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Barriers and Facilitators to Diabetes Self-Management in a Primary Care Setting – Patient and Physician Perspectives

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BARRIERS AND FACILITATORS TO DIABETES SELF-MANAGEMENT IN A PRIMARY CARE SETTING – PATIENT AND PHYSICIAN PERSPECTIVES

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By

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ABSTRACT

BARRIERS AND FACILITATORS TO DIABETES SELF-MANAGEMENT IN A PRIMARY CARE SETTING – PATIENT AND PHYSICIAN PERSPECTIVES

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May 2017

Thesis Supervised by Dr. Khalid M. Kamal

OBJECTIVES: To identify patient- and physician-perceived barriers to self-management of type-2 diabetes (T2DM) and explore the challenges physicians face in managing these patients. **METHODS:** This cross-sectional study of T2DM patients and their physicians used a mixed-methods approach (combination of patient survey and electronic medical record (EMR) database). A random stratified sample of 2,100 patients (age≥18 years) with a recorded diagnosis of T2DM (ICD-9 code: 250.xx) and having ≥2 physician visits was selected from a large physician group's EMR database, and based on HbA1c level, was categorized into three groups: HbA1c<7, 7–9, and >9. Patients were administered a survey containing standardized instruments to collect information on demographics and diabetes self-care behaviors. Physician survey measured physician perceptions of patient barriers to self-management and their challenges in managing uncontrolled T2DM patients. **RESULTS:** 210 responses were received (10%

response rate). Mean age was 63.68 years (+/-11.79), 102 (48.6%) were females, 197 were Caucasian (93.8%). Univariate analysis revealed that age (X^2=15.73, p<0.01), insurance status (X^2=12.03, p<0.05), referral to an endocrinologist (X^2=6.17, p<0.05), level of self-management (X^2=12.01, p<0.05), and willingness to take insulin (X^2=9.8, p<0.01) were associated with HbA1c control. Older age, lower willingness to take insulin, and less than graduate level education were significant determinants of glycemic control. Of the 21 physicians who responded (53.8% response rate), 71.2% were over the age of 50 years, 54.16% had ≥25 years of clinical experience, and 50% practiced in an urban setting. Barriers leading to clinical inertia as identified by the physicians include cost of medications, non-compliance with diet and medications, polypharmacy, lack of patient motivation, knowledge, time, and social support.

CONCLUSIONS: Self-management behavior of T2DM patients is strongly associated with HbA1c control. Interventions directed towards improving self-management in T2DM population that take both physician and patient perspectives in to consideration may result in improved clinical outcomes.

DEDICATION

I dedicate this thesis to my parents, Ramesh and Alka Khairnar, without whom, I would not be where I am today. I am eternally grateful to them for all the sacrifices they have made to give wings to my dreams. I also dedicate this work to my sister, Pooja, for her unconditional love and constant support. A big thank you to all my friends in Pittsburgh and Baltimore, for all the fun times we have had together, and for being there for me through the ups and downs of life. You all are a source of inspiration for me. Finally, I dedicate this work to my advisor, Dr. Kamal, who taught me how to conduct research, and without whom, this thesis would not have been possible.

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CHAPTER ONE – INTRODUCTION

Diabetes Mellitus – An Overview

Diabetes Mellitus (DM), or simply Diabetes, is a group of metabolic disorders characterized by inefficient utilization of blood glucose.[1] Glucose is the primary source of energy for the body. Insulin, a hormone secreted by pancreas, facilitates the uptake of blood glucose by body cells and tissues. In a healthy individual, the pancreas secretes adequate amounts of insulin required for this blood glucose transfer. This secretion is triggered by the amount of food consumed by an individual. In an individual with DM, there is either little or no production of insulin by the pancreas, or improper utilization of insulin by body cells, or a combination of both.[2]

The three most commonly recognized forms of diabetes are as follows[3]:

1. Type 1 Diabetes Mellitus (T1DM) OR Insulin Dependent Diabetes Mellitus (IDDM)
2. Type 2 Diabetes Mellitus (T2DM) OR Non-Insulin Dependent Diabetes Mellitus (NIDDM)
3. Gestational Diabetes

T1DM is an autoimmune disorder where the body produces antibodies against its own pancreas. These antibodies damage the pancreas and stop insulin production. The etiology of T1DM is unclear. It may be caused by genetic predisposition, environmental factors, or as a result of faulty beta cells in the pancreas which normally produce insulin.[1] T1DM accounts for around 5 – 10% of the diagnosed cases of diabetes in the United States (US).[3]

T2DM, also known as Non-Insulin Dependent Diabetes Mellitus (NIDDM), is the most common form of diabetes accounting for around 90% of the 26 million Americans with diabetes. It occurs due to insufficient or no production of insulin by the pancreas, or ineffective utilization of insulin by body cells due to insulin resistance. It has been observed that African Americans, Latinos, Native Americans, and Asian Americans (Pacific Islanders) are at an increased risk of developing T2DM.[2] Aging, obesity, family history of diabetes, previous history of gestational diabetes, and physical inactivity are other factors associated with T2DM. Over 80% of the patients with T2DM are overweight.[4]

Gestational diabetes is a form of glucose intolerance that occurs in 2 – 10% of pregnant women due to pregnancy.[5] It can cause several health problems during pregnancy, to both mother and child. Women with gestational diabetes and their children are at an increased risk of developing T2DM in the future. Women with gestational diabetes have 35 – 60% chance of developing T2DM in the next 10 – 20 years while 5 – 10% of women with gestational diabetes are found to have T2DM after pregnancy.[5]

Diabetes Mellitus (DM) is one of the primary causes of heart disease and stroke. According to the Centers for Disease Control (CDC) Diabetes Report Card 2012, adults with diabetes have 2- to 4-fold higher mortality rate for heart disease and 2- to 4-fold higher risk of stroke. Hypertension is the most common co-morbidity associated with diabetes with around 67% of the adults with DM reported to have hypertension. Diabetes is also associated with other complications such as blindness, kidney failure, gangrene and amputations of the lower limbs.[5]

Type-2 Diabetes Mellitus (T2DM)

T2DM is a chronic metabolic disorder that affects over 25.8 million people in the US with an estimated seven million people remaining undiagnosed.[5] An alarming 79 million people are reported to be in the pre-diabetes phase and have an increased likelihood of suffering from diabetes in the future.[5] T2DM is attaining epidemic proportions and in 2010 alone, 1.9 million incident cases of diabetes were reported, almost three times as much in 1990.[5] This sudden rise in the incidence of T2DM is associated with an increase in obesity, decrease in leisure-time physical activity, and aging population.[5, 6] Diabetes was the sixth leading cause of death in the US in 2002. In 2010 alone, 69,071 certificates listed diabetes as the underlying cause of death, while it was mentioned as a cause of death in over 234,051 death certificates. The true extent of the effect of diabetes, however, is likely to be underestimated as diabetes-related deaths are often attributed to other causes.[7] Studies show that diabetes was listed as a cause of death in 35 - 40% of people with diabetes while only 10 -15% had it listed as the underlying cause of death.[2, 7]

Elevated blood glucose levels, a defining characteristic of diabetes, is associated with increases in blood pressure and dyslipidemia. These lead to long-term complications such as cardiovascular disease, diabetic neuropathy, diabetic retinopathy, kidney disease, gangrene and amputation of lower limbs. These complications are primarily responsible for the increased mortality and morbidity in patients with diabetes.[7] The risk of death is approximately 2 times higher in people with diabetes, as compared to those without it.[7] Given the chronic nature of diabetes, the economic impact associated with the disease is substantial. The total healthcare cost for people with diabetes is 2.3 times higher compared to those without diabetes.[6] In 2012, diabetes (only diagnosed cases) cost the nation a total of $245 billion, of which $176 billion were direct medical costs while $69 billion were due to loss in productivity.[5] The American Diabetes

Association (ADA) has predicted a significant rise in the number of people having diabetes in the coming decades, which would further impose a huge burden on the allocation of healthcare dollars.[5]

Diabetes Self-Management

'Diabetes self-management (DSM),' an essential component of diabetes care, is defined as the ability to manage the symptoms, treatment, and lifestyle changes inherent in living with a chronic condition.[8] DSM involves modifying health behaviors (incorporate changes in daily plan when necessary) to suit the treatment regimen and completion of self-care activities such as following a regular diet and exercise plan, self-monitoring of blood glucose levels, and adherence to medication.[9] There is strong evidence linking DSM with optimal glycemic control, enhanced quality of life and improved psychosocial functions.[8] However, it is important to note that DSM by itself is not sufficient in managing T2DM and the patients may eventually require pharmacologic treatment(s) along with DSM to effectively manage and control their disease.

Diabetes complications such as obesity, gangrene, neuropathy (peripheral or autonomic), retinopathy and poor renal function are often debilitating, costly, and could be fatal. These complications are more common and more severe in patients whose diabetes is poorly controlled (HbA1c > 7%). The term HbA1c refers to glycated hemoglobin, an index that clinicians use to measure average blood sugar levels over a certain time-period. The normal HbA1c level for a person without diabetes is 4 – 5.9%, for those who have diabetes, the target is around 6.5 – 7%, and for those at a greater risk of hypoglycemia, it is 7.5%. The goal of DSM is to improve the HbA1c control in individuals with diabetes and bring it closer to the optimal level (HbA1c ≤ 7). The American Association of Diabetes Educators (AADE) has summarized evidence-based

recommendations for DSM into the following behaviors: being active, eating healthy, taking medications, blood glucose monitoring, problem solving (particularly in patients with high or low blood glucose levels), reducing the risks for diabetes related complications and modifying psychosocial behaviors to adapt to living with diabetes. In addition, the American Diabetes Association (ADA) recommends weight loss or energy restriction, monitoring carbohydrate intake, high fiber intake, limitation of saturated fat, trans-fat, cholesterol, and sodium and lastly, consumption of fish twice a week. Diabetes care and management, and clinical preventive care practices such as annual eye exams, annual foot exams, daily monitoring of blood glucose, and diabetes self-management education (DSME), help control diabetes, thereby keeping people with diabetes healthy. The management of diabetes requires coordinated medical care coupled with patient self-management to decrease the risk of serious complications such as vascular, renal, and ophthalmologic morbidities.[10]

Problem Statement

According to the 2003-04 State of Diabetes in America Report, only 33% of the patients with diabetes achieved the American Association of Clinical Endocrinologists (AACE) glycosylated hemoglobin level (HbA1c) target of <6.5%.[6] Moreover, the proportion of patients failing to achieve their target glucose levels appears to be rising. Patients who failed to achieve the ADA target of HbA1c <7% increased from 55.5% during 1988 - 1994 to 64.2% during 1999 - 2000.[2] It has been observed that these patients are likely to be non-responsive to their treatments. Strong evidences have linked uncontrolled HbA1c levels to increased risk of comorbidities such as diabetic neuropathy, retinopathy, CVD, and higher mortality rates.[5] Failure to achieve glycemic control is attributed to various patient factors such as lack of knowledge,

comorbidities, financial resources (personal cost of care), non-compliance to therapy (adherence), as well as physician-related factors such as beliefs, attitudes, knowledge, communication with patients, type of health care system, and clinical inertia (inaction by physicians to initiate or intensify therapy when indicated).[11-19] Despite advances in treatment options, an increasing number of patients fail to attain glycemic control. Evidence suggests that the lapse in treatment failure and therapy advancement could be a factor responsible for these unmet goals in disease management. Self-management of T2DM is a key element of the overall management of the disease.[9]

Conceptual Framework

The overall study objective is to identify the barriers to self-management of diabetes in a primary care setting and addressing these barriers using a theoretical framework. This is a cross-sectional study of patients with T2DM and their physicians in a primary care setting in Southwestern PA. The study employed a mixed method approach and combined the patient survey data with the patient's information extracted from their physician's EMR database. Responses from the patient survey were linked to different clinical outcomes available in the EMR database. The EMR database includes data from patient records including demographics and clinical diagnoses, procedures, laboratory test results, medication types and dosages, HbA1c levels, lipid profile, BMI, office visits, and comorbidities. Physicians were administered a survey to assess their perceptions of patient barriers and challenges in managing uncontrolled T2DM patients. This study aimed to identify the barriers and facilitators to diabetes self-management and determine the strength and direction of their predictive value over the metabolic control in

these patients. The interrelationship of barriers and facilitators with each other were also assessed.

Study Objectives

Few studies exist on improving diabetes self-management among patients. In addition, views and practices of practitioners caring for these patients have received little attention. Thus, the overall study objective is to identify the barriers to self-management of diabetes in a primary care setting and addressing these barriers using a theoretical framework.

Specific aims

Aim 1: To identify patient perceived barriers and facilitators to diabetes self-management.

Aim 2: To assess patients' readiness to change their diabetes self-management behavior.

Aim 3: To identify physician perceived barriers to diabetes self-management.

Aim 4: To explore physicians' challenges to overcome the barriers to self-management.

Following identification of physician and patient barriers and challenges to diabetes self-management, a pharmacist-initiated individualized approach to these barriers will be conceptualized.

Research Questions and Overall Hypothesis

Research Questions for Aim 1:

One aim of this study was to identify the barriers and facilitators to diabetes self-management (DSM). Additionally, the objective was to explore which of these factors significantly predict DSM in the study population.

Q1. Is there a relationship between HbA1c control and diabetes self-management questionnaire (DSMQ) score for the study population?

- *Hypothesis 1* – There is no association between HbA1c and DSMQ scores.

Q2. Is there a relationship between various barriers and facilitators (factors) and HbA1c control?

- *Hypothesis 2* – There is no association between various factors and HbA1c control.

Q3. Is there a relationship between various barriers and facilitators (factors) and DSMQ scores?

- *Hypothesis 3* – There is no association between various barriers and facilitators (factors) and DSMQ scores.

Research Question for Aim 2:

Another aim of this study was to identify the differences in patients' characteristics based on their readiness to change their health behavior.

Q4. Is there a relationship between patient's readiness to change (as measured by their scores on the stages of change ruler) and their diabetes self-care behaviors such as DSM, knowledge, attitudes and beliefs related to diabetes, and their demographic characteristics?

- *Hypothesis 4* – There is no association between patients' readiness to change and their diabetes self-care behaviors such as DSM, knowledge, attitudes and beliefs about diabetes and their demographic characteristics.

Research Question for Aim 3:

Apart from assessing the patients' perspectives about their diabetes self-care behaviors, the aim was also to assess their physicians' perceptions about their practice and what prevented their patients from achieving optimal self-management.

Q5. Which physician-related factors that affect DSM were significant?

- *Hypothesis 5* – No physician-related factors that affect DSM were found to be significant.

Research Question for Aim 4:

We aimed at exploring physicians' challenges in improving their diabetes patients' diabetes self–management.

Q6. Are there any recurrent themes that emerge from the physician reported challenges in addressing patient barriers?

- *Hypothesis 6* – No recurrent themes emerge from the physician reported challenges to address patient barriers.

Significance of the Study

Identifying barriers and facilitators to self-management and addressing them is a critical step in achieving improved health outcomes in T2DM. Existing literature focuses mainly on patient factors and less so on physician factors or physician-patient interactions.[20] A disconnect between the patients' and physicians' perceptions, knowledge, and attitudes can cause confusion and conflict, which may potentially lead to poor patient health outcomes.[20] There is a need to explore the factors responsible for the patient's non-responsiveness to their therapy. Additionally, better understanding of physician's perceptions is needed to improve diabetes care and to promote self-management in this patient group.

Another important factor that needs to be assessed during the identification of barriers and facilitators is the patient's readiness to change their health behaviors. The Trans-Theoretical Model (TTM) of change assesses patients' readiness to change their health behaviors, and measures the continual progression of individuals through a series of stages. These stages are pre-contemplation (not ready to change/ unaware of the problem), contemplation (realizing the existence of problem, weighing its pros and cons), preparation (intending to act in a near future), action (adopting new behaviors), and maintenance (sustaining new behavior to prevent relapse).[21] It is important to recognize the degree to which patients are reluctant to change and then addressing their conviction systematically using a stepped care model. Interventions using the TTM framework in combination with other strategies have resulted in improved outcomes in previous studies. Another aspect of this model is 'Self-Efficacy.' As the patients progress through the various steps in the model, they become more confident and self-sufficient in managing their disease.[21]

This study is the first to explore both primary care physicians' and patients' perceptions about the barriers to self-management of T2DM in a primary care setting. Results from our systematic review of literature suggest that diabetes management can be achieved best in a primary care setting with an individualized approach to address the barriers to improved outcomes. These barriers include but are not limited to patient-related barriers such as adherence, attitudes and beliefs, knowledge, culture/ethnicity/language, financial resources, comorbidities, and social support. Health care provider factors such as beliefs, attitudes and knowledge, patient-provider communication and interaction, and type of health care system were also identified as potential barriers. Assessment of these barriers is an essential step in developing interventions that are targeted at improving the health of patients with uncontrolled diabetes. Successful development and implementation of effective interventions such as regular monitoring and increased patient control on disease management can help improve their clinical outcomes as well as the overall quality of life. A large proportion of patients with controlled diabetes (HbA1c $\leq$ 7%) will ensure reduction in the overall healthcare expenditure in diabetes as well.

