy eating	Resources, food availability and scarcity	"Sometimes we don't manage to eat as recommended by the doctor because things nowadays are expensive. For example, fruits are expensive and scarce. Hence, I don't eat it as required, I can stay for days without eating fruits. Things are expensive and sourcing money is difficult because some of us depend on small businesses and help from well-wishers, especially children". **FGD#1, gender=female, age=52 years, BMI=obese, A1C=5.5%, location=urban** "I sometimes buy food recommended for my condition when I have money for myself such as fruits and brown bread but not for the whole family. When money is not available, I eat anyhow. I do not really follow dietary recommendations." **FGD#3, gender=male, age=61 years, BMI= normal, A1C=8.7%, location=urban**

		"I do not have proper budget to eat food recommended for diabetes, I buy what is available on the market and according to the money I have. For fruits, I buy bananas because they are cheap and always available compared to apples" **FGD#3, gender=male, age=45 years, BMI=overweight, A1C=9.5%, location=urban** "Even if we are advised to eat fruits like bananas each day, after one week we couldn't eat. We eat fruits in the rainy season, because fruits are cheaper and available especially mangoes and guavas and we are used to that. But we don't eat fruits frequently. The main issue here is lack of resources such as money" **FGD#1, gender=female, age=63 years, BMI=obese, A1C=7.6%, location=urban** "Where I live is far from main town. We can't find brown rice, and even vegetables and fruits are very scarce and going to town to buy them is very expensive. I have to use transportation money for that, so the best way is not to go to town.**FDG#1, gender=female, age=61 years, BMI=obese, A1C=9.3%, location=urban** "Diabetes can be managed using locally available food, but in the villages, we live, the foods are not available, and the only cheap food available is maize. At the hospital the emphasis is to buy expensive fruits such as apples, which I can't afford, even if I work. We have been advised to use artificial sweetener instead of normal sugar which is also expensive here in Kasungu. Therefore, most of the times we mostly just eat what is available at that time. Most of the times my blood sugar levels are elevated, because I really do not have the resources to buy expensive foods such as fruits and artificial sweeteners" **FGD#2, gender=female, age=42 years, BMI=obese, A1C=10.0%, location=semi-urban** My eating pattern is mostly *nsima ya mgaiwa* (whole maize thick porridge). I eat fruit such as apples based on the money that I have. When I have no money, which happens quite often, I'll have *phala la mgaiwa* in the morning and I omit fruit from my dietary regimen. Mostly I eat *phala la mgaiwa* in the morning. Then, (I) have lunch which is usually *nsima ya mgaiwa*. I don't eat fruit most of the time, because they are not available, and (this) depends on my financial status. **FGD#3, gender=male, age=45 years, BMI=obese, A1C=9.5%, location=urban** "I always omit fruits from my diet regimen because fruits like apples are expensive and brown rice and bread are always not available on the market. Hence it is very difficult. No wonder my blood sugar is always high" **FGD#3, gender=male, age=63 years, BMI=normal, A1C=10.4%, location=urban**

		"Here in Kasungu food are not available and are scarce in the market such as fruits, coke rite, brown bread, and skimmed milk. I always take full cream milk because it is the only milk available at the market. Sometimes I really wish to take coke rite, but I always substitute with sweetened beverages to quench my thirst. **FGD#4, gender=male, age=43 years, BMI=overweight, A1C=12.9%, location=semi-urban** "Sometimes I truthfully don't manage (diabetes) because of lack of money and sometimes because we don't find recommended foods at the market. Sometimes where you are, affects what food is available and we just eat what is available although it's not recommended. Some fruits like apples are not found depending on the location you stay, even bananas can't be found everywhere". **FGD#1, gender=Female, age=44 years, BMI= normal, A1C=7%, location=urban** "Most times we do not follow the recommended eating pattern because of money and food availability at the market. If my own produce is not enough, especially maize and vegetables, it affects my eating pattern. I eat limitedly because I do not have a choice." **FGD#3, gender=male, age=63 years, BMI= normal, A1C=10.4%, location= urban**
	Household size & resources	"It is difficult to buy food like fruits and skimmed milk because of the size of my family. Due to financial constraints I cannot manage to buy for everyone. As such I don't like eating fruits, and I don't follow the recommendations. I just eat what is available for the entire family". **FGD#2, gender=female, age=48 years, BMI=obese, A1C=14%, location=semi-urban** "As for me, money is the big issue. For example, I may want to buy food for my condition, but considering that my children and other relatives want to be fed and have fees for school, I always prioritize these fees and eat what is available on that day without even thinking about my condition". **FGD#2, gender=male, age=53 years, BMI=normal, A1C=14%, location=semi-urban** "When there is not enough food, I tell my wife to just cook whole maize porridge so that there is enough food for everyone at home. We just eat everything. I do that so enough food is available at home; if there is no food, we just eat maize porridge for breakfast, lunch and dinner". **FGD#2, gender=male, age=45 years, BMI=normal, A1C=5.2%, location=semi-urban** "I have difficulties dividing money between my family and food. It is difficult to buy recommended foods with the little money I get. I always prioritize my family

		more than food" **FGD#2, gender=male, age=52 years, BMI=normal, A1C=8.8%, location=semi-urban**
	Preparing and buying food separately for diabetes patients	"Sometimes I get tired of cooking my own food, because my children don't like whole maize thick porridge, so I just eat what the rest of the family members are eating, for instance refined maize thick porridge, fried beef and sobo (sweetened beverage)." **FGD#2, gender=female, age=42, BMI=obese, A1C=10%, location=semi-urban** "I buy food recommend for diabetes for me first, then for the rest of the family. But sometimes I am limited, and I just buy what is cheap and on the market for the whole family, although it is very difficult to be buying food separately, considering that food in Malawi are expensive and not as available like in Zambia and South Africa"**FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%, location=urban** "My children cook food separately from the rest of the family, because they don't like the food recommended for diabetes. But sometimes, they get tired and I just eat what is available on that day". **FGD#1, gender=female, age=61 years, BMI=overweight, A1C=14%, location=urban** "I cook my own food because most of the time, the food cooked at my household is refined maize thick porridge or fried foods with a lot of salt. Sometimes I get tempted" **FGD#1, gender=female, age=45, BMI=obese, A1C=11.3%, location=urban** "It is difficult to find money because it depends on my small business or farming. In my family, it's only me with diabetes. Hence, it's difficult to buy the recommended foods. I just eat what is available on that particular day. Whenever I find money and buy the recommended foods such as fruits or brown bread every household member wants to eat that, so I just resolved to buying general foods for everyone not specifically for diabetes". **FGD#4, gender=male, age=42 years, BMI=normal, A1C=14%, location=semi-urban**
	difficulties in changing dietary habits,	"It is not easy to change especially for me. I still do not follow what I have been told at the hospital, especially when I am alone. I assume that no one is watching me, so I eat a lot of fried potatoes, sugary foods and soft drinks. Most times large quantity of thick maize porridge at once. Thus, when I come to the hospital my