When patients are unable to reach their specified HbA1c goal, the ADA recommends several interventions. These may include intensifying the treatment regimen, identifying barriers to adherence, and increasing frequency of patient contact.[22] Prior studies have reported improvements in patient's glycemic control through pharmacist intervention. In particular, physician-pharmacist collaboration has been shown to significantly improve glycemic control in patients who did not reach their treatment goals with usual medical care.[23] An intervention where a pharmacist follows-up on the patient's self-monitored goals and assists them in identifying and overcoming barriers can be implemented. Thus, the results from this study will serve as an important resource to design and implement targeted patient interventions that help improve the

health of the diabetes population and also enhance their quality of life. A follow-up to this study could be to employ a pharmacist-based intervention to address the identified barriers, following which a cost benefit analysis could be performed to examine whether the pharmacist-based intervention is an economically viable option that can be implemented on a large scale.

CHAPTER 2: REVIEW OF LITERATURE

Limited data exists on improving diabetes self-management among patients with T2DM. In addition, views and practices of primary care physicians caring for these patients have received little attention. Thus, the overall study objective was to identify the barriers to self-management of diabetes in a primary care setting from the perspective of both patients and physicians.

Objectives of the Review

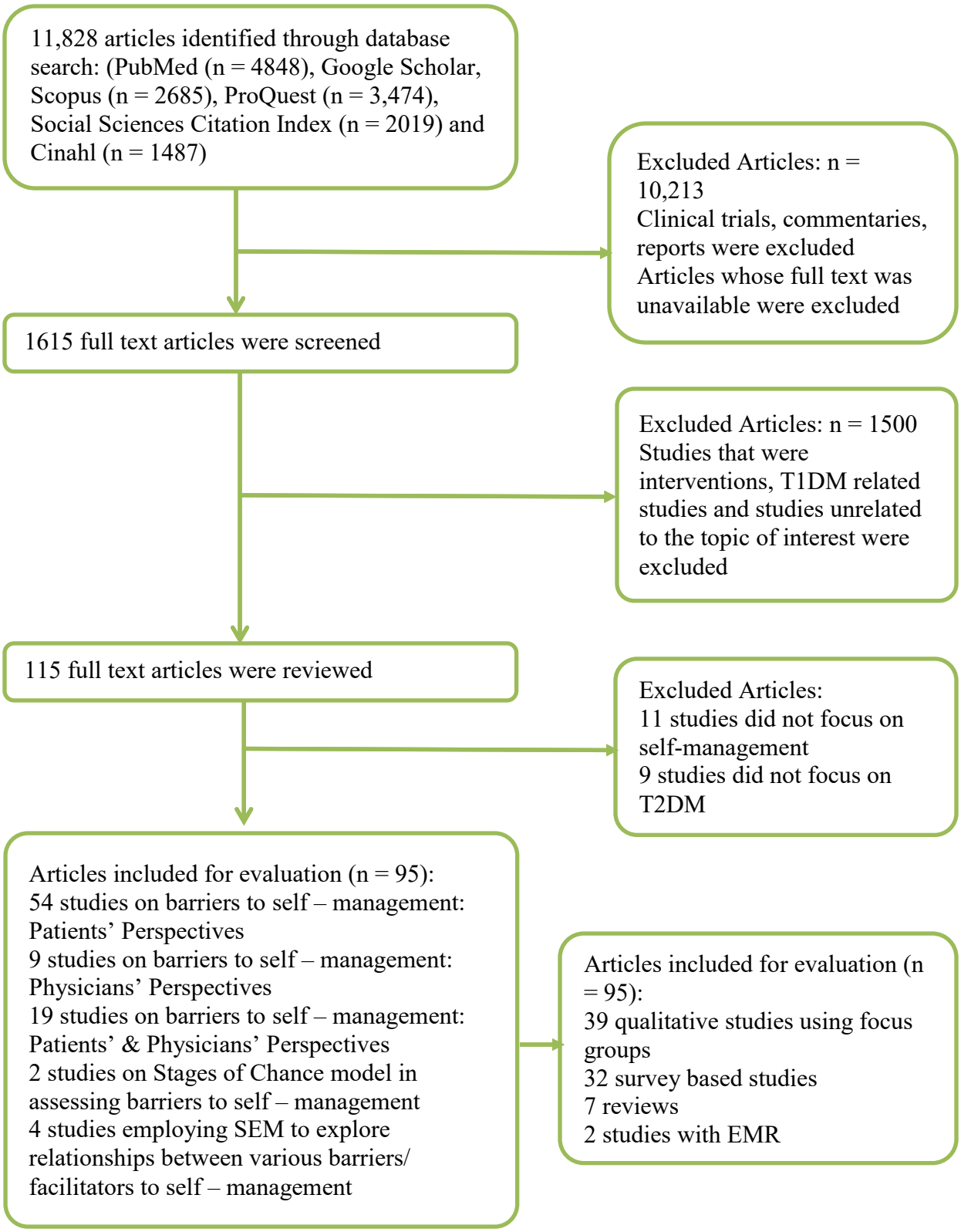
The goal of the review was to identify studies that have reported barriers and facilitators to self-management of T2DM from the perspectives of patients and healthcare providers such as physicians, nurse practitioners and/ or medical assistants, or both patients and healthcare providers. The review also included studies that employed the Transtheoretical Model of Change (Stages of Change Model) in identifying barriers and facilitators of self-management. Further, articles exploring the relationship between these factors and self-management and/ or glycemic control using a structural equation modeling (SEM) framework were also examined.

Methods

Search Strategy

A systematic literature search was conducted among peer-reviewed journals from year 1990 to year 2014 across electronic databases such as PubMed, Scopus, Google Scholar, and CINAHL. The search was conducted in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Figure 2.1).

Figure 2.1: Schematic Presentation of Methodology and Search Criteria



The search strategy included the following keywords and their combinations: *Diabetes, type 2 diabetes, self–management, self–care, barriers, facilitators, factors, clinical inertia, stages of change, readiness to change, transtheoretical model of change.* The search was expanded by the identification of additional key search and MESH terms uncovered in the initial review. Some searching on other databases, such as ProQuest and Social Sciences Index was also fruitful, in identifying articles of interest. Bibliographies of identified articles were screened for additional studies of relevance that may have been cited. The search was limited to studies published in the English language. However, the search was not limited by geographic location of the study population.

The aim of this search was:

1. To identify studies that assessed barriers and facilitators to diabetes self–management in patients with T2DM from the perspectives of patients and/ or their health care providers
2. To explore studies that assessed health care providers' challenges in addressing these barriers
3. To evaluate studies that assessed changes in patient behavior based on the Stages of Change Model
4. To identify studies that explored the relationships between various barriers and facilitators to self–management and glycemic control in patients with T2DM

Inclusion and Exclusion Criteria

Articles were included in the final review if they explored the barriers and facilitators to DSM in T2DM population or explored the providers' challenges in addressing these barriers. Articles that evaluated the self-management behavior of patients with T2DM using a theoretical framework were also included in the review. Studies focusing on T1DM or on interventions for improving the self–management in patients with T2DM were excluded from the final review. Randomized clinical trial studies that reported only clinical outcomes, articles that assessed non-pharmacological treatments, psychometric studies, conference abstracts, dissertations, commentaries, editorials, or summary reports and review articles were excluded from the review.

Data Extraction

After applying the inclusion/exclusion criteria, the identified studies were further subjected to extensive review in order to extract the relevant data. For studies assessing barriers and facilitators to diabetes self- management, the following information was collected: barriers/ facilitators/ factors assessed, study population (patients/ health care providers), sample size, socio-demographic variables (age, ethnicity and geographic location), study setting, methods and key findings. Studies describing the instruments utilized to measure these factors were evaluated for the type of scale utilized and their psychometric properties such as reliability and validity. Data regarding the relationships between various patient and physician related factors associated with diabetes self-management, using a SEM framework, was also collected.

Results of Literature Search

1. Assessment of Barriers and Facilitators to Diabetes Self–Management:

Self-management plays an important role in the overall management of diabetes. A number of psychological factors such as knowledge, adherence, readiness to change and medication preferences contribute to the overall self-care behaviors of patients with T2DM. Although knowledge of the disease is paramount in coping with the stress related to living with diabetes and effectively managing it, it is not sufficient to bring about behavior change regarding self-care management to achieve optimal glycemic control. Patient's attitudes and beliefs also play a significant role in influencing their overall self-care behaviors. Other factors such as relational conflicts (disagreements or misperceptions in relations that lead to strong negative thoughts), lack of social support, financial barriers, and access to health care could influence patient's self-management of diabetes. A deeper understanding of patient's perspectives will assist health care professionals to recognize his/her specific needs and devise treatment plans to optimize the outcomes.[24]

The past two decades have seen a paradigm shift in the treatment of patients with diabetes. Surprisingly, this time period has also witnessed an increasing number of patients failing to achieve optimum glycemic control. These changes may have contributed to an increased incidence of diabetes complications over time. Evidence shows that optimum glycemic control can be achieved through early, aggressive management of diabetes.[25] However, there are several challenges to diabetes management. These include optimization of the use of treatment options to ensure adequate glycemic control, blood pressure management and lipid control, reducing the resulting complications, improving patient education on diabetes self-management

and patient adherence to pharmacologic and non-pharmacologic interventions, reducing barriers to insulin use and improving the delivery of health care.[26] This review of literature focuses on various barriers and facilitators to diabetes self-management and self-care behaviors in patients with T2DM.

Patients' Perspectives on Factors Contributing to Diabetes Self-Management

Seven standard self-management behaviors are identified by the American Association of Diabetes Educators: Healthy eating habits, active lifestyle, regular monitoring of blood glucose, medication adherence, problem solving for diabetes self-care related issues, healthy coping mechanisms and reducing the risk factors of acute and chronic complications. However, several barriers prevent the patients from performing these activities effectively. Identification of these barriers and development and implementation of realistic self-management strategies marked by collaborative alliances between patients and health care providers will ensure improved health outcomes in this population.[27] This section highlights patients' perspectives of these barriers and facilitators to diabetes self-management as elucidated in the literature search.

Self-efficacy is an important characteristic that influences patients' self-care behaviors in managing their diabetes. Rosenstock's proposal of incorporating the attribute of self-efficacy of patients in an expanded health belief model was corroborated by a study, which found that the perceived barriers to self-efficacy were associated with poor self-care behaviors while a perception of self-efficacy was associated with better adherence to self-care activities and consequentially, improved outcomes.[28]A randomized control study evaluated the 'superiority of assessment of barriers to self-care and strategies to cope with these barriers' over 'usual care with attention control' in an elderly population with diabetes.[29] It was found that diabetes-related

distress was lowered by providing attention alone, but focused strategies to cope with barriers employed by diabetes educators improved glycemic control and self-care frequency, and maintained functionality in addition to lowering distress in this population.

Self-monitoring of blood glucose (SMBG) is considered one of the major components of diabetes self-management since the results from Diabetes Control and Complications Trial demonstrated the efficacy of intense glycemic control through insulin therapy and SMBG in improving health outcomes.[30] A study by Ong et al (2014) explored the barriers and facilitators to self-monitoring of blood glucose (SMBG) in patients with T2DM dependent on insulin through semi-structured individual in-depth interviews of 15 participants in Malaysia.[31] Frustration regarding high HbA1c levels, stigma, fear of needles and pain, costs of test strip and needles, inconvenience, unconducive workplace, and lack of motivation, knowledge and self-efficacy were identified as barriers in the study. The identified facilitators to SMBG were: experiencing hypoglycemic symptoms; desire to see the effects of dietary changes; desire to please the physician; and family motivation. The authors concluded that the health care providers must take into account participant's perceptions of the purpose of SMBG, the emotions associated with SMBG, and the complexity, pain, and cost related to SMBG as well as personal and family motivation, when counseling people with diabetes on SMBG. A cross-sectional study explored similar barriers to SMBG in adults with diabetes in a Health Maintenance Organization (HMO).[32] They concluded that it is a difficult task to change the self-monitoring behavior of patients with greatest risk for poor outcomes such as the elderly, minorities and those with lower socioeconomic status.

An analysis of patient perceptions of barriers and facilitating factors to disease self-management was performed using 12 focus group interviews of 70 patients with T2DM and

hypertension in San Jose, Costa Rica and Tuxtla Gutierrez, Mexico.[33] The analysis employed a Transtheoretical Model of Change framework, where various barriers/ facilitators and themes emerging from the focus groups were categorized into different stages of change namely pre-contemplation, contemplation, preparation, action and maintenance. Another study explored the level of physical activity, barriers to physical activity and strategies employed to meet physical activity goals in patients with T2DM using a Transtheoretical Model of change framework. This study found out that patients who opted to work on physical activity participated in more general and specific physical activity and had a higher stage of change for physical activity.[34]

Poor patient–healthcare provider relationship, inadequate education and psychosocial problems were some of the themes identified in a qualitative study by Zamzam et al whose goal was to assess barriers to diabetes control in Syrian women.[35] The need to explore patient's psychological barriers was pointed out by another study that assessed the relationship between depression, self-esteem, diabetes-care and self-care behaviors in a middle-aged Mexican population.[36] Barriers to medication adherence were explored in a poorly controlled diabetes population by Odegard et al (2008) and they found that taking more than two doses of DM medication daily and difficulty reading the diabetes medication labels were two factors that had a significant association with higher HbA1c levels.[37]

The results from a study by Cox et al (2004) in low income African-American and Caucasian adults with T2DM showed that best disease management is possible in patients with high degree of knowledge of diabetes, positive attitudes, adherence to diet, and few perceived barriers to physical activity. They also found that similar educational strategies can be implemented effectively for patients with T2DM belonging to both races.[38] However, another study by Lynch et al (2012) focusing on racial differences between African American and

Mexican American low income T2DM patients pointed out that several differences exist between these races with respect to diabetes self-management and that an understanding of these differences may facilitate development of effective self-management interventions in these high risk populations.[39] The need for improving diabetes self-management knowledge is also underscored by a cross-sectional survey based study of 30 Puerto Rican adults with T2DM.[40]

A qualitative survey based study by Zgibor and Simmons (2002) explored the barriers to blood glucose monitoring (BGM) in a multiethnic community.[41] Following categories of barriers to diabetes care were generated: Internal psychological (self-efficacy/health beliefs), external psychological (psychosocial environment), internal physical (comorbidities/side effects of treatment), external physical (finance/access to care) and educational (knowledge of diabetes/services) barriers. The findings indicated that patients reporting both internal and external psychological barriers and external physical barriers were unsuccessful at performing BGM irrespective of their age, ethnicity, insulin use, sex, diabetes knowledge, and glycemic control.

Depression is associated with a higher number of barriers to self-management in patients with T2DM. This underscores the importance of depression screening and depression treatment in these patients.[42] Another important factor identified by Tiedt et al in a Native American population was perceived unsatisfactory care, which served as a barrier to self-management. Other barriers to self-management in this population were communication barriers (distrust, misunderstanding, and educational methods) and organizational barriers (quality of care and access issues).[43] Interventions addressing these barriers should have cultural relevance and incorporate family support and diabetes self-management skills education.[44] Good social support is a significant indicator of health promoting activities and overall well-being among patients

with T2DM.[45] Family support can play an important role in improving self-efficacy of patients with diabetes and thus, improve their overall self-management adherence. On the other hand, non-supportive behaviors by family members can influence the patients' self-management adherence negatively.[46]

In a study by Strauss et al (2006), driving distance was identified as an important barrier to glycemic control in a population comprising of older, rural individuals.[47] In patients whose diabetes is resistant to the standard diabetes care and who persistently exhibit poor glycemic control, strategies should selectively target those barriers responsible for this resistance.[48, 49]

Health Care Provider's Perspectives on Factors Contributing to Diabetes Self-Management

A few studies have reported health care providers' perspectives regarding self-management in their patients with diabetes. A study by Scrambler and colleagues utilized in-depth semi-structured interviews to explore health care professional's opinions about the opportunities and barriers in empowering patients with T2DM. The result showed that empowerment of patients is beneficial for both, patients and Health Care Practitioners (HCPs). However, there are some important barriers such as lack of resources, time and HCPs' training in patient empowerment, which the HCPs face in the clinical implementation of empowerment on a daily basis. In patients who remain uncontrolled in a primary care setting, it has been suggested that directing the patients to an endocrinologist or diabetes educators who focus on addressing barriers to improving glycemic control may produce positive results.[50] This can be achieved through improved patient engagement. Intrinsic factors such as attitudes and health beliefs, depression, self-efficacy, level of diabetes knowledge and technical skill, ethnic perspectives, functional health literacy and medication adherence, impact patient engagement. In addition,

patient engagement is affected by extrinsic factors such as financial capabilities, family influences, workplace environment, community environment, clinical relationships and access to effective diabetes healthcare delivery.