		blood sugar is always high" **FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%, location=urban** "I sometimes eat what the retired nurse advises us to eat, though it's not my desire because the food is not delicious, but with time, I will get used to it. What has really changed is switching from refined to whole maize thick porridge. And sometimes I really crave coke. I was really enjoying food before getting diagnosed with diabetes". **FGD# 2, gender=male, age=58 years, BMI=overweight, A1C=6.3%, location=semi-urban** "Sometimes, I get tempted to eat what other family members are eating, especially the good food like fried chicken, which they don't even share one piece. But it is very difficult to change." **FGD# 2, gender=male, age=59 years, BMI=normal, A1C=8.8%, location=semi-urban** "It is very difficult to change, even now I still eat large quantities of whole maize thick porridge during one meal. I use a lot of sugar in my tea and still take fatty meat and full cream milk. I find it a burden to stop. I hope with time I will change**". FGD#4, gender=male, age=53 years, BMI=normal, A1C=14%, location=semi-urban**
	lack of awareness and knowledge on proper eating	We have been advised to stop eating meat, rice [rich in starch], beans, sugar and eggs [high cholesterol]. But how can one eat only maize thick porridge with vegetables. I feel like we are being punished" **FGD#4, gender=male Age=57 years, BMI=overweight, A1C=14%, semi-urban** "I eat a lot of fried potatoes, maize thick porridge, sugar and soft drinks, because I believe that after eating all this, we will drink to clean up everything" **FGD#1, gender=female, age=45 years, BMI=obese, A1C=11%, location=urban**. "We have been advised not to eat a lot of beans because they have a lot of protein which will make us gain weight. For animal sources like meat and fish, we should not eat both at one meal because of high protein content" **FGD#1, gender=female, age=44 years, BMI= normal, A1C=7%, location=urban.** "We have been advised to reduce the quantity of food, but the problem is that we don't know how much we should reduce it by, and it is not clear which foods to reduce except changing from refined to whole maize thick porridge. If they showed us the quantities that would be good" **FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%** "When the retired nurse is not around, newly recruited nurses just advise us to not eat refined maize porridge, meat, sugar etc. without explaining why and then what

		we should eat" **FGD#3, gender=male, age=45 years, BMI=overweight, A1C=9.5%, location=urban**
	not knowing what eat during functions and travel,	"When I travel, especially visiting others, they cook what they want. Sometimes I buy food, but I still don't manage since it's not at my house, so I just eat even though I do not feel well. In most cases, they add a lot of oil and salt to the food. When I eat such kinds of foods, I don't even take medications, I just drink a lot of water". **FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%, location=urban** "Sometimes, it's really a burden when I travel to church functions, even if they communicate that we have diabetes, but they still cook refined maize flour thick porridge. So, I spend the whole day drinking water without eating any food. Sometimes they bring Fanta for me to drink, it is so tempting I sometimes do drink it, because I have no other option. I thank God my blood sugar is not always high". **FGD#1, gender=female, age=52 years, BMI=obese, A1C=5.5%, location=urban** During weddings or funerals, it is very difficult for someone with diabetes, because if the event is not at your place you don't get to choose the type of food to eat. I just eat everything available. I just try to control the amount of food that I eat, eating a small quantity. **FGD#1, gender=female, age=54 years, BMI=overweight, A1C=14%, location=urban.** During wedding ceremonies, I eat anything available. I don't choose, I eat whatever is available. This also applies to funerals, but I try to drink a lot of water at home to clear the gut. **FGD#1, gender=Female, age=57 years, BMI=obese, A1C=12.7%, location=urban.** I don't drink coke unless I am traveling long distances and I have no choice but to eat what is found where I go. It is generally hard when choosing what to eat when I travel, because fruits are expensive**. FGD#2, gender=female, age=48 years, BMI=obese, A1C=14%, location=semi-urban.** At parties, I do eat the foods that are there because the foods are usually delicious. On Christmas day, I neglected my condition and I ate delicious foods with my children, and my blood sugar is always high. **FGD#2, gender=female, age=42 years, BMI=obese, A1C=10%, location=semi-urban.** "When travelling, going to my home village in *Chitipa* for example, it is hard to eat foods because all the foods sold on the way have a lot of oil, are fried or are sweetened beverages. So, we look for places like restaurants and before we order I always ask if they have uncooked fresh meat, and ask them to roast it for me, but sometimes restaurant owners are unwilling to

		do so" **FGD #4, gender=male, age=52 years, BMI=normal, A1C=8.8%, location=semi-urban**
	Inconsistence dietary information from different sources	"When I go to the private clinic the doctors advise me to stop taking meat, salt, sweet beverages, and not to use cooking fat/oil, but without telling me the reasons. When I come at the government hospital the retired nurse explains that I should take food in moderation, so I don't know who to believe" **FGD#3, gender=male, age =58 years, BMI=overweight, A1C=6.3%, location=urban** "On the radio and internet, there is a lot of information on what a person with diabetes should eat, which is different from what the retired nurse advises us. As such she has told us not to follow what we hear or read on social media" **FGD#1, gender=female, age=61 years, BMI=obese, A1C=9.3%, location=urban**
Facilitators to physical activity	Family and friend support	"I exercise at home. Sometimes, I walk distances to the field and help my children do household chores. I also play netball with my grandchildren every now and then." **FGD#2, gender=female, age=48 years, BMI=obese, A1C=14%, location=semi-urban** "I have a friend pick me up in the morning to go for a run before work. Sometimes I play football with my younger children at home as part of exercise, we really enjoy it". **FGD #4, gender=male, age=52 years, BMI=normal, A1C=8.8%, location=semi-urban** "I am reminded by my husband to do physical activity. I am a muslim so my husband plays Islamic songs for me and I dance heavily, then we switch to Christian [my husband is] songs which I dance for a while, that is what I do for physical activity, though all in the house". **FGD#1, gender=female, Age=53 years, BMI=overweight, A1C=8.3%, location=urban**

	Type of work/household chores involved	"I briskly walk as part of my exercise. I also go to Lilongwe river to wash my clothes either 2 or 3 times a week and I wash for over 40 minutes. I even wash my wife clothes which I also consider as part of my exercise and it's really helping me"**. FGD#3, age=61, gender=male, BMI=normal, A1C=8.7%, location=urban** For me I don't get any help, so I do house work alone until I sweat even though others say I am old fashioned because I don't have a housemaid to help with household chores, but I am healthy. I sweep the outside and clean my big house alone without problems as part of my exercise each day. **FGD#1, gender=female, age=52 years, BMI=obese, A1C=5.5%, location =urban** "As for me, physical activity is important for people with diabetes and it really helps, just as the retired nurse has been teaching us. I do farm a lot and my work involves carrying heavy metals, because I am a welder. So, I do physical activity through work". **FGD#3, gender=male, age=63 years, A1C=10.4%, location=urban** "I don't do physical activity a lot because when I do my heart beats fast. However, my work is manual, I am a carpenter, so I carry heavy and chop wood a lot each day". **FGD#4, gender=male, age=52 years, BMI=normal, A1C=8.3%, location=semi-urban** "Now we have electronic mortars; but I still prefer pounding maize by hand for exercise. At times I also walk long distances". **FGD#2, gender=female, age=63 years, BMI=obese, A1C=9.3%, location=semi-urban**
	Emphasis from the health worker	"I run two or three times a week and when I do, my heart feels light unlike the time I don't. the retired nurse always reminds us to do physical activity and it really helps a lot". **FGD#3, gender=male, age=45 years, BMI=overweight, A1C=9.5%, location=urban** "I get support to do physical activity from the hospital. We are encouraged to engage ourselves in several activities at home such as washing cloth and walking for long distance as exercise, of which I always do. I even help my wife some of the household chores such as sweeping"**. FGD#4, gender=male, age=55 years, BMI=overweight, A1C=6.4%, location=semi-urban** "At the hospital I have been advised to go running, but because I walk frequently, going for long distances like from *Chilinde* to where I stay, I am tired and don't even go for a walk or do exercise". **FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%, location=urban**
	Diabetes support group	"At the diabetes groups which we often meet, everyone is the messenger of the other, we advise each other to live