Carratala-Munuera and colleagues used Delphi technique to draw consensus between the opinions of health care experts of T2DM on a 41-item questionnaire that explored barriers associated with poor glycemic control in a Spanish population with diabetes.[51] The study found that non-compliance to therapy improved with a well-informed partner/ family/ caregiver, patient education, motivation and the health care provider's ability to share and agree on decisions with the patients. Clinical Inertia, described as the lack of treatment intensification in a patient not at evidence-based goals for care, was found to improve with motivation and education of the health care professionals. It gets worse with lack of consultation time, missing data in medical records, misinterpreting border high readings as normal, lack of treatment goals and teamwork between physicians and nurse, scarcity of resources, and lack of alarm systems or flags in the EMR on potential goals. The consensus was that interventions should focus on non-therapeutic compliance and clinical inertia in order to improve glycemic control in patients with T2DM.

The need for continuous diabetes education for patients and healthcare professionals was emphasized in a study by Sprague et al (2013), which assessed diabetes educators' perspectives on barriers affecting patient access to and utilization of diabetes education and its utilization.[52] A qualitative analysis of 25 Delaware physicians identified the following barriers to diabetes management: a persistent orientation towards acute care, lack of patient based proactive patient management, insufficient diabetes self-management education, poor integration of payer-driven disease management activities, lack of available clinical information and public health support.

These findings suggest that barriers like these limit the ability of primary care providers to manage their patients with T2DM.[53]

Patient's and Health care provider's perspectives on Factors Contributing to Diabetes Self-Management

A comprehensive assessment of patient barriers from both patient's and physician's perspectives may aid in designing specific, measurable, achievable, relevant and time-bound (SMART) interventions to address these barriers. The literature review yielded the following studies that took into account both these perspectives. Nam et al (2011) published a review on barriers to diabetes management with an objective of exploring both patient and provider factors.[20] They summarized the following patient factors that could affect self-management: Adherence, attitudes and beliefs, knowledge of diabetes, culture and language capabilities, health beliefs, health literacy, financial resources, co-morbidities and social support. They also identified the following provider factors: Attitudes, beliefs and knowledge of diabetes and patient- physician communication. Another review of barriers to self-management of diabetes by Ahola et al (2012) observed knowledge, empowerment, health literacy, health beliefs, self-efficacy, coping, problem solving skills, locus of control, depression, fear of hypoglycemia, and social support as the major patient barriers while physician-patient communication and physician's knowledge, beliefs and attitudes were noted as provider barriers.[15]

Shultz et al (2001) assessed the views of patients with T2DM and their diabetes educators regarding barriers to diet and exercise, which are two of the essential components of diabetes self-management.[52] They employed cross–sectional mail survey design to gather information from patients (n = 97) from three small regional hospitals from eastern Washington and diabetes

educators (n = 147) from the Washington Association of Diabetes Educator (WADE). The results indicated a difference in patients' and diabetes educators' perceptions regarding these barriers, suggesting the need for focusing on barriers that may be specific to a given patient, thereby providing an individualized approach to care. Beverly et al (2012) explored physicians' and patients withT2DM's views on their perceived responsibility and self-blame regarding patients' difficulty in achieving diabetes treatment goals.[16] It was a qualitative study that employed in-depth interviews with a semi-structured interview guide, of 19 endocrinologists and primary care physicians and 34 patients with diagnosed T2DM. Physicians were reported to accept responsibility for patients not achieving treatment goals and felt like they may not be doing enough to help their patients. On the other hand, patients blamed themselves for not being able to achieve the recommended goals. Both physicians and patients perceived that the other felt frustrated and disappointed regarding unmet goals. The authors concluded that these factors may act as barriers to an effective relationship between physicians and patients. A better understanding of each other's frustrations and challenges in management of diabetes may result in improved outcomes in these patients and increased satisfaction in their physicians.

A total of 13 themes of barriers and facilitators to T2DM emerged in a study by Jones et al (2013) who employed a cross-sectional qualitative study design through focus group (n = 8) and telephone interviews of patients (n = 10), and telephone interviews with health professionals (n = 18). These themes include interpersonal (stress and relationships), organizational (access to recommended foods, transport, health professional, and exercise options) and societal (engagement and social attitudes).[54] Overall, the participants found it difficult to maintain preferred management behaviors.

A study by Renfrew et al (2013) conducted in Cambodia utilized focus group interviews of health care providers, staff and patients with diabetes.[55] The authors reported that certain cultural beliefs, low health literacy, and language barriers strongly affected Cambodian patients' understanding of diabetes and self- management, as well as clinicians' ability to care effectively for Cambodian patients with diabetes. Focus group interviews of 15 physicians and 37 patients with T2DM conducted by Carbone et al (2006) assessed the physicians' perceptions of patient knowledge, attitudes and behaviors. Patient knowledge, beliefs, practices, barriers and facilitators were also assessed.[56] Findings indicated that the patients frequently had negative thoughts about self-management while their religious beliefs and support of the practitioners positively affected their self-management behaviors.

Wu et al (2014) examined the differences in perceptions of self-care, health education barriers and educational needs between patients with DM and their nurses.[57] A cross-sectional survey based design was utilized in a convenience sample of 312 patients with T2DM and 202 nurses. The patients perceived that they performed self-care activities successfully while the nurses perceived the patients to be inefficient in performing these tasks. The need for diabetes education was highlighted by nurses more than patients and the nurses also perceived that the patients my experience difficulties in diabetes health education more than the patients themselves perceived.

A study by Piette et al (2003) highlighted the importance of patient physician communication in improving diabetes self-management.[58] Simmons et al (2007) found that discordance exists in the perceptions of patients and healthcare professionals regarding the importance of different barriers to diabetes care.[12]

A multinational Diabetes Attitudes, Wishes and Needs (DAWN) study assessed the psychological problems and barriers to improved diabetes management from healthcare provider and patient perspective.[59] Patients were found to rate themselves better at self-care activities in comparison to their physicians. Most patients were found to have poor psychological well-being as reported by the healthcare providers. Providers often lack the critical resources such as skill, time and adequate referral sources to improve diabetes management through addressing these barriers. The results from a South African study emphasized the need for patient-centered approach to care in enhancing their knowledge of the disease and encouraging change in health behaviors.

Summary

The articles in this review focused on several patient related factors that influence diabetes self-management and glycemic control. Facilitators such as improved self-efficacy and adherence, regular self-monitoring of blood glucose, positive attitudes, adherence to diet and physical activity and family support and social support were identified. Barriers such as lack of knowledge and motivation, frustration, stigma, poor physician – patient relationship and comorbidities such as depression were also identified. The relationships between these factors and diabetes self-management were explored using different tools such as focus groups and semi-structured interviews. Health Belief Model and Transtheoretical Model of Change were also employed in assessment of these relationships. In addition to the patient factors, several physician-related factors were identified in the review, which included barriers such as lack of time, resources and proper training of HCPs to empower patients, lack of motivation, poor physician-patient relationship and clinical inertia. The findings of this review underscore the need for a comprehensive assessment of the overall factors that influence/ affect diabetes self-

management and glycemic control. Doing so will enable health care practitioners to design and implement targeted interventions to improve health outcomes in patients with T2DM.

2. Instruments assessing various Barriers to self-management:

This section discusses various instruments assessing diabetes self-management or related self-care activities that were identified in the literature review. Van Dijk-de Vries et al (2011) developed 'Health Promotion Diabetes' (HEPRODIA) instrument to identify the needs of patients with diabetes mellitus for activities that promote health through preferred change in their lifestyle behavior.[60] The study by Mollem et al (1996) attempted to assess perceived barriers to self-care in insulin-dependent diabetes patients using Barriers in Diabetes Questionnaire (BDQ).[24] This instrument can serve as a valuable and reliable tool to find focus points for patient education in different populations. On an individual level, BDQ can help explore patient's specific problems such as difficulty in injecting insulin at regular intervals before meals, controlling the blood glucose levels, managing dietary requirements, and attitudes towards these behaviors. Lin et al (2007) developed Diabetes Self-Management Instrument (DSMI) to measure self-management of adults with T2DM.[61] Cox ED et al developed and validated PRISM (Problem Recognition in Illness Self-Management); an instrument that assesses barriers to self-management in adolescents with DM.[62] Factor analysis of the instrument identified the following domains: Understanding and Organizing Care, Regimen Pain and Bother, Denial of Disease and Consequences, and Healthcare Team, Family, or Peer Interactions. All these domains were found to be significantly related to HbA1c. Another instrument, Diabetes Self-Management Assessment Report Tool (D-SMART) collects information about patients' behaviors and identifies their priorities and barriers to change, thus providing valuable inputs for diabetes self-management education (DSME). Abubakari et al (2011) assessed the factor structure and internal

consistency of the Revised Illness Perception Questionnaire (IPQ-R) in a population with T2DM and found its psychometric properties satisfactory.[63] A modified 34-item model of IPQ-R by Brzoska et al (2012) showed good reliability and validity in in assessment of illness perception in a Turkish healthcare setting.[64] Diabetes Self-Management Questionnaire (DSMQ) was designed by Schmitt et al (2013) to assess the self-care activities that can predict glycemic control in patients with DM.[65] It demonstrated acceptable psychometric properties and has value in scientific analyses as well as clinical use for this population. The Patient perceived Difficulty in Diabetes Treatment (PDDT) scale is a 12-item questionnaire developed by Tamir et al (2012) that measures the following characteristics: adherence to self-monitoring of glucose schedule, frequency of self-monitoring of glucose, adherence to medication administration schedule, frequency of medication administration, multiple number of medications, synchronization between meals and medications, dependence on the medications, pain associated with treatment, diet restrictions, self-care, multiple healthcare providers, and costs of treatment.[66] This instrument is a resource in identifying the potential barriers to adherence to treatment guidelines and new treatment options. A 28-item Diabetes, Hypertension and Hyperlipidemia (DHL) knowledge instrument assesses the knowledge of patients regarding these diseases and medications.[67] This instrument can be used to test the baseline patient knowledge of these diseases and/ or determine the effectiveness of an educational intervention.

Table 2.1: Instruments Assessing Barriers and Facilitators to Diabetes Self-Management

Abbreviation	Instrument	Items	Domains	Domain Description	Scaling and Scoring	Administration	Psychometric Properties
HEPRODIA	Health Promotion Diabetes	14 fixed 4 – 20 variable	2	Intention to change health care behavior, Self-efficacy and needs for support to overcome obstacles (in smoking cessation, dietary behavior, physical activity and other health promoting activities)	5 point Likert scale (Strongly disagree to strongly agree)	Patients	Reliability: Cronbach's α = 0.46 to 0.74 Validity: Face validity
BDQ	Barriers in Diabetes Questionnaire	28	3	NA	5 point Likert scale (very good – very bad)	Patients	Reliability: Cronbach's α = 0.73 Validity: Unknown
DSMI	Diabetes Self-Management Instrument	35	5	Self-integration, self-regulation, interaction with health professionals and significant others, self-monitoring of blood glucose, adherence to recommended regimen	4 point Likert scale (not relevant to very relevant)	Patients	Reliability: Cronbach's α = 0.94
PRISM	Problem Recognition in Illness Self-Management	32	6	Understanding and Organizing Care, Regimen Pain and Bother, Denial of Disease and	5 point Likert scale (Strongly disagree to	Patients	Reliability: Unknown Validity: Construct,

				Consequences, and Healthcare Team, Family Interactions, Peer Interactions	strongly agree)		Discriminant, Concurrent
PDQ	Personal Diabetes Questionnaire	68	13	Perceived blood glucose control, Weight change readiness, Diet knowledge and skills, Diet change readiness, Diet decision making, Eating problems, Diet barriers, Medication use, Medication Barriers, Blood glucose monitoring, Blood glucose monitoring barriers, Physical activity, Exercise barriers	Variable scaling and scoring for each domain	Patients	Reliability: Cronbach's α = 0.650 – 0.834 Validity: Critetion
D-SMART	Diabetes Self-Management Assessment Report Tool	-	-	-	-	Patients	Reliability: Test-Retest, Inter item consistency Validity: Face, Content, Concurrent
IPQ-R	Revised Illness Perception Questionnaire	34	3	Psychological causes, Biological risk factor causes, External/ other causes.	5 point Likert Scale (Strongly agree to	Patients	Reliability: Cronbach's α > 0.61 for each subscale

					strongly disagree)		Validity: Factorial, discriminant
DSMQ	Diabetes Self-Management Questionnaire	16	5	Glucose management, Dietary control, Physical activity, Healthcare use and Sum scale	4 point Likert Scale (Applies to me very much – does not apply to me)	Patients	Reliability: Cronbach's α > 0.6 Validity: Factorial, known group, convergent
PDDT	Patient perceived Difficulty in Diabetes Treatment scale	12	1	NA	5 point Likert Scale (Not difficult at all – very difficult)	Patients	Validity: construct, discriminant
DHL	Diabetes, Hypertension and Hyperlipidemia Knowledge Instrument	28	5	Diabetes, Hypertension, Hyperlipidemia, Medications and General issues	True or False, Scoring from 0 – 28, converted to percentage	Patients	Reliability: Cronbach's α = 0.79 Validity: Content, Discriminant

Abbreviations - HEPRODIA: Health Promotion Diabetes, BDQ: Barriers in Diabetes Questionnaire, DSMI: Diabetes Self-Management Instrument, PRISM: Problem Recognition in Illness Self-Management, PDQ: Personal Diabetes Questionnaire, D-SMART: Diabetes Self-Management Assessment Report Tool, IPQ-R: Revised Illness Perception Questionnaire, DSMQ: Diabetes Self-Management Questionnaire, PDDT: Patient perceived Difficulty in Diabetes Treatment scale, DHL: Diabetes, Hypertension and Hyperlipidemia Knowledge Instrument

CHAPTER 3: METHODOLOGY

The objective of this study was to understand the perspectives of patients with T2DM and their physicians regarding the barriers and facilitators to diabetes self-management. Prior research has focused on patient- and physician-related factors separately. However, this study was conceptualized to gain a comprehensive understanding of the perceptions of patients as well as their physicians in a primary care setting, using a theoretical framework.

This chapter encompasses information on the research design, sampling methodology, data collection and statistical analyses.

Research Design

The study utilized a cross-sectional design and was conducted in two groups – physicians working in the Preferred Primary Care Physicians (PPCP) group (n = 39) and patients with T2DM who maintained an active status in the PPCP database. A mixed method approach was utilized in patients with T2DM and a combination of survey research and electronic medical record (EMR) database analysis were used to identify barriers and facilitators to self-management of T2DM. Responses from the patient survey were linked to selected clinical outcomes available in the EMR database, which was useful in gaining additional information on patients, and also validating some of the self-reported patient information from the patient surveys. For the physician group, survey research was utilized to understand their perceptions of patient barriers, and challenges they encounter in managing patients with uncontrolled T2DM.

Data Sources

Electronic Medical Records (EMR) Database

An electronic medical record (EMR) can be defined as 'a digital version of a paper chart that contains all of a patient's medical history from one practice'.[68] An EMR is essentially an electronic database for healthcare, with data recorded, developed, maintained, and/ or provided by clinicians and providers in direct patient care (diagnosis and treatment). EMR offers several advantages over paper based records, in that they allow the providers to track patient data over time, help them identify patients who require screening and other preventive visits, help monitor patients for parameters such as vaccinations or blood pressure readings, and finally help improve the quality of care provided in their practice.[68] Adoption of EMR has been initiated by several integrated health providers in the US, such as Kaiser Permanente, Harvard Pilgrim Health System, and the Department of Veteran Affairs. EMR captures important clinical information from each patient visit and thus, enables measurement of clinical outcomes and resource utilization for each patient. Bates et al. argued in favor of implementation of EMR in primary care setting; they believed that primary care is at the center of all medical care and that providing excellent primary care demands that providers have all the necessary information while providing care.[69] This information and all the decision support needs, they argued, can be made available through EMRs. The vision statement of the National Alliance for Primary Care Informatics reads:

"To provide all U.S. citizens with good quality, affordable health care, every primary care provider must be given the opportunity of using an electronic ambulatory information

system, including a fully functional electronic medical record and with ability to access needed clinical information at the time and place of care."[69]

The management of diabetes requires coordinated medical care coupled with patient self-management to decrease the risk of serious complications such as vascular, renal, and ophthalmologic morbidities. Our study focused on identifying the factors (barriers and facilitators) that are associated with diabetes self-management in a primary care setting. In addition to the self-management related behaviors of the patients, it was also of interest to measure their clinical outcomes, and examine any association these outcomes may have with the patient's level of self-management. Clinical data was pulled from the GE Centricity EMR database utilized by PPCP group. The database contains data from 2010-2014 of over 7,000 active patients receiving care from 39 primary care providers in Southwestern Pennsylvania. The EMR data constitutes longitudinal patient data that includes patient demographics and clinical diagnosis, prescribed medications, procedures and laboratory tests. The PPCP group provided the required data from EMR for the purpose of study analysis.