		well and exercise. We even sometimes text each other". **FGD#1, gender=female, age=63 years, BMI=obese, A1C=7.6%, location=urban** "In our diabetes groups we remind each other of what kinds of exercise to do such as jogging and pushups". **FGD#1, gender=female, age=44 years, BMI=normal, A1C=7%, location=urban**
Barriers to physical activity	fear of public ridicule	"Most of the times the burden is from neighbors on physical activities. When doing household chores, they say I do them as if I did not have children because children can employ a house maid to help me with household chores. Sometimes they say that I pressure myself. My neighbors always demotivate me". **FGD#1, gender=female, age=52 years, BMI=obese, A1C=5.5%, location=urban** "Indeed, neighbors disappoint us. One day a neighbor said, "Why do you do all the household chores as if you don't have children?" But for me this is part of my exercise". **FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%, location=urban** "Physical activity is one part we are taught. My work is tailoring, and I do cycle on a bike every day to work. When I get home at night, I do push-ups inside my house as part of the exercise, my wife always reminds me of that. I don't exercise outside my house cause my neighbors will think am doing witchcraft". **FGD#3, gender=male, age=58 years, BMI=overweight, A1C=6.3%, location=urban** "I sometimes [once in a while] dance in my bedroom as part of exercise, because my children and other family members including the neighbors laugh at me when I dance as exercise outside the house" **FGD#1, gender=female, age=61 years, BMI=obese, A1C=9.3%, location=urban**
	Comorbidities	"In terms of physical activity, I don't run, but I dance sometimes but not always because of my leg problem and minor stroke I had. I do physical activity through household chores, though I clean plates, and wash clothes while seated. But sometimes I can even sweep and mop my house slowly till I sweat". **FDG#1, gender=female, age=61 years, BMI=obese, A1C=9.3%, location=urban** "Due to my leg problems, I just jog in my bedroom until I sweat. Then I take a bath then when I go to work and I feel fine or I go out and have a heavy wash of my clothes after work, especially weekends". **FGD#1, gender=female, age=63 years, BMI=obese, A1C=7.6%, location=urban**

		"I don't do a lot of exercise; at times I try my best to exercise in the morning despite having leg problems and I can't see far especially when I feel like my blood sugar is high. I walk slowly with my children who escort me daily for at least one hour. After I exercise, my body feels better". **FGD#3, gender=male, age=69 years, BMI=overweight, A1C=8.1%, location=urban**
Support system for diabetes management	Family and friends members	"As for me my grandchild is the one that reminds me to take my medicine. I have raised that grandchild alone so most of the times the grandchild reminds me to take the medicine and sometimes I even send him to get the medicine for me. Most of the times, my wife and I forget about the medicine, but my grandchild never does, he is always there to remind me to take my medications. When I take a bath before eating, he always reminds me to take my medications**" FGD#3, gender=male, age=61 years, BMI=normal, A1C=8.7%, location=urban** "Children provide me with my medication because I always take medications in the evening after meals and they know that I need to take medication." FGD#3**, gender=male, age=57 years, BMI=overweight, A1C=9.5%, location=urban** "My children remind me that I should not forget that I have diabetes and they even do that when we are travelling. They remind me to carry medications and that I should not eat food that isn't recommended. My children remind me to take medication since my husband is always away". FGD#1, gender=**female, age=54 years, BMI=overweight, A1C=14%. Location=urban** "I get support from my 7-year-old boy. When I am going to work, he always reminds me "daddy, have you taken your medicine today". My wife is also involved, and her friends also encourage me, and remind me of the condition I have". **FGD#4, gender=male, age=53 years, BMI=normal, A1C=14%, location=semi-urban** "I get support from the family at home. They try so that I eat whole maize flour. My medication is kept in a safe place and they remind me, even my child reminds me to take it". FGD#4, gender=**male, age=43 years, BMI=overweight, A1C=12.9%, location=semi-urban** "I even told my neighbors of the condition and showed them the medicine that I take, so that if anything happens, they should be able to take me to the hospital and explain because sometimes a person with diabetes can just faint". FGD#3, gender=**female, age=42 years, BMI=obese, A1C=10 years, location=urban**
	Workplace/workmate	My workmates as well take part. I previously used to like Fanta but now they bring me water, and they tell other coworkers that I can't have FANTA. Even at

		teacher training college (TTC) where I work, the women there say that I should take care of myself because I have a little child who needs my help. So, it is best that I take care of myself to help my kids. FGD#3, gender=male, **age =52 years, BMI=normal, A1C=8.8%, location=semi-urban** "Even workmates help with of my condition. During workshop, they don't give us Coke and Fanta, and they always give me full cream milk because skimmed milk is not available. When budgeting, they exclude us on their food choices, and they get milk". **KU151, male, age=43, FGD# 3, BMI=overweight, A1C=12.90** "At the workplace, I told my boss of my condition, so he allows me to leave whenever I don't feel well. We are protected at work because I told my boss who allows me to go home when I do not feel well to rest". FGD#2, gender=**female, age=42 years, BMI=obese, A1C=10%, location=semi-urban.** "When I go to work, I get some support from colleagues. When there are functions, those with diabetes have their own foods while others drink sweetened drinks". **FGD#2, gender=female, age=61 years, BMI=overweight, A1C=5.4**
	Diabetes support group	"In our groups as, fellow diabetics we encourage each other to lose weight. And tell each other not to eat the skin of chicken because it has a lot of oil. Even a member of our group asked me how different my sugar is from hers since she lives a sedentary lifestyle and she doesn't exercise or anything". **FGD#1, gender=female, age=45 years, BMI=obese, A1C=11.3%, location=urban** "At the diabetes groups everyone is the messenger of the other, we advise each other to live well and not to eat too much just because there is food, and we need to control ourselves". FGD#1, gender=**female, age=63 years, FGD#1, BMI=obese, A1C=7.6%, location=urban**
	Church/religious grouping	"I am supported at church because I keep praying and they say God will heal us. However, I still take medication as needed and follow the advice given on food, like eating mustard without oil added to it, although I have to force myself to eat it. I also get some support from church where people tell me that God will someday answer my prayers, but I still take medication". **FGD#2, gender=female, age=42 years, BMI=obese, A1C=10%, location=semi-urban** "At my church people understand that I have diabetes and as such they prepare foods suitable for me. Other people ask me the symptoms that I felt before I was diagnosed with the condition and I explain to them e.g. fever,

		excessive thirst or frequent urination but for malaria I have spent four years now without suffering from it. Sometimes even some church members call me on my phone to ask for the symptoms of diabetes". **FGD#1, gender=female, age=45, BMI=obese, A1C=11.3%, location=urban** "For me I get encouragement when I ask God to guide me in everything and that he should take part even when I'm taking medication. When we stand with Jesus everything is possible." FGD#1, gender=**female, age=54 years, BMI=overweight, A1C=14%, location=urban**
Dietary changes and perceived implications	Stopped eating certain foods and changes in preparation methods	"My eating pattern is different from before. Previously, I used to eat refined maize flour thick porridge with fatty meat and chicken, but now I have changed. I don't eat meat at all, just small dry fish such as *usipa, utaka,* and *micheni."* **FGD#1, gender=female, age=52 years, BMI=obese, A1C=5.5%, location=urban** "I have changed because I used to like milk. I used to drink a big cup of milk almost half a liter and margarine spread on bread, at least six slices. In the past I used to like milk a lot, I could not manage to take tea without milk. Now, I use artificial sweeteners in my tea and lemons, and I have minimized my intake of milk. I used to drink alcohol more frequently, but I have stopped. I don't usually eat refined maize thick porridge". **FGD#1, gender=female, age=45, BMI=obese, A1C=11.3%, location=urban** "But when I was diagnosed with diabetes, here at the hospital I was told to eat whole maize flour thick porridge and not to eat margarine and sugar. This was hard to adopt when I was first diagnosed. I forced myself to follow the doctor's recommendations and when I visited the hospital for the second time, I was told my blood sugar level was decreasing. I usually have roasted fish or boiled or roasted meat with no oil added. I don't eat rice because I was told it has a lot of starch". **FGD#1, gender=female, age=63 years, BMI=obese, A1C=7.6%, location=urban** "The only change in my eating pattern is switching to whole maize thick porridge (*nsima ya mgaiwa*) but other foods I eat in the same amount. I eat minimal amounts of *nsima*, only 2 scoops resembling the size of a fist because when one eats huge amounts, their blood sugar level will rise. Additionally, I don't eat foods with too much oil". FGD#2, gender=**female, age=51 years, BMI=obese, A1C=14%, location=semi-urban** **"**I used to eat anything, meat, fanta and coke, but since my diagnosis I stopped, and have become too selective on what I eat. I don't drink coke unless I am traveling long distances and I have no choice but to eat what is