Patients

Identification of Patient Sample

Patients were identified from the EMR database of the PPCP group. Patients >18 years, having 2 or more visits to their physicians (01/01/2012 to 12/31/2013) with a recorded diagnosis of T2DM (ICD-9-CM: 250.xx) were identified in the EMR database. From the EMR sampling frame of 7,000+ adult patients with T2DM, a random stratified sample of 2,100 patients was drawn. The stratification technique involved creating three different strata of patients based on their HbA1c levels: 'Well Controlled' (HbA1c < 7), 'Moderately Uncontrolled' (7 < HbA1c > 9) and 'Severely Uncontrolled' (HbA1c > 9), and then randomly choosing 700 patients from each strata. We retrieved information such as the patient names, addresses, and patient unique ID for our mailing purposes from the PPCP office. All patient records were assigned unique patient IDs, which were utilized to link the patient survey responses to the patient records in the EMR database so as to extract selected clinical information such as comorbidity, HbA1c, LDL, and diabetes medications. To ensure anonymity of the respondents, each patient in the sample was assigned a unique code corresponding to the patient's unique ID before mailing out the surveys. All the identifying information such as patient name, address, and unique ID were deleted after mailing out the surveys. EMR data was extracted by PPCP group for those patients who responded to the surveys (n = 210).

Patient Survey

The patient survey was designed to collect information about the patients' demographic characteristics, their knowledge of diabetes, attitudes and health beliefs, level of self-management, and their readiness to change health related behaviors. Standardized instruments

with acceptable psychometric properties were employed to collect this information. These instruments include Diabetes Self-Management Questionnaire (DSMQ) to measure DSM related behavior, Revised Illness Perception Questionnaire (IPQ -R) to measure attitudes and beliefs towards diabetes, Readiness to Change Ruler to assess their willingness to change health related behavior, and Medication Preference Scale to identify patient preference for oral medications and insulin. In addition, clinical information such as the patient's most recent HbA1c level was also collected through the patient survey.

Description of Patient Survey Instruments

The standardized instruments included in the patient survey are summarized below. These instruments were selected as they demonstrated acceptable psychometric properties (reliability and validity) and measured the variables of interest. Permission for use of these instruments in this study was sought and received from the authors of the respective instruments.

1. Diabetes Self-Management Questionnaire (DSMQ)

Diabetes Self-Management Questionnaire (DSMQ) is a 16-item questionnaire that assesses the level of self-management in patients with T2DM. It consists of the following subscales: 'Glucose Management' (GM: items 1, 4 6, 10 and 12), 'Dietary Control' (DC: items 2, 5, 9 and 13), 'Physical Activity' (PA: items 8, 11 and 15), and 'Health-Care Use' (HU: items 3, 7 and 14), as well as a 'Sum Scale' (SS: item 16) as a global measure of self-care. The questionnaire consists of some items that are worded negatively to minimize respondent bias. Higher score represents more effective self-care. The scale scores are calculated by summing the individual item scores and transforming it to a scale ranging from 0 to 10 (raw score/ theoretical maximum score * 10). (Refer Table 3.1)

2. Diabetes Instrument

The diabetes subsection of the Diabetes, Hypertension and Hyperlipidemia (DHL) instrument was utilized to assess the patient knowledge of diabetes. It consists of 10 questions with true or false type response. Each correct answer gives 1 point to the respondent and a wrong answer gives 0 point. A higher score indicates higher diabetes knowledge. (Refer Table 3.2)

3. Revised Illness Perception Questionnaire (IPQ–R)

IPQ-R is a 34-item questionnaire that assesses the attitudes and health beliefs of patients with T2DM. The questionnaire consists of a 5-point Likert scale type response with 1 being 'strongly agree' while 5 being 'strongly disagree'. The following domains are identified in IPQ-R: Timeline (acute/ chronic), Consequences, Personal control, Treatment control, Illness coherence, Timeline cyclical, and Emotional representations. Some items are negatively worded to minimize respondent bias (Refer Table 3.3).

4. Readiness to Change Ruler

The Readiness to Change Ruler is a 5-point Likert scale that assesses the patients' willingness to change their health related behaviors. The scoring on this ruler is based on the Stages of Change Model. A score of '1 = Pre-contemplation (I do not think about changing my diabetes self-management behavior)', '2 = Contemplation (I think about changing my diabetes self-management behavior)', '3 = Preparation (I have decided to change my diabetes self-management behavior)', '4 = Action (I am already trying to change my diabetes self-management behavior)' and '5 = Maintenance (my diabetes self-management behavior has changed. I manage my diabetes efficiently)'. (Refer Figure 3.1)

5. Medication Preference Scale

This scale gathers information about the patients' preferences for medications. It's a 2-item, 10-point Likert scale seeking preference for insulin and other injectable preparations as well as for oral hypoglycemic agents, with responses ranging from 1: 'not willing at all' to 10: 'totally willing'. (Refer Figure 3.2)

Table 3.1: Diabetes Self-Management Questionnaire (DSMQ)

Sr. No.	INSTRUCTIONS: The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the last 8 weeks, please specify the extent to which each statement applies to you. Please answer the questions carefully. All responses will be kept confidential.	(3) Applies to me very much	(2) Applies to me to a considerable degree	(1) Applies to me to some degree	(0) Does not apply to me
1.	I check my blood sugar levels with care and attention ☐ Blood sugar measurement is not required as a part of my treatment	☐	☐	☐	☐
2.	The food I choose to eat makes it easy to achieve optimal blood sugar levels	☐	☐	☐	☐
3.	I keep all doctors' appointments recommended for my diabetes treatment	☐	☐	☐	☐
4.	I take my diabetes medication (e.g. insulin, tablets) as prescribed ☐ Diabetes medication/ insulin is not required as a part of my treatment	☐	☐	☐	☐
5.	Occasionally I eat lots of sweets or the other foods rich in carbohydrates	☐	☐	☐	☐
6.	I record my blood sugar levels regularly (or analyze the value chart with my blood glucose meter) ☐ Blood sugar measurement is not required as a part of my treatment	☐	☐	☐	☐
7.	I tend to avoid diabetes-related doctors' appointments	☐	☐	☐	☐
8.	I do regular physical activity to achieve optimal blood sugar levels	☐	☐	☐	☐
9.	I strictly follow the dietary recommendations given by my doctor or diabetes specialist	☐	☐	☐	☐
10.	I do not check my blood sugar levels frequently enough as would be required to achieve good blood glucose control ☐ Blood sugar measurement is not required as part of my treatment	☐	☐	☐	☐
11.	I avoid physical activity, although it would improve my diabetes	☐	☐	☐	☐
12.	I tend to forget to take or skip my diabetes medication (e.g. insulin, tablets) ☐ Diabetes medication/ insulin is not required as a part of my treatment	☐	☐	☐	☐
13.	Sometimes I have real 'food binges' (not triggered by hypoglycemia)	☐	☐	☐	☐

14.	Regarding my diabetes care, I should see my medical practitioner(s) more often	☐	☐	☐	☐
15.	I tend to skip planned physical activity	☐	☐	☐	☐
16.	My diabetes self-care is poor	☐	☐	☐	☐

Table 3.2: Diabetes, Hypertension and Dyslipidemia (DHL) Questionnaire

Item	Question	True	False
1.	Diabetes occurs in people with insufficient or no insulin	☐	☐
2.	As long as a diabetic person's fasting blood sugar level in the morning is in the normal range, he/she can eat anything for that day	☐	☐
3.	Diabetes can be cured after taking medicines for a period of time	☐	☐
4.	If the blood sugar level is high for long period of time, it may cause other health problems such as blindness	☐	☐
5.	Normal fasting blood sugar is between 70-130 mg/dL	☐	☐
6.	There is no problem for our blood pressure to remain high as long as we do not feel sick	☐	☐
7.	Blood pressure of 140/90 mmHg and above is considered as high	☐	☐
8.	If not treated, high blood pressure can lead to kidney damage	☐	☐
9.	We can feel whether our blood pressure is high or not	☐	☐
10.	Diabetic people can eat as much fruits (such as banana, papaya, orange, water melon) as they like	☐	☐

Table 3.3: Revised Illness Perception Questionnaire (IPQ-R)

Sr. No.	Question	Response				
		Strongly Agree				**Strongly Disagree**
1.	My illness will last a short time	**1**	**2**	**3**	**4**	**5**
2.	My illness is likely to be permanent rather than temporary	**1**	**2**	**3**	**4**	**5**
3.	My illness will last a long time	**1**	**2**	**3**	**4**	**5**
4.	This illness will pass quickly	**1**	**2**	**3**	**4**	**5**
5.	I expect to have this illness for the rest of my life	**1**	**2**	**3**	**4**	**5**
6.	My illness will improve in time	**1**	**2**	**3**	**4**	**5**
7.	My illness is a serious condition	**1**	**2**	**3**	**4**	**5**
8.	My illness has major consequences on my life	**1**	**2**	**3**	**4**	**5**
9.	My illness does not have much effect on my life	**1**	**2**	**3**	**4**	**5**
10.	My illness strongly affects the way other see me	**1**	**2**	**3**	**4**	**5**
11.	My illness has serious financial consequences	**1**	**2**	**3**	**4**	**5**
12.	My illness causes difficulties for those who are close to me	**1**	**2**	**3**	**4**	**5**
13.	There is a lot I can do to control my illness	**1**	**2**	**3**	**4**	**5**
14.	What I do can determine whether my illness gets better or worse	**1**	**2**	**3**	**4**	**5**
15.	The course of my illness depends on me	**1**	**2**	**3**	**4**	**5**
16.	Nothing I do will affect my illness	**1**	**2**	**3**	**4**	**5**
17.	I have the power to influence my illness	**1**	**2**	**3**	**4**	**5**
18.	The negative effects of my illness can be prevented by my treatment	**1**	**2**	**3**	**4**	**5**
19.	Treatment can control my illness	**1**	**2**	**3**	**4**	**5**
20.	There is nothing that can help my illness	**1**	**2**	**3**	**4**	**5**
21.	The symptoms of my illness are puzzling to me	**1**	**2**	**3**	**4**	**5**
22.	My illness has no meaning to me	**1**	**2**	**3**	**4**	**5**
23.	I don’t understand my illness	**1**	**2**	**3**	**4**	**5**
24.	My illness doesn’t make any sense to me	**1**	**2**	**3**	**4**	**5**
25.	I have a clear picture or understanding of my illness	**1**	**2**	**3**	**4**	**5**
26.	The symptoms of my illness change from day to day	**1**	**2**	**3**	**4**	**5**
27.	My symptoms come and go in cycles	**1**	**2**	**3**	**4**	**5**
28.	I go through cycles in which my illness gets better and worse	**1**	**2**	**3**	**4**	**5**
29.	I get depressed when I think about my illness	**1**	**2**	**3**	**4**	**5**
30.	When I think about my illness I get upset	**1**	**2**	**3**	**4**	**5**
31	My illness makes me feel angry	**1**	**2**	**3**	**4**	**5**
32.	My illness does not worry me	**1**	**2**	**3**	**4**	**5**
33.	My illness makes me feel anxious	**1**	**2**	**3**	**4**	**5**
34.	My illness makes me feel afraid	**1**	**2**	**3**	**4**	**5**

Figure 3.1: Readiness to Change Ruler

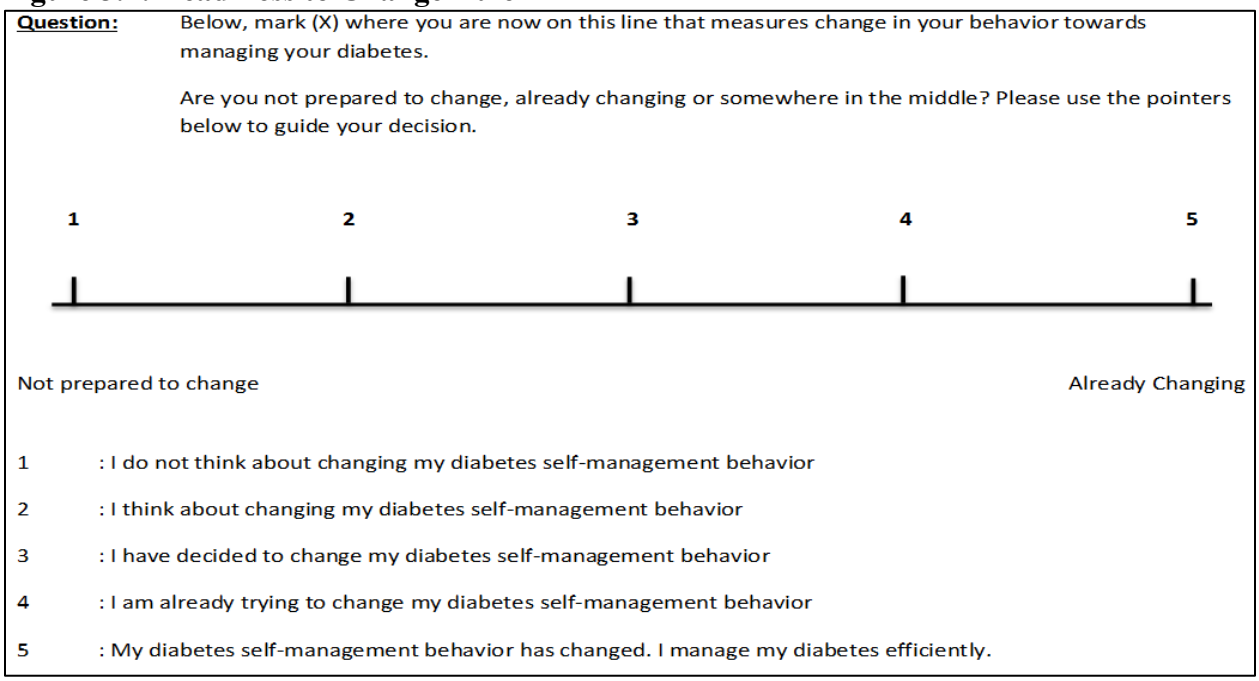


Figure 3.2: Medication Preference Scale:

Question: Based on your current medication, please circle the number that indicates your willingness to take the following medications on a scale of 1 to 10 where, 1 indicates total unwillingness and 10 indicates total willingness?

Sr. No.	Medication	Response									
		Not willing at all									Totally Willing
1.	Insulin or Injectable Preparation	1	2	3	4	5	6	7	8	9	10
2.	Oral Hypoglycemic Agents	1	2	3	4	5	6	7	8	9	10

Patient Survey Administration

A mail survey was utilized for collecting patient data. In accordance with the Health Insurance Portability and Accountability Act (HIPAA), patients were mailed a consent form at the time of study enrollment informing them of the use of their medical information for research purposes and requesting their voluntary participation. The participants were also mailed a cover letter describing the study, the questionnaires, and a self-addressed reply envelope. The survey administration was conceptualized in accordance with the Dillman Total Design Survey Method, which requires the survey population to be administered with the questionnaire booklet, which should be fewer than 12 pages.[70] The Dillman method requires four mailings (including a follow-up post card) and a non-response survey for those who did not respond to any of the mailings. Due to financial constraints (cost of survey and mailing charges), this study utilized a one-time mailing. A nonresponse analysis was conducted by comparing early to late responders since research has shown that late responders have characteristics similar to non-responders. In this study, the initial surveys were sent out in accordance with the Dillman Method but due to limited funding, follow up surveys and reminder post cards were not mailed. However, the responses received from the single mailing were enough to be able to conduct the proposed analyses.

Patient Variables Extracted from Survey Report and EMR Database

Age

Age was reported by the participants through the surveys. It was measured in years and categorized as 18 – 40 years, 41 – 50 years, 51 – 60 years, 61 – 70 years and ≥ 71 years. The survey reported age was validated from the age variable found in the EMR database.

Gender

The gender variable was used as the indicator of sex. This variable was also validated using the EMR database.

Ethnicity

For the purpose of analysis, this variable was categorized as Caucasian, African-American, Asian, Hispanic and Others. This variable was also reported in the EMR database.

Education (survey reported)

This variable records the educational status of the participants in the following groups: less than high school, high school/ vocational/ technical/ G. E. D. (General Educational Development), some college, college and graduate.

Marital Status (survey reported)

This variable measured the marital status of the participants as currently married, divorced/ separated, widowed and never married.

Yearly Household Income (survey reported)

For the purpose of analysis, the yearly household income of the participants was recorded as less than $25,000, $25,001 - $50,000, $50,001 - $75,000, $75,001 -$100,000 and greater than $100,000.

Insurance Type

We were interested to know if insurance status had any effect on the patient's self-management behaviors and HbA1c control. The variable 'Insurance Type' was used to identify the type of Insurance coverage that the participants received and was categorized into the following: Medicare, Medicaid, private, self-paid, uninsured and other.

Employment Status (survey reported)

The employment status of the participants was recorded through the patient survey as full time, part-time, retired and not employed.

Years since Diagnosis of Diabetes

This variable measures the number of years for which the participants have been diagnosed with T2DM. This information was validated using the diagnosis date obtained from the EMR database.

Recent HbA1c Level

This variable measures the most recent self-reported HbA1c reading of the participants. This value was matched to the entry in their EMR records.

Smoking Status (survey reported)

The smoking status of the participants was categorized into 3 groups: non-smoker (a person who has no history of smoking), former smoker (a person with a history of smoking, but is currently a non-smoker) and current smoker (a person who currently smokes).

Co-morbidities

This variable assesses the number of comorbidities the participants have a diagnosis for such as cardiovascular diseases (angina, heart attack, cardiovascular surgeries), hypertension, poor renal (kidney) function, peripheral neuropathy, autonomic neuropathy, retinopathy, amputation, depression, anxiety, obesity and gangrene (dead tissue).

Physicians

Identification of Physician Sample

The physicians of the PPCP group were administered with a survey to gather information on their perceptions of patient barriers and their own challenges in addressing these barriers. The PPCP group consists of 39 physicians, who were all eligible for inclusion in the survey sample.

Physician Survey Administration

The physician survey was administered at a monthly meeting of the PPCP group. A total of 24 responses were collected of which three responses were from medical staff members. Since the perceptions of physicians who were directly involved in managing patients with T2DM were being assessed, the staff responses were not included in the analysis giving a final sample of 21 physicians.

Physician Survey

The physician survey utilized both open- and closed-ended questions. Specifically, the questions probed how important and difficult the physicians perceived self-care activities was for their patients including regular moderate exercise, following a recommended diet, regular blood glucose testing, proper insulin administration and adherence to oral medications. The survey also asked the physicians about the proportion of their patients they believed were adherent to these self-care activities. Additionally, the study evaluated how important the physicians believed aspects of their practice such as physician-patient communication, patient health literacy and patient follow-up and how the physicians rated their performance on these measures and how satisfied they were with their performance. There was an interest in knowing the challenges

physicians encountered in managing their patients whose HbA1c levels are uncontrolled (HbA1c > 7); this data was collected using an open-ended question. Recurrent themes were identified using techniques suggested by Ryan and Bernard (repetitions, cutting and sorting, similarities and differences). Demographic information related to the physicians and their practice was collected in the survey.

Description of Physician Survey Instruments

The objective of the physician survey was to identify the

1. Demographic characteristics of the physician practices such as its location (urban/ rural), availability of staff support, and so on
2. Information about the physician's age, years in practice, number of T2DM patients examined per week and so on
3. The physicians' perceptions about their patients' self-management behaviors and their practice's performance in improving self-management in their patients
4. The barriers that contribute to clinical inertia (physician's inability to intensify treatment to help patients reach their unmet goals of care) in these physicians

The questionnaire was examined for its face validity and content validity through expert opinions (opinions of investigators, PPCP physicians and PPCP pharmacist) about whether the items in the questionnaire measure the above objectives adequately and completely. The items which seemed not useful were removed from the questionnaire and those that received consensus among the experts were included in the final questionnaire.

Physician Related Variables

Demographic Information

Age

This variable measures the age of the participating physicians in years.

Gender

The gender variable was used as an indicator of sex of the Physicians

Years in Practice

This variable records the number of years the physicians have spent in diabetes practice.

Patients /Week

This variable records the average number of patients with T2DM, the physicians examine per week.

Reasons for Referral

This variable enquires about the physicians' reasons for referring the patients uncontrolled on T2DM to endocrinologists.

Location

The location variable identifies the physician practice as rural or urban.

Staff Support

This variable seeks information about the type of staff support available in the physician practice: Nurse, Pharmacist, Others or None.

Variables Assessing Physician Perceptions

An important goal of the physician survey was to understand physician's perceptions about the importance and level of difficulty of various self-care activities in their T2DM patients. The study also aimed to assess the proportion of patients the physicians believed were adherent to different self-care activities. The study also sought to understand the physicians' perceptions about the importance of practice-related measures such as physician-patient communication, patient health literacy and patient follow-up. There was an interest in measuring how the physicians rated their performance on these measures and how satisfied they were with their performance. The physician survey also measured the challenges these physicians encounter in managing their T2DM patients through an open-ended question. The following variables were used to collect this information:

Importance (Self-Care Activities)

This variable assesses physician perceived importance of performing diabetes self-care activities such as regular moderate exercise, following a recommended diet, regular blood glucose testing, proper insulin administration and adherence to oral medication, using a 5-point Likert scale.

Difficulty (Self-Care Activities)

This variable assesses physician perceived difficulty in performing diabetes self-care activities such as regular moderate exercise, following a recommended diet, regular blood glucose testing, proper insulin administration and adherence to oral medication, using a 5-point Likert scale.

Adherence (Self-Care Activities)

This variable assesses physicians' perceptions about the proportion of their patients adhering to diabetes self-care activities such as regular moderate exercise, following a recommended diet, regular blood glucose testing, proper insulin administration and adherence to oral medication, using a 5-point Likert scale.

Importance (Physician Practice Factors)

This variable assesses physician perceived importance of practice related factors such as patient-physician communication, patient health literacy and patient follow-up, using a 5-point Likert scale.

Performance (Physician Practice Factors)

This variable assesses the physicians' perceptions of their performance on practice related factors such as patient-physician communication, patient health literacy and patient follow-up, using a 5-point Likert scale.

Satisfaction (Physician Practice Factors)

This variable assesses the physicians' satisfaction with practice related factors such as patient – physician communication, patient health literacy and patient follow-up, using a 5-point Likert scale.

Face-to-Face Interaction

This variable collects information about the average number of face-to-face interactions the physicians have with their T2DM patients in a 3-month interval.

Follow-Up

This variable collects information on the number of times the physicians follow up with their patients between any two face-to-face visits.

Reasons for No Follow up

This variable enquires about the various reasons that are responsible for patients not seeking follow-up care.

Responsibility of failure

This variable records the extent to which the physicians feel responsible for their patients' failure to achieve their self-management goals using a 4-point Likert scale.

Challenges

This variable gathers information about the challenges faced by Physicians in managing their patients with T2DM, using an open-ended question: "Please list the 5 most important barriers

responsible for clinical inertia n your practice." Clinical inertia is defined as the lack of treatment intensification in patients who are not on evidence based goals for care.

Institutional Review Board (IRB) Approval

The proposed study was conducted in accordance with the Institutional Review Board policies and procedures of Duquesne University. The study attempted to link the data collected from surveys to the patients' clinical data, as obtained from their electronic medical records. Additionally, this study also probed the primary care physicians of these patients regarding their beliefs about their practice. Given the nature of the proposed study, an expedited review was approved by Duquesne University Institutional Review Board.

Informed Consent

The patients in the sample were mailed an informed consent form at the time of study enrollment, informing them of the use of their medical information for research purposes and requesting their voluntary participation. To ensure confidentiality, patients who responded were tracked by the Principal Investigator (PI) using a code that was linked to the patient's unique patient ID. The survey data from the patients did not contain any identifying information except for the code corresponding to their unique patient IDs which were used to link the survey data with the EMR data extract. The primary care physicians in the practice also had to provide an informed consent prior to participating in the study.

Statistical Analysis Plan

The statistical analyses for this study were performed using IBM SPSS Statistics 23 software package. Two separate datasets were created from the patient survey and physician survey respectively. The analysis plan for the study objectives is described below:

Patient Survey

One aim of this study was to identify the barriers and facilitators to diabetes self-management (DSM). Additionally, the objective was to explore which of these factors significantly predict DSM in the study population. Descriptive statistics were conducted for patient characteristics. Correlation between the variables that were both collected through patient survey and EMR database was reported using Cronbach's α. Means and standard deviations were reported for continuous variables such as age. Frequencies and percentages were reported for categorical variables such as gender, marital status, level of education, race, insurance status, and so on. Some continuous variables such as age, HbA1c level and BMI (captured from EMR database) were converted to categorical variables to conduct appropriate analyses. Univariate regression models were run to study the impact of various study variables on DSMQ score and HbA1c level. Based on the results of the univariate regression analyses, significant predictors were entered in multinomial regression models, to identify a set of predictors that best predict HbA1c levels and DSMQ scores in these patients. Another aim of this study was to identify the differences in patients' characteristics based on their readiness to change their health behavior. Univariate analyses were conducted to identify a set of predictors that best predict the patients' readiness to change their health care behaviors.

Physician Survey

Apart from assessing the patients' perspectives about their diabetes self-care behaviors, an aim of this study was to assess their physicians' perceptions about their practice and about what prevented their patients from achieving optimal self-management. Descriptive statistics were conducted to report the characteristics of the responding physicians and their practices. Means and standard deviations were reported for continuous variables such as age and years in practice. Frequencies and percentages were reported for categorical variables such as physicians feeling responsible for patient's failure to reach self-management goals. Physicians' perceptions about their patients' self-management behaviors and their beliefs about their practices were also summarized. A qualitative component of the physician survey probed the physicians regarding the challenges they face in improving their diabetes patients' self-management. Recurrent themes were identified using techniques suggested by Ryan and Bernard (repetitions, cutting and sorting, similarities and differences) and the most common themes were reported.[71]

CHAPTER 4: RESULTS

The primary aims of this study were to identify patient perceived barriers and facilitators to diabetes self-management, to assess patients' readiness to change their diabetes self-management behavior, to identify physician perceived barriers to diabetes self-management and to explore physicians' challenges to overcome the barriers to self-management. This chapter provides an overview of the study findings.

Patient Survey

Survey Administration and Response Rate

In order to collect the information about patient perceived barriers and facilitators to diabetes self-management, a one-time mail survey was administered to a random stratified sample of 2,100 patients. The survey was mailed on June 06, 2014 and the survey responses were collected over the next three months. A total of 210 responses (10% response rate) were received of which 161 responses (76.7%) were received within the first two weeks of survey administration (early responders) while 49 responses (23.3%) were received after two weeks of survey administration (late responders). The 10% response rate is lower than the average response rate for patients with T2DM as found in the literature (around 40%). The low response rate could be attributed to the absence of multiple mailings as per Dillman method and appropriate incentives. [23] Despite the low response rate, a sample size (n = 210) was sufficient to conduct all the proposed analyses.

Nonresponse bias analysis:

We examined if early responders of the patient survey differed from late responders with respect to their characteristics. Late responders typically have characteristics similar to non-responders and it is important to assess if there is any non-response bias due to low response rate. [82, 83] It was found that early responders did not differ significantly from late responders with respect to the any patient characteristic or self-care behavior, with the *p*-value set at 0.05 thereby, increasing the confidence in the responses received (refer Table 4.1).

Objective 1: To identify patient perceived barriers and facilitators to diabetes self-management

Demographic characteristics

Table 4.2 presents the demographic and clinical characteristics of the respondents. The respondents were predominantly Caucasians (93.80%), married (60%) and the sample consisted of 108 males (51.4%). The respondents' age ranged from 24 years to 88 years (mean age= 63.68 $\pm$ 11.79 years). A majority of respondents (55.70%) were in the 55-75 years' age group. 17 respondents did not report their age. Age of the respondents was also collected from their electronic medical records (EMR) which was consistent with the age reported by the patients in the survey. Interestingly, age was missing for 6 respondents in their EMR as well. A sizable proportion of the respondents (53.4%) had at least some college education.

Table 4.1: Baseline Characteristics of Patient Sample (Stratified by Response Status)

Characteristics	Total Sample (N= 210) N (%)	Early Responders (N=162) N (%)	Late Responders (48) N (%)	P Value
Mean age (SD)	63.7 (11.7)	63.1 (11.5)	65.6 (12.3)	
Age Group				< 0.09
46 – 55 Years	41 (21.2)	36 (24.3)	5 (11.1)	
56 – 65 Years	64 (33.2)	50 (33.8)	14 (31.1)	
> 65 Years	88 (45.6)	62 (41.9)	26 (57.8)	
Gender				0.23
Male	108 (51.4)	87 (53.7)	21 (43.7)	
Female	102 (48.6)	75 (46.3)	27 (56.3)	
Ethnicity				< 0.01*
Caucasian	197 (95.2)	154 (96.3)	43 (91.5)	
African-American	5 (2.4)	5 (3.1)	0 (0.0)	
Asian	2 (1.0)	0 (0.0)	2 (4.3)	
Other	3 (1.4)	1 (0.6)	2 (4.3)	
Education				0.28
High school/ vocational	97 (46.4)	73 (45.3)	24 (50.0)	
College or Some College	74 (35.4)	55 (34.2)	19 (39.6)	
Graduate	38 (18.2)	33 (20.5)	5 (10.4)	
Marital Status				0.93
Currently Married	126 (60.3)	99 (61.5)	27 (56.3)	
Divorced/ Separated	32 (15.3)	24 (14.9)	8 (16.7)	
Widowed	31 (14.8)	23 (14.3)	8 (16.7)	
Never Married	20 (9.6)	15 (9.3)	5 (10.4)	
Yearly Income				0.92
≤ $25,000	58 (30.7)	47 (31.8)	11 (26.8)	
$25,001 - $50,000	54 (28.6)	43 (29.1)	11 (26.8)	
$50,001 - $75,000	33 (17.5)	24 (16.2)	9 (22.0)	
$75,001 - $100,000	21 (11.1)	16 (10.8)	5 (12.2)	
> $100,000	23 (12.2)	18 (12.2)	5 (12.2)	
Insurance				< 0.5
Medicare	107 (52.5)	79 (50.6)	28 (58.3)	
Medicaid	9 (4.4)	8 (5.1)	1 (2.1)	
Private	66 (32.4)	49 (31.4)	17 (35.4)	
Self-Paid	6 (2.9)	6 (3.8)	0 (0.0)	
Other	15 (7.4)	1 (0.6)	0 (0.0)	
Employment				0.62
Full – Time	53 (25.7)	40 (25.3)	13 (27.1)	
Part – Time	15 (7.3)	13 (8.2)	2 (4.2)	
Retired	114 (55.3)	85 (53.8)	29 (60.4)	
Unemployed	24 (11.7)	20 (12.7)	4 (8.3)	
Smoking				0.41
Current Smoker	18 (8.7)	15 (9.5)	3 (6.3)	

Former Smoker	72 (35.0)	58 (36.7)	14 (19.4)	
Non-Smoker	116 (56.3)	85 (53.8)	31 (64.6)	
Referral to an Endocrinologist				0.93
Yes	56 (27.7)	43 (27.6)	13 (28.3)	
No	146 (72.3)	113 (72.4)	33 (71.7)	
Comorbidities				
Cardiovascular Disease	57 (27.1)	44 (27.2)	13 (27.1)	0.17
Hypertension	156 (74.3)	120 (74.1)	36 (75.0)	0.90
Renal Failure	14 (6.7)	8 (4.9)	6 (12.5)	0.19
Peripheral Neuropathy	39 (18.6)	30 (18.5)	9 (18.8)	0.97
Retinopathy	26 (12.4)	20 (12.3)	6 (12.5)	0.51
Depression	50 (23.8)	36 (22.2)	14 (29.2)	0.48
Anxiety	43 (20.5)	32 (19.8)	11 (22.9)	0.63
Obesity	62 (29.5)	49 (30.2)	13 (27.1)	0.67

Chi square test were used with significance level set at $p < 0.05$.
* Significant associations

The yearly household income of 53.5% respondents was under $50,000; 32.3% of the respondents were employed, 54.3% were retired, and 11.4% were unemployed. The respondents greatly varied in the number of years since their first diagnosis of diabetes. The duration ranged from 1 to 60 years with a mean duration of 13.03 ± 9.749 years. Over half of the respondents (55.2%) were non-smokers. A total of 107 patients (51%) were insured with Medicare while 71 patients (33.8%) patients reported more than one source of insurance.

The patient survey also assessed patients' clinical attributes such as the comorbidities, latest HbA1c level and if the patients received any referrals to an endocrinologist by their primary care physician. Majority of respondents had comorbid hypertension (74.3%) and some other major comorbid conditions included obesity (29.5%), cardiovascular (27.1%), depression (23.8%) and anxiety (20.5%). 27.7% of the respondents were referred to an endocrinologist by their primary care physician.

The HbA1c levels of the respondents ranged from 4.5 to 14.0 with a mean of 7.83 ± 1.69. A total of 59 survey respondents (28.10%) did not report their HbA1c level. The challenges of missing data or self-reports were overcome as HbA1c data was also collected from the EMR. The EMR HbA1c levels of the respondents ranged from 5.0 to 14.6 with a mean of 7.87 ± 1.69. EMR HbA1c was missing for only seven patients (3.30%). Wherever possible, missing survey data was supplemented with EMR data extracted from the patient records and was used for further analysis. Based on the HBA1c levels, three groups were created - 'Well controlled' (HbA1c $\leq$ 7), 'Moderately Uncontrolled' (7 < HbA1c $\geq$ 9), and 'Severely Uncontrolled' (HbA1c > 9).

Table 4.2: Baseline Characteristics of Patient Sample (Stratified by Glycemic Control)

Characteristics	Total Sample (N= 210) N (%)	HbA1c ≤ 7 (N=67) N (%)	7 < HbA1c ≤ 9 (N=82) N (%)	HbA1c > 9 (N=37) N (%)	P Value
Mean age (SD)	63.5 (11.8)	66.3 (10.2)	62.7 (12.7)	60.6 (11.9)	
Age Group					< 0.01*
46 – 55 Years	41 (19.5)	5 (12.2)	25 (61.0)	11 (26.8)	
56 – 65 Years	64 (30.50)	21 (35.6)	23 (39.0)	15 (25.4)	
> 65 Years	88 (25.20)	41 (47.7)	34 (39.5)	11 (12.8)	
Gender					0.24
Male	108 (51.40)	33 (44.0)	50 (56.8)	22 (55.0)	
Female	102 (48.60)	42 (56.0)	38 (43.2)	18 (45.0)	
Ethnicity					0.17
Caucasian	197 (93.80)	70 (94.6)	83 (95.4)	38 (95.0)	
African-American	5 (2.4)	4 (5.4)	0 (0.0)	5 (2.5)	
Asian	2 (1.0)	0 (0.0)	2 (2.3)	2 (1.0)	
Other	3 (1.4)	0 (0.0)	2 (2.3)	3 (1.5)	
Education					0.40
High school/	97 (46.20)	34 (36.5)	38 (40.9)	21 (22.6)	
vocational	35 (16.70)	13 (37.1)	14 (40.0)	8 (22.9)	
Some College	39 (18.60)	16 (44.4)	14 (38.9)	6 (16.7)	
College	38 (18.10)	12 (31.6)	22 (57.9)	4 (10.5)	
Graduate					
Marital Status					0.91
Currently Married	126 (60.00)	46 (37.4)	52 (42.3)	25 (20.3)	
Divorced/ Separated	32 (15.20)	11 (35.5)	16 (51.6)	4 (12.9)	
Widowed	31 (14.80)	11 (37.9)	13 (44.8)	5 (17.2)	
Never Married	20 (9.50)	7 (36.8)	7 (36.8)	5 (26.3)	
Yearly Income					0.81
≤ $25,000	58 (27.60)	19 (33.9)	22 (39.3)	15 (26.8)	
$25,001 - $50,000	54 (25.70)	17 (32.7)	26 (50.0)	9 (17.3)	
$50,001 - $75,000	33 (15.70)	12 (38.7)	13 (41.9)	6 (19.4)	
$75,001 - $100,000	21 (10.00)	8 (40.0)	10 (50.0)	2 (10.0)	
≥ 100,001	23 (11.00)	6 (26.1)	11 (47.8)	6 (26.1)	
Insurance					< 0.05*
Medicare	107 (51.00)	51 (49.0)	38 (36.5)	15 (14.4)	
Medicaid	9 (4.30)	3 (33.3)	4 (44.4)	2 (22.2)	
Private	66 (31.40)	16 (24.6)	34 (52.3)	15 (23.1)	
Self-Paid	6 (2.90)	3 (50)	2 (33.3)	1 (16.7)	
Other	15 (7.10)	1 (7.7)	8 (61.5)	4 (30.8)	
Employment					0.58
Full – Time	53 (25.20)	15 (28.3)	27 (50.9)	11 (20.8)	
Part – Time	15 (7.10)	6 (42.9)	4 (28.6)	4 (28.6)	
Retired	114 (54.30)	45 (41.3)	46 (42.2)	18 (16.5)	
Unemployed	24 (11.40)	8 (34.8)	9 (39.1)	6 (26.1)	
Smoking					0.50

Current Smoker	18 (8.60)	6 (33.3)	6 (33.3)	6 (33.3)	
Former Smoker	72 (34.30)	27 (39.7)	31 (45.6)	10 (14.7)	
Non-Smoker	116 (55.20)	40 (35.4)	50 (44.2)	23 (20.4)	
Referral to an Endocrinologist	56 (26.70)	14 (25.9)	24 (44.4)	16 (29.6)	< 0.05*
Comorbidities					
Cardiovascular Disease	57 (27.10)	20 (37.0)	19 (35.2)	15 (27.8)	0.17
Hypertension	156 (74.30)	59 (39.3)	65 (43.3)	26 (17.3)	0.29
Renal Failure	14 (6.70)	3 (23.1)	5 (38.5)	5 (38.5)	0.19
Peripheral Neuropathy	39 (18.60)	11 (29.7)	17 (45.9)	9 (24.3)	0.55
Retinopathy	26 (12.40)	6 (26.1)	12 (52.2)	5 (21.7)	0.51
Depression	50 (23.80)	15 (30.6)	22 (44.9)	12 (24.5)	0.48
Anxiety	43 (20.50)	18 (42.9)	18 (42.9)	6 (14.3)	0.53
Obesity	62 (29.50)	22 (36.7)	28 (46.7)	10 (16.7)	0.73

Chi square test were used with significance level set at $p < 0.05$.
*Significant associations

Validation of survey responses using EMR

This study utilized survey methods to collect information about patient demographic characteristics, clinical outcomes such as most recent HbA1c level and patient beliefs about self-care activities. Additionally, information regarding their demographic characteristics and most recent HbA1c level was also collected from their EMR. For variables collected through both sources, the correlation between the survey responses and recorded EMR responses were examined to validate the survey responses. It was found that age measured through EMR was strongly correlated with age captured through survey response (Pearson's correlation $r = 0.940$, $p < 0.0001$). Similarly, the HbA1c recorded in the EMR significantly correlated with the self-reported HbA1c level, though the correlation was moderate (Pearson's correlation $r = 0.629$, $p < 0.001$).

Patients' Self-Care Behaviors

In addition to the demographic variables, the patient survey collected information about the patient's self-care behaviors such as diabetes self-management, knowledge of diabetes, attitudes and beliefs regarding their disease, their readiness to change their health related behaviors, and their preference for oral hypoglycemic agents and/ or insulin. These self-care behaviors were measured using standardized questionnaires:

a. *Diabetes Self-Management Questionnaire (DSMQ)*

The total DSMQ scores ranged from 2.08 to 9.17 with a mean score of 6.75 ± 1.31. Higher scores indicate more desirable self-management behavior. DSMQ scores were divided into 4 quartiles: 0.00-2.50, 2.51-5.00, 5.01-7.50 and 7.50-10.00. As only one respondent scored below 2.51, we merged the lower two categories into 0.00-5.00 for the purpose of further

analyses. The final categories were 'Low self-management' (DSMQ score of 5 or below), 'Average self-management' (DSMQ score between 5.01 and 7.50), and 'High self-management (DSMQ score above 7.50). A total of 17 respondents (8.4%) reported low self-management, 124 respondents (61.1%) reported average self-management and 62 respondents (30.5%) reported high self-management. A higher proportion of patients with HbA1c < 7 had higher DSMQ scores as compared to uncontrolled HbA1c groups (refer Table 4.3).

b. Diabetes subscale of Diabetes, Hypertension and Dyslipidemia (DHL) Questionnaire

The possible scores on the DHL instrument range from 0-10. The DHL scores were categorized as 'Low knowledge' for scores ≤ 5 and 'High knowledge' for scores > 5. The respondents' DHL scores ranged from 0 to 8 with a mean DHL score of 4.82 ± 1.31. A total of 159 respondents (75.70%) were found to have low knowledge of their diabetes while 51 respondents (24.30%) were found to have high knowledge of their diabetes (Table 4.4).

c. The Revised Illness Perception Questionnaire (IPQ - R)

The Revised Illness Perception Questionnaire (IPQ - R) was employed to understand the patients' attitudes and beliefs about their disease. Some items are negatively worded to minimize respondent bias. In the IPQ-R questionnaire (refer Table 4.5), items 1 through 6 capture the respondents' beliefs about the timeline (acute/ chronic) of their disease. A majority of respondents perceived that their illness is chronic in nature and will last a long time. A majority of the patients perceived their illness to have serious consequences (items 7 through 12). However, the financial consequences were perceived to be serious by only 42.8% of the respondents. A small proportion of respondents (29.60%) agreed that their illness caused difficulties for those who are close to the patients (caregivers). Items 13 through 17 measured the

respondents' perceptions about their personal control. A majority of respondents believed that they had the power to control their illness. Items 18 through 20 measure the respondents' perceptions about their treatment control. A majority of respondents perceived that their treatment can control their illness. Items 21 through 25 measures perceived coherence of disease. A majority of respondents did not find their disease puzzling, and had a clear picture or understanding of their illness. Items 26 through 28 measured the respondents' perceptions about the cyclic nature of the symptoms of their illness. Relatively few respondents agreed that the symptoms of their illness changes from day to day or they come and go in cycles. A greater proportion of respondents perceived the symptoms of their disease to be consistent over time. Items 29 through 34 measured the emotional representations of respondents about their disease. A majority of respondents disagreed that their illness makes them depressed or upset, worries them, makes them angry, anxious or afraid.

d. Readiness to Change

The respondents were enquired about their readiness to change their healthcare behavior in accordance with the Trans-theoretical model of change. It was found that of the patients for whom HbA1c level was available through the EMR (N = 193), 21 patients (10.9%) were in the pre-contemplation or contemplation phase, 41 patients (21.2%) were in the preparation phase, 93 patients (48.2%) were in the action phase and 38 patients (19.7%) were in the maintenance phase. A higher proportion of patients who had HbA1c levels < 7, were in Action and Maintenance phase, as compared to patients in other groups (Table 4.6).

e. Willingness to take Medications

A total of 63 patients (30%) showed low willingness for taking insulin (score: 0-5) while 122 patients (58.1%) showed high willingness to take insulin (score: 6-10) (Table 4.7). The mean willingness to take insulin score was 6.94 ± 3.58. Responses were missing for 25 patients (11.9%), who chose not to answer that question. Only 18 patients (8.6%) had a low willingness for taking oral hypoglycemic agents (score: 0-5), with 174 patients (82.9%) in favor of taking them (score: 6-10). The mean willingness to take hypoglycemic agents score was 9.06 ± 2.24. 18 respondents (8.6%) did not respond to this question. The willingness to take either medication was not correlated with the patients' readiness to change.

Table 4.3: Diabetes Self-Management Questionnaire (DSMQ)

Category	Total Sample N (%)	HbA1c ≤ 7	7 < HbA1c ≤ 9	HbA1c > 9	P value
0.00 to 2.50	1 (0.5)	0 (0)	0 (0)	1 (2.5)	< 0.05
2.51 to 5.00	16 (7.9)	1 (1.3)	8 (9.1)	7 (17.5)	
5.01 to 7.50	124 (61.1)	47 (62.7)	56 (63.6)	21 (52.5)	
7.51 to 10.00	62 (30.5)	27 (36.0)	24 (27.3)	11 (27.5)	

Chi square test was performed with significance level set at $p < 0.05$.
Higher DSMQ score suggests better self-management of diabetes.

Table 4.4: Diabetes, Hypertension, and Hyperlipidemia (DHL) Questionnaire

Category	Total Sample N (%)	HbA1c ≤ 7	7 < HbA1c ≤ 9	HbA1c > 9	P value
Low (0-5)	159 (75.7)	59 (78.7)	71 (80.7)	26 (65.0)	0.13
High (6-10)	51 (24.3)	16 (21.3)	17 (19.3)	14 (35.0)	

Chi square test was performed with significance level set at $p < 0.05$.

Table 4.5: Revised Illness Perception Questionnaire (IPQ-R)

Sr. no.	Item	Proportion of respondents (%)				
		Strongly Agree				Strongly Disagree
	A. Timeline of disease (acute/ chronic)					
1	My illness will last a short time	10.0	1.0	3.8	9.5	73.3
2	My illness is likely to be permanent rather than temporary	62.4	10.0	9.0	3.3	11.9
3	My illness will last a long time	62.9	9.5	11.4	3.3	8.6
4	This illness will pass quickly	9.0	0.0	3.8	7.1	76.2
5	I expect to have this illness for the rest of my life	61.4	9.5	9.5	2.4	12.9
6	My illness will improve in time	11.4	15.7	21.0	14.8	32.4
	B. Consequences					
7	My illness is a serious condition	63.8	15.7	5.7	2.9	9.5
8	My illness has major consequences on my life	56.2	14.8	11.0	6.7	9.5
9	My illness does not have much effect on my life	9.5	6.2	18.1	13.3	51.0
10	My illness strongly affects the way other see me	8.6	4.8	21.4	13.3	49.0
11	My illness has serious financial consequences	25.2	17.6	27.1	12.4	14.3
12	My illness causes difficulties for those who are close to me	14.8	14.8	21.9	12.4	31.4
	C. Personal Control					
13	There is a lot I can do to control my illness	61.4	22.4	8.6	1.4	3.8
14	What I do can determine whether my illness gets better or worse	59.0	19.0	11.4	1.4	5.2
15	The course of my illness depends on me	54.8	22.9	9.0	5.7	5.2
16	Nothing I do will affect my illness	8.1	3.8	5.7	10.0	68.6
17	I have the power to influence my illness	54.3	21.9	12.4	3.8	5.2
	D. Treatment Control					
18	The negative effects of my illness can be prevented by my treatment	34.8	28.6	22.9	4.8	5.7
19	Treatment can control my illness	49.0	28.1	11.9	2.4	6.2
20	There is nothing that can help my illness	6.2	2.4	8.6	11.4	68.1
	E. Perceived Coherence					
21	The symptoms of my illness are puzzling to me	7.6	11.9	21.0	18.6	38.1
22	My illness has no meaning to me	7.1	2.9	8.6	8.6	69.5
23	I don't understand my illness	5.7	7.6	19.0	15.7	48.6
24	My illness doesn't make any sense to me	6.7	8.1	14.8	17.6	49.0
25	I have a clear picture or understanding of my illness	36.7	20.5	23.3	10.0	5.7
	F. Timeline (Cyclic Nature of Disease)					
26	The symptoms of my illness change from day to day	16.2	13.3	25.7	16.2	25.2
27	My symptoms come and go in cycles	13.8	10.5	20.5	19.5	32.4
28	I go through cycles in which my illness gets better and worse	17.1	12.4	26.7	16.7	23.3

	G. Emotional Representation of Disease					
29	I get depressed when I think about my illness	16.2	13.8	18.1	13.3	36.2
30	When I think about my illness I get upset	13.8	11.9	21.0	9.0	40.5
31	My illness makes me feel angry	14.8	11.0	17.6	13.3	40.0
32	My illness does not worry me	8.1	10.5	17.6	19.5	40.5
33	My illness makes me feel anxious	11.4	11.0	26.7	10.5	27.1
34	My illness makes me feel afraid	11.4	13.8	19.5	20.0	32.4

Table 4.6: Readiness to Change

Category	Total Sample N = 193 (%)	HbA1c ≤ 7	7 < HbA1c ≤ 9	HbA1c > 9	P value
Pre-contemplation & contemplation	21 (10.9)	6 (8.5)	10 (11.8)	5 (13.5)	< 0.61
Preparation	41 (21.2)	11 (15.5)	23 (27.1)	7 (18.9)	
Action	93 (48.2)	38 (53.5)	37 (43.5)	18 (48.6)	
Maintenance	38 (19.7)	16 (22.5)	15 (17.6)	7 (18.9)	

Chi square test was performed with significance level set at $p < 0.05$.

Table 4.7: Willingness to Take Medications

Category	Total Sample N (%)	HbA1c ≤ 7	7 < HbA1c ≤ 9	HbA1c > 9	P value
OHAs					0.59
0-5	18 (8.6)	8 (11.0)	7 (9.5)	2 (5.1)	
6-10	174 (82.9)	65 (89.0)	67 (90.5)	37 (94.9)	
Insulin					< 0.01
0-5	63 (30.0)	30 (47.6)	23 (28.4)	7 (19.4)	
6-10	122 (70.0)	33 (52.4)	58 (71.6)	29 (80.6)	

Chi square tests were performed and significance level was set at $p < 0.05$.
Willingness to take insulin was higher in severely uncontrolled patients compared to other groups.

Univariate Relationships

Univariate relationships between HbA1c control and respondent characteristics and self-care behaviors were examined to identify variables that were significantly associated with HbA1c control in this population. Other dependent variables in this study were readiness to change and level of self-management as measured by the DSMQ questionnaire. Univariate associations between these variables, and respondent characteristics and self-care behaviors were also examined. Chi square statistic was used to examine these associations. Fisher's exact test was used by SPSS instead of a chi square test, if any cell size was less than or equal to 5.

Relationships between HbA1c control and Patient Characteristics:

Age was significantly associated with HbA1c control, indicating that the HbA1c control varied significantly across age groups (chi square = 15.73, $p < 0.01$) (Table 4.8). Other variables that were significantly associated with HbA1c control were referral to an endocrinologist (chi square = 6.17, $p < 0.05$), diabetes self-management measured through DSMQ (chi square = 12.01, $p < 0.05$), willingness to take insulin (chi square = 9.8, $p < 0.01$), and insurance status (chi square = 12.03, $p < 0.05$). HbA1c control was not associated with years since diagnosis, willingness to take OHAs, readiness to change, gender, education level, marital status, annual income, employment status, smoking status, knowledge of diabetes measured by DHL questionnaire.

Relationships between DSMQ Scores and Patient Characteristics:

The Diabetes Self-Management Questionnaire (DSMQ) measured the level of self-management in the study population. The DSMQ scores were significantly associated with the HbA1c control as measured from EMR (chi square = 12.01, $p < 0.05$) and with readiness to

change (chi square = 33.04, $p < 0.001$) (Table 4.9). The association between DSMQ score and variables such as age, willingness to take insulin or OHAs, response status, the patient's knowledge of diabetes as measured by the DHL questionnaire, years since diagnosis of diabetes, referral to an endocrinologist, smoking status, employment status, insurance coverage, marital status, annual income, and level of education.

Table 4.8: Relationship between HbA1c and Patient Characteristics

Characteristics	χ^2	D.F.	p – value
Age	17.19	4	< 0.01
Diabetes Self-Management (DSMQ)	12.01	4	< 0.05
Willingness to take Insulin	9.80	2	< 0.01
Insurance Status	12.03	4	< 0.05
Referral to an Endocrinologist	6.17	2	< 0.05

Chi square tests were performed and significance level was set at $p < 0.05$.

Table 4.9: Relationships between Self-Management (DSMQ) and Patient Characteristics

Characteristics	χ^2	D.F.	p – value
HbA1c Control	12.01	4	< 0.05
Readiness to Change	33.04	6	< 0.001

Chi square tests were performed and significance level was set at $p < 0.05$.

Determinants of Glycemic Control

An objective of this study was to identify the factors associated with glycemic control in the study population. Glycemic control measured through most recent HbA1c value in EMR is the primary outcome variable in this study. It is operationalized as well-controlled (HbA1c ≤ 7), moderately uncontrolled (7 < HbA1c > 9), and severely uncontrolled (HbA1c ≥ 9). As the response variable (HbA1c control) has more than two categories, multinomial logistic regression was utilized. A backward stepwise approach was used to specify the model. The first model tested for main effects and all the independent (predictor) variables were entered in the model. The backward stepwise approach utilized 0.1 as the probability for a variable to exit the model. This procedure provided a model with age, DSMQ score, 'willingness to take insulin', and level of education. In the second model, the variables observed in the first model were forced entered and the interactions of age with other variables were entered in a stepwise manner. None of the interaction terms were significant and the resulting model was the same as model 1. The results of the multinomial regression model are presented in the Table 4.10 below:

$$
\begin{aligned}
&logit\,[E(Y)|X_i] \\
&\quad = \beta_0 + \beta_1 self - management\ (DSMQ) + \beta_2 age\ less\ than\ 50 + \beta_3 age\ 50 \\
&\quad - 65 + \beta_4 low\ willingness\ to\ take\ insulin \\
&\quad + \beta_5 education\ high\ school\ or\ less \\
&\quad + \beta_6 education\ college\ or\ some\ college
\end{aligned}
$$

Table 4.10: Parameter Estimates from Multinomial Logistic Regression for HbA1c control

	95% CI for Odds Ratio		
	Lower	Odds	Upper
Moderately Uncontrolled Vs. Well-controlled			
DSMQ score	0.47	0.67	0.95
Age < 50 years	1.45	4.90	16.49
Age 50 – 65	0.62	1.65	4.42
Age > 65	Ref.		
Low willingness to take Insulin	0.11	0.30	0.80
High willingness to take Insulin	Ref.		
Education high school or less	0.15	052	1.77
Education college or some college	0.07	0.25	0.86
Education graduate	Ref.		
Severely Controlled Vs. Well-controlled			
DSMQ score	0.38	0.57	0.76
Age < 50 years	1.42	6.37	28.51
Age 50 – 65	0.95	3.20	10.85
Age > 65	Ref.		
Low willingness to take Insulin	0.03	0.14	0.56
High willingness to take Insulin	Ref.		
Education high school or less	0.41	2.68	17.61
Education college or some college	0.16	1.03	6.85
Education graduate	Ref.		

Note: $R^2 = 0.27$ (Cox and Snell) and 0.31 (Nagelkerke); Model χ^2 (16) = 41.23, $p < 0.01$

Patient's level of self-management as measured by DSMQ scores was significantly associated with HbA1c control. A unit increase in DSMQ score was associated with 49% decreased odds of being moderately uncontrolled, and 75% decreased odds of being severely uncontrolled than well-controlled. Age was significantly associated with HbA1c control. Specifically, patients aged younger than 50 years were 4.9 times more likely to be moderately uncontrolled (OR=4.9, 95%CI=1.45, 16.49), and 6.4 times more likely to be severely uncontrolled (OR=6.37, 95%CI=1.42, 28.51) than well-controlled as compared to patients over 65 years of age. Patients who showed low willingness to take insulin were 7.15 times less likely to be moderately uncontrolled than well-controlled as compared to patients who showed high willingness to take insulin (OR=0.30, 95%CI=0.11-0.80), and 3.3 times less likely to be severely uncontrolled than well-controlled (OR=0.14, 95%CI=0.03-0.56). Interestingly, patients with college education were 4 times less likely to be moderately uncontrolled than well-controlled as compared to patients with graduate level education (OR=0.25, 95%CI=0.07-0.86). The associations of other variables in the regression model with HbA1c control remained non-significant.

Objective 2: To assess patients' readiness to change their diabetes self-management behavior

Relationships between Readiness-to-Change and Patient Characteristics

The variable 'readiness to change' measured the patients' willingness to change their diabetes related behaviors. Patients who were referred to an endocrinologist by their primary care physicians differed significantly in their readiness to change their diabetes related behaviors (chi square = 11.86, $p < 0.01$) (Table 4.11). Additionally, self-management level as measured by DSMQ was significantly associated with readiness to change (chi square = 33.04, $p < 0.001$).

Demographic variables such as age, gender, ethnicity, education, marital status, annual income, insurance status, employment status, and knowledge as measured by DHL, were not significantly associated with readiness to change.

Physician Survey

Objective 3: To identify physician perceived barriers to diabetes self-management.

The physician survey collected information about the physicians' beliefs about their clinical practice and their patients' self-management behaviors. The target sample was composed of physicians working in the PPCP group (n = 39). The survey was administered during the PPCP group's monthly meeting held in June 2014. Out of a total sample of 39, 24 responses were obtained which included 21 physicians and 3 medical staff members (1 physician assistant, 1 transition-of-care liaison and 1 nurse practitioner). The physicians were all males and the medical staff members were all females. The analyses only included responses from the 21 physicians (response rate = 53.8%) as we were interested in assessing the barriers to diabetes self-management as perceived by providers, who were directly involved in treating this patient population.

Table 4.11: Relationships between Readiness to Change and Patient Characteristics

Characteristics	χ^2	D.F.	p – value
Level of Self-management (DSMQ)	33.04	6	< 0.001
Referral to an Endocrinologist	11.11	3	< 0.01

Chi square tests were performed and significance level was set at $p < 0.05$.

Demographic and Practice Characteristics:

The survey respondents included 21 physicians and 3 medical staff members. The analyses were conducted on responses from the 21 physicians only. 71.42% respondents were older than 50 years of age (mean = 53.81 ± 8.93). Over 50% of the respondents (13 out of 24) had more than 25 years of clinical experience (mean = 23.90, SD ± 9.19). 50% of the respondents had their practice in an urban setting. The respondents examined from 5 to 60 patients with T2DM per week (mean = 20.95 ± 12.06) and a majority of physicians (76.20%) spent less than 20 minutes on a face-to-face visit (refer Table 4.12).

The physician questionnaire also enquired about other attributes of the physicians' practices such as the number of face-to-face interactions they have with their patients with T2DM in a 3-month period and the number of follow-ups they conduct between two face-to-face interactions. A majority of physicians had 1 – 2 face-to-face interactions with their patients with T2DM every 3 months. Interestingly, around 20% of physicians interacted face-to-face with their T2DM patients more than 5 times in a 3-month interval. Follow-up was conducted by over 80% of the respondents, with 14.28% respondents following up with their patients at least 3 times between two face-to-face visits. Follow-up care was offered by all of the participating physicians' practices. Therefore, the physician survey also enquired about the reasons for not receiving follow-up care in those patients who did not receive/ seek follow-up. Over half of the respondents (57.10%) agreed that follow up care was not sought by some patients as they believed they have adequate knowledge of the disease and thus, do not require follow-up. The respondents did not believe that their lack of contact with patients was a reason for no follow up.

Table 4.12: Characteristics of Physician Practice

Continuous Variables	
Characteristics	Mean (SD)
Age	53 ± 8.93
Years in Practice	23.9 ± 9.19
Number of Patients Examined Per Week	20.95 ± 12.06
Categorical Variables	
Characteristics	Total Sample (21) N (%)
Age Category	
≤ 50 years	6 (28.58)
> 50 years	15 (71.42)
Years of Experience	
≤ 25 years	8 (38.1)
> 25 years	13 (61.9)
Location of Practice	
Urban	11 (52.4)
Rural	10 (47.6)
Average time per patient per visit	
15 min	9 (42.9)
20 min	7 (33.3)
25 min	2(9.5)
30 min	3 (14.3)
Number of patients per week	
≤ 10	3 (14.3)
11 – 20	10 (47.6)
> 20	7 (33.3)
Number of interactions in a 3-month interval	
1	14 (66.7)
2	7 (33.3)
Number of follow up visits in a 3-month interval	
2	18 (85.7)
3	3 (14.3)

Around 19% of the respondents believed lack of time to interact with patients to be a reason for no follow up in their patients. 23.8% of the respondents believed that patients cannot afford follow-up care. Lack of internal support (staff, funding, materials and equipment) was not considered as a reason for 'no follow-up' by over 80% of the respondents. Other reasons provided by physicians include non-compliance, patient indifference and patients' lack of concern for their own health and their inability to keep up with appointments.

The respondents were requested to report the reasons for referring their patients with T2DM to an endocrinologist. 19 respondents considered the uncontrolled nature of their patients' disease as a reason for the referral. Six respondents cited the need for insulin therapy or insulin pump as a reason for referral to an endocrinologist. Non-compliance and poor adherence were the other reasons commonly cited by the respondents as reasons for referral to the endocrinologist. Presence of co-morbidities (other endocrine disorders such as T1DM), extreme resistance to insulin, necessity of multiple adjustments to therapy, and patient request were other reasons noted by the respondents for the referral.

Beliefs about Patient Self-Care:

An important objective of the physician questionnaire was to identify the physicians' perceptions about the importance and level of difficulty of their patients' self-care activities. These activities include regular moderate exercise, following a recommended diet, regular blood glucose testing, proper insulin administration and adherence to oral medication. In doing so, a 5-point Likert scale was utilized where 1 = 'not important at all/ not difficult at all' and 5 = 'extremely important/ extremely difficult'. Additionally, physicians were asked the proportion of their patients who were adherent to these self-care activities. Again, a 5-point Likert scale (1 =

'less than 30%', 2 = '30-50%', 3 = '50-70%', 4 = '70-90%' and 5 = 'more than 90 %') was utilized to measure the proportion of adherent patients (as perceived by their physicians).

Table 4.13 summarizes the survey responses about the physicians' beliefs about their patients' self-care activities. Self-care activities included Regular moderate exercise, following a recommended diet, regular blood glucose testing, proper insulin administration (in patients who need insulin therapy), and adherence to oral medications. It was observed that a majority of physicians (around 95%) considered these self-care activities extremely important. A higher degree of variation was observed in the physicians' perception of the level of difficulty the patients face in performing these activities. However, over half the respondents considered regular moderate exercise (85.71%), following a recommended diet (80.95%) and proper insulin administration (61.90%) as at least 'difficult'. Interestingly over half the respondents perceived adherence to medication and regular blood glucose testing as 'slightly difficult' or 'not difficult at all' (52%, 38%). 76.19% of the respondents believed that less than 50% of their patients are adherent to regular moderate exercise or following a recommended diet. However, at least 60% of the respondents believed that over half of their patients were adherent to regular blood glucose testing, proper insulin administration and took their oral medications as prescribed.

Beliefs about Physician Practice:

The study sought to identify the physicians' beliefs about aspects of their practices such as the physician-patient communication, patient health literacy and patient follow-up. Specifically, the study assessed how important the physicians believed these aspects of their practice to be in managing their patients with T2DM, how they rated their performance on these aspects, and how satisfied they were with their performance. A 5-point Likert scale was utilized

to collect this information. It was found that all the aforementioned aspects were considered extremely important or very important by a majority of respondents (95.23% - 100.00%). Overall, physicians rated their performance on these measures positively. A majority of respondents (over 90%) showed satisfaction with their performance on these measures (Table 4.14).

A sizable proportion of the respondents (66.67 %) considered themselves responsible to some extent for their patients' failure to achieve their self-management goals. However, around 30% of the respondents believed they are not responsible for their patients' failure to achieve their self-management goals. Interestingly, there was a strong association between physician perceived responsibility of patient's failure to achieve self-management goals and self-rated performance on patient follow-up (chi square = 27.34, $p < 0.001$), self-rated satisfaction with patient follow up (chi square = 21.83, $p < 0.01$), and self-rated satisfaction with patient health literacy (chi square = 17.68, $p < 0.01$).

Table 4.13: Self-care activities

	Regular moderate exercise N (%)	Following a recommended diet N (%)	Regular blood glucose testing N (%)	Proper insulin administration N (%)	Adherence to oral medication N (%)
			Importance		
Not important at all	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Slightly Important	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Important	0 (0)	0 (0)	7 (33.3)	0 (0)	0 (0)
Very important	1 (4.8)	2 (9.5)	4 (19.0)	1 (4.8)	1 (4.8)
Extremely Important	20 (95.2)	23 (90.5)	10 (47.6)	20 (95.2)	20 (95.2)
Total	21 (100)	21 (100)	21 (100)	21 (100)	21 (100)
			Difficulty		
Not difficult at all	0 (0)	2 (9.5)	6 (28.6)	2 (9.5)	5 (23.8)
Slightly difficult	3 (14.3)	2 (9.5)	5 (23.8)	6 (28.6)	11 (52.4)
Difficult	9 (42.9)	6 (28.6)	6 (28.6)	10 (47.6)	4 (19)
Very difficult	3 (14.3)	5 (23.8)	4 (19.0)	2 (9.5)	1 (4.8)
Extremely difficult	6 (28.6)	6 (28.6)	0 (0)	1 (4.8)	0 (0)
Total	21 (100)	21 (100)	21 (100)	21 (100)	21 (100)
			Proportion of adherent patients		
Less than 30%	9 (42.9)	7 (33.3)	3 (14.3)	1 (4.8)	1 (4.8)
30-50%	7 (33.3)	9 (42.9)	4 (19.0)	1 (4.8)	1 (4.8)
50-70%	4 (19.0)	3 (14.3)	9 (42.9)	9 (42.9)	9 (42.9)
70-90%	1 (4.8)	2 (9.5)	5 (23.8)	9 (42.9)	7 (33.3)
More than 90%	0 (0)	0 (0)	0 (0)	1 (4.8)	3 (14.3)
Total	21 (100)	21 (100)	21 (100)	21 (100)	21 (100)

Table 4.14: Physician Beliefs regarding their Practices

	Physician-Patient Communication N (%)	Patient Health Literacy N (%)	Patient Follow-Up N (%)
		Importance	
Not at all important	0 (0)	0 (0)	0 (0)
Slightly important	0 (0)	0 (0)	0 (0)
Important	0 (0)	1 (4.8)	0 (0)
Very important	0 (0)	7 (33.3)	3 (14.3)
Extremely important	21 (100)	13 (61.9)	18 (85.7)
Total	21 (100)	21 (100)	21 (100)
		Performance	
Very poor	0 (0)	0 (0)	0 (0)
Poor	0 (0)	2 (9.5)	1 (4.8)
Average	2 (9.5)	10 (47.6)	5 (23.8)
Good	11 (52.4)	6 (28.6)	11 (52.4)
Very good	8 (38.1)	2 (9.5)	4 (19.0)
Total	21 (100)	20 (95.2)	21 (100)
		Satisfaction	
Not satisfied at all	0 (0)	0 (0)	0 (0)
Slightly satisfied	1 (4.8)	2 (9.5)	1 (4.8)
Satisfied	4 (19.0)	10 (47.6)	6 (28.6)
Very satisfied	10 (47.6)	7 (33.3)	9 (42.9)
Extremely satisfied	6 (28.6)	2 (9.5)	5 (23.8)
Total	21 (100)	21 (100)	21 (100)

Objective 4: To explore physicians' challenges to overcome the barriers to self-management.

In order to identify the challenges physicians faced in managing their T2DM patients, the questionnaire further probed the major reasons of clinical inertia in their practices. 'Clinical Inertia' or 'Therapeutic Inertia' is defined as the lack of treatment intensification in patients who are not on "evidence-based goals" for care. The information was collected using open-ended questions and the analysis of this qualitative data was conducted to identify the common themes from the physicians' and their medical staff members' responses. Ryan and Bernard suggest various techniques to identify themes in qualitative research.[71] Based on the nature of the responses collected in this survey, coding of responses into themes was performed using simple techniques such as:

1. Repetitions: The words or phrases that were repeated in different responses were identified. Same thoughts expressed across responses irrespective of different wordings were also identified.
2. Cutting and Sorting: The identified content within each theme was cut into individual ideas and sorted into subthemes.
3. Similarities and Differences: The subthemes created were based on the similarities or difference between the ideas expressed.

There were several themes that emerged from the physicians' responses about the barriers that led to clinical inertia in their practice and these are summarized below.[71, 72]

a. Costs

The most common theme resonating in the responses was the costs associated with managing T2DM. Cost of medications was the most cited barrier that led to clinical inertia. Other costs such as those incurred for office visits (due to copay issues), costs for purchasing insulin monitoring equipment, and additional costs associated with healthy food choices (lean proteins and vegetables) were also mentioned by the respondents as barriers to intensification of therapy in their T2DM patients.

b. Patient Motivation and Interest

A few respondents noted that lack of patient interest and their unwillingness to change their health-related behaviors prevented the practitioners from intensifying treatment and improving the health outcomes of their patients. Furthermore, as mentioned by one of the respondents, the lack of motivation from the patient made the practitioner pessimistic about being able to manage this type of patients. It was observed by another respondent that patients find it difficult 'to curb their appetite for good tasting bad foods and prefer to watch TV than exercise'. Patient's lack of confidence in guidelines, which are often inconsistent among various organizations that publish them, was cited as another reason for patient's reluctance to change.

c. Knowledge

A respondent noted that there was lack of in-office diabetes education for the patients in their practice while another respondent found it difficult to get the patients to attend diabetes education outside of office visits. In general, the respondents believed that their patients did not feel they were ill or were in denial about their problems, some being unaware of secondary problems such as blindness and renal failure associated with unmanaged T2DM. Patients' fear of

injectable medications and hypoglycemia also prevented their physicians from intensifying treatment.

d. Non-compliance with Diet and Medications

Patient's non-compliance with diet, exercise and medications was cited as a barrier to treatment intensification by many respondents (47.62%). A respondent also mentioned that the patients do not keep up with scheduled visits and follow ups.

e. Polypharmacy

The respondents noted that their patients were already on multiple medications as part of their therapy and thus, it was difficult for the physicians to add more medications to their treatment regimen. Comorbidities often led to increased number of prescribed medications and could cause drug-drug interactions. Some patients were also reported to develop resistance to oral medications as well as insulin, making treatment difficult. A respondent mentioned that 'newer medications and their changing roles caused the patients and providers to stick to old patterns'. All these factors associated with polypharmacy also lead to clinical inertia according to the survey respondents.

f. Lack of Time

The respondents acknowledged that they do not have enough time to focus on their patients' diabetes related complications as the patients often have other chronic illnesses that require their attention during the office visits. Consequentially, the physicians have to let the patients work on their diet regimen and exercise, without being able to provide much care in that regard. They also

believed that the office visits were too few to be able to allocate enough time to address their patients T2DM related complications.

g. Social support

Family dynamics and lack of support from home (family members) to embrace a healthy lifestyle that includes proper diet regimen and regular exercise, was reported to be a barrier to treatment intensification by the physicians.

h. Miscellaneous

Apart from the aforementioned themes, barriers such as medication side-effects, reimbursement issues, and patients' frustration due to not reaching goals or seeing immediate results were also reported by the respondents.

CHAPTER 5: DISCUSSION

The current study provides a comprehensive assessment of barriers and facilitators to diabetes self-management from the perspectives of patients and their physicians. This chapter highlights the findings of this study, while comparing and contrasting them to existing literature. Additionally, this chapter details the conclusion of this study and provides directions for future research.

This is one of the few studies to have utilized a mixed methods design (survey report to identify patient characteristics and self-care behaviors, and EMR to obtain clinical data) to identify patient perceived barriers and facilitators to DSM in a primary care setting. Supplementing the survey responses with the EMR data provides a unique advantage of validating self-reported survey responses using the EMR data. The data collected in this study have better validity than simple surveys since some self-reported variables captured in patient surveys were validated from the data obtained from patient records in the EMR. Our analysis showed a strong correlation between the age observed in EMR and the survey reported age. The HbA1c level of the patients measured through survey report was also strongly correlated with their recent HbA1c recorded in EMR. This correlation was not as strong as age, as the survey reported HbA1c levels were approximations based on memory (measured twice a year by the physician practices), and there was also missing data. Another advantage of linking EMR data to the survey report was that it enabled us to use the HbA1c variable from EMR as a substitute for the survey recorded HbA1c to account for the higher proportion of missing values.

The identification of sample and their inclusion for survey administration was carefully planned to include a heterogeneous group of patients with varying HBA1c values. A stratified

sampling strategy was employed based on the patients' HbA1c level as observed from their EMR. Three equal groups of 700 patients each were randomly selected from patients with HbA1c ≤ 7, 7.01 < HbA1c < 9, and HbA1c > 9, respectively. Among the respondents, the three groups were well represented (67, 82, and 37 respondents respectively), due to which all analyses were conducted across the three groups. The study population was predominantly Caucasian (94%) but the race distribution in the study sample, however, was consistent with the overall demographic distribution of Southwestern PA.[73] Yet, caution should be exercised while generalizing the findings of this study in other settings with more diverse patients or comparing it with results from nationwide studies. Another issue with survey is the response rate. In this study, the response rate was 10% and thus, a question can arise if those who responded were different on measured characteristics to those who did not respond. The nonresponse bias was addressed by comparing early responders to late responders, since literature shows that late responders had characteristics similar to non-responders.[74, 75] There was no significant difference seen between these two groups, which suggest that non-response bias may not be a threat to our study findings.

Glycemic control is an important clinical marker in the overall management of T2DM. In the multivariate regression analysis, it was found that patients with higher self-management (higher DSMQ score) were more likely to have better glycemic control compared to patients with poor self-management. This is consistent with previous literature that suggest a strong link between self-management and better glycemic control, and also with better quality of life and overall prognosis of disease.[8] Another interesting observation was that patients younger than 50 years were more likely to be uncontrolled than patients 65 years and older. This is contrary to existing knowledge that age is an important risk factor for poor glycemic control.[76,77] However, a

recent US study using National Health and Wellness Survey (NHWS) found that glycemic control was the poorest in patients aged 18-64 years compared to older age groups.[78] The authors suspected increasing medication adherence with age as a potential reason for better glycemic control in the older age group as compared to the 18-64 year olds. They also found that respondents in 18 to 64 year age group had higher lack of awareness of their HbA1c levels. Thus, both low knowledge and poor adherence could have contributed to these findings. A post-hoc analysis of patient DSMQ scores across different age groups in our sample was conducted which revealed that a much lower proportion of patients aged 50 or younger (14.6%) reported high DSMQ scores compared to patients in the older age groups (31.3% and 33.2%, respectively) ($p = 0.07$) confirming our above inferences. Poor self-management in younger age group as compared to other age groups can help explain the poor glycemic control in these patients. Patients who showed low willingness to take insulin were less likely to be uncontrolled. This finding is consistent with previous literature that suggests that patients, who are uncontrolled despite using oral hypoglycemic agents and self-management tools, are more likely to receive insulin for more intensive blood glucose reduction.[26, 79] Another observation that may seem counterintuitive was that patients with graduate level education were more likely to be uncontrolled than patients with college level education. There was no difference found in glycemic control among other categories of educational attainment. The evidence on the effect of educational attainment on glycemic control in the literature is mixed. Some studies have found educational status to be a strong predictor of glycemic control while others have found no association. [80, 81] The counterintuitive findings in this study makes sense, when combined with physician's perceptions, according to whom, patients often do not seek follow-up care as they feel they have enough knowledge of their disease.

Adherence has always been a challenge in any disease area with an average documented adherence rate of 24.8%.[82] A variety of factors influence adherence rates including treatment-related factors (dosing, administration, side effects), social and financial factors (copays, insurance coverage, access, social support), patient related factors (health literacy, motivation), health team and system factors (communication, provision of care), and condition specific factors (comorbidities, depression).[82] Adherence is a patient-reported outcome and ultimately, the patient is responsible for keeping up with prescribed treatment regimens. Establishment of therapeutic relationship that improves patient knowledge and self-management skills is essential in improving adherence. It is also important to address patient motivation, which often is the hardest patient factor to target.[78, 82] In this study, we assessed patient motivation and readiness to change self-management behaviors using a readiness ruler, where a majority of patients (67.9%) reported being in the "action" or "maintenance" phase of changing their diabetes-related self-care behaviors. Moreover, the self-management scores reported on the DSMQ questionnaire were also high (> 5) for a majority of respondents (91.6%). Despite the higher readiness to change self-care behaviors, the patients were found to have low knowledge of diabetes on the DHL instrument with 75.7% patients unable to answer more than half the questions (> 5) correctly. The findings strongly suggest that these patients practice good self-management, and are willing to change their self-care behaviors, but a rate-limiting step in moving from "uncontrolled" to "controlled" HbA1c level could be their low knowledge regarding the disease. Use of multiple measures which can explore different aspects of patient knowledge may help tease out these differences. Clearly, this aspect needs to be further explored and if it is the case, then future interventions such as in-clinic diabetes education programs can be designed to selectively target these areas and improve patient knowledge of diabetes. These findings also

underscore the importance of comprehensive assessment of all these aspects of diabetes management to provide a complete picture of patient's self-management behaviors.

In addition to knowledge of T2DM, attitudes and beliefs of patients about their treatment and illness are important determinants of self-management and glycemic control. The attitudes and beliefs of patients with better self-care behaviors have been found to be different from patients with poor self-care behaviors, and are more in accordance with the views of medical experts.[85] Previous studies have also found strong associations between patient perceptions of their treatment and illness, and adherence to medications, diet and regular exercise.[86] The current study employed the revised version of the Illness Perception Questionnaire (IPQ-R), an instrument validated in T2DM population.[64] The responses on different domains within this scale suggest that a majority of patients perceived their disease to be chronic in nature, and a serious condition that had major consequences on their lives. They, however, believed that they could control the course of their illness, through proper treatment control. A majority of patients believed they understood their disease; which is in sharp contrast to their performance on the DHL questionnaire, where a majority of respondents demonstrated poor knowledge of the disease. This is indicative of patients perceiving good general awareness of their disease while, in fact, not having enough knowledge about the specific symptoms and risks associated with T2DM. This concern was also raised by their physicians in the physician survey, who cited patient's perception of having adequate knowledge of diabetes as a reason for lack of follow-up care. A majority of patients reported that they do not have negative emotional representations with respect to T2DM, such as feeling upset, anxious, depressed, worried, afraid or angry because of their illness. A small proportion of patients (around 10-15%, refer Table 4.6), however, reported having at least one of these emotional representations. This warrants an

investigation about whether the attitudes and beliefs about T2DM in this population relate to outcomes such as self-management and glycemic control. Existing literature underscores the importance of attitudes and health beliefs in improving diabetes care outcomes, and some studies have suggested use of educational tools to modify these beliefs and improve DSM.[85-88] The American Diabetes Association (ADA) has called for an individualized assessment and development of an educational plan, which takes into account relevant medical history, cultural influences, health beliefs and attitudes, diabetes knowledge, self-management skills and behaviors, readiness to learn, cognitive ability, physical limitations, family support, and financial status.[88]

Previous studies have shown that concordance between perceptions of patients and their physicians about self-care behaviors is associated with improved self-care.[88] Successful management of T2DM requires collaborative efforts between patients an\d their physicians.[89] These efforts involve improving patient-physician communication, patient-health literacy, and addressing specific barriers to self-care in these patients.[89-91] Pharmacist-led interventions such as Medication Therapy Management (MTM) services can be used to improve patient health literacy, overall self-management and self-efficacy in patients with T2DM.[91] In addition to this, strategies and policies that focus on improving medication adherence in this population may have the potential for cost savings to the healthcare system and improved health outcomes to the patients.[92] In this study, we sought to examine physician perceptions about self-care behaviors of their T2DM patients and the discordance between their perceptions and their patients'. The physician group in this study perceived the diabetes related self-care activities to be extremely important for overall management of T2DM; however, their perceptions about how difficult their patients perceived these activities varied considerably. The physicians acknowledged that

patient-physician communication, patient health literacy, and patient follow up are extremely important aspects of providing quality care to their patients; a majority of them considered the performance of their practices on these measures average or good, and a majority of them were at least satisfied with their performance. Physicians who rated their performance and satisfaction with patient follow-up and satisfaction with patient health literacy were more likely to consider themselves responsible for patients' failure to achieve self-management goals. An area where the discordance between patient and physician perceptions was highlighted in this study was patients' knowledge of the disease. Physicians cited that patients often do not seek follow-up care, as they perceive they have adequate knowledge of the disease. Interventions such as MTM services, or in-clinic patient education, can help identify and narrow such gaps in perceptions of patients and their providers.

A sizable proportion of physicians considered inability to afford follow-up care as a reason for not seeking follow-up care by their patients. Our analysis showed that a higher proportion of patients with Medicaid as a source of insurance, privately insured patients and those with other sources of insurance had moderately or severely uncontrolled HbA1c levels, as compared to patients with Medicare as a source of insurance. This finding is contrary to a published retrospective study, which found that Medicare beneficiaries were more likely to be uncontrolled as compared to privately insured individuals.[93] The mixed evidence regarding the association of type of insurance coverage with glycemic control may be due to systematic differences in the study populations. However, it is important to note that type of insurance coverage may affect receipt of follow-up care, and consequentially diabetes-management, and future studies should explore this association further. The physicians cited inability to control their patients' HbA1c levels as a reason for referral to an endocrinologist. This is consistent with

the finding from the current patient survey that a higher proportion of patients who were moderately or severely uncontrolled received a referral to an endocrinologist.

Key Takeaway Findings

In this study, patient characteristics such as age, diabetes self-management, willingness to take insulin, educational status, insurance status, and referral to an endocrinologist were associated with glycemic control. Specifically, better self-management, as measured by DSMQ scores, older age, and higher education predicted optimal glycemic control. Diabetes self-management and referral to an endocrinologist were also associated with the patient's readiness to change their diabetes self-care behaviors. Physicians in this study perceived practice characteristics to be very/extremely important. Considerable variation was observed in their perceptions about performance and satisfaction about these characteristics. Self-care activities were perceived to be very important. Recommended diet and exercise were perceived to be more difficult to follow than adhering to insulin or oral medications.

The perceived knowledge of disease and illness coherence of patients measured by the IPQ-R questionnaire was high in a majority of the respondents; their performance on the DHL questionnaire, however, was poor, with a majority of respondents unable to answer more than 50% questions correctly. This discrepancy in perceived knowledge and actual knowledge of the disease was highlighted by the physicians as well; they expressed frustration about patients not seeking follow-up care, thinking that they have enough knowledge of their disease. The pharmacist led intervention can target this area and focus on improving patient knowledge of their T2DM, through in clinic diabetes education.

Strengths

This is one of the few studies that looked at the perspectives of both patients and their physicians for comprehensive assessment of patient barriers and facilitators to DSM. Moreover, few studies in the past have combined EMR data with self-reported survey data for assessment of barriers and facilitators to DSM. Combining these data enabled validation of survey responses through the variables in the EMR data, and also provided additional clinical information about the respondent, such as comorbidities, medications, and BMI, which would have been difficult to capture accurately through surveys alone. The stratified sampling technique employed in this study allowed us to get adequate responses from all three strata. The results of this study not only help identify the predictors of glycemic control in this population, but also identify areas of discordance between physicians and their patients. These aspects can serve as targets for interventions aimed at improving glycemic control and DSM in this population.

Limitations

This study is not without limitations. The patient sample consisted of 210 responses, which translates to a 10% response rate, which is significantly lower than the response rates observed in the literature. However, this sample size was sufficient to conduct the proposed analyses. Non-response bias is a potential threat to the study findings, when responses are collected through mail-based surveys. There were no significant differences in the characteristics of early vs. responders, which suggest that non-response bias was not a threat to this study. The potential reason for a low response for this study, was the absence of multiple