		found where I go. It is generally hard when choosing what to eat, because fruits are expensive. What has really changed is the kind of food and preparation methods, including reducing the quantity". **FGD#2, gender= female, age=48 years, BMI=obese, A1C=14%, location=semi-urban** "In the past, I used to drink a lot of soft drinks such as juice (*sobo*), fanta, milk, coke, and squash. I stopped eating rice because we were told that rice contains a lot of starch and it will raise my blood sugar. I even stopped eating white bread, and only have brown bread. I find it very difficult to consume foods suitable with my condition because food such as brown bread and fruits are very scarce and expensive especially where I live". **FGD#2, gender=female, age =61 years, BMI=overweight, A1C=5.4%, location=semi-urban** "When I was diagnosed with diabetes, my eating pattern changed. But I wasn't happy with the changes because a lot of foods that I like; I was told to avoid. So, I just follow what I was told. I eat vegetables with *nsinjiro*, twice a day. I also, like dried catfish. I am a tailor, so where I work especially during hot/dry/summer season I used to drink at least 20 bottles of Coke per day, which I have gradually stopped because of my condition. I don't like *phala la mgaiwa* but I am forced to eat it, though in small amounts with little salt added. I drink one bottle of Coke Rite with zero sugar per day, and (I) am glad of that because it has replaced the ordinary Coke with sugar, that I used to like. I drink fresh low-fat milk, not Cremora and other kinds of milk. I do have *phala la mgaiwa* as I was advised with *nsinjiro* added but without sugar added". **FGD#3, gender=male, age =58%, BMI=overweight, A1C=6.3%, location=urban** "I used to eat sugary foods like sugar, tea with milk and a lot of sugar, oranges and fatty meat, but all these I have now stopped eating. At first, it was a burden to stop eating these foods which I liked eating, but not now because I am used to it. My weight used to be over 80 kg, but now it's around 70 Kg, mainly because I stopped eating certain foods". FGD#4, gender=**male, age=53 years, BMI=normal, A1C=14%, location=semi-urban**

Perception of the disease and management	Need expensive food to manage the diseases	"Indeed, foods for a person with diabetes are expensive. Cheaper fruits such as mangoes are seasonal and are only found during the rainy season. The recommended foods such as apples are expensive which are at MK350 each (USD $.50 each)". **FGD#2, gender=female, age=42 years, BMI=obese, A1C=10%, location=semi-urban**
	Disease of the rich and western people	"This disease [diabetes] is for Western people, well to do people and obese, but nowadays everyone has diabetes including young children, so we too are western people. At first only well-to-do people got this condition but now it is everyone even children are suffering from diabetes". **FGD#1, gender=male, age=45 years, BMI=overweight, A1C=9.5%, location=urban** "Some people do understand that I have diabetes, but other people even if you should tell them that that you have diabetes, so that they should give you recommended foods, they don't care, and they think we are boasting especially in group gathering at community level". **FGD#1, gender= female, age=61 years, BMI=Obese, A1C=14%, location=urban**

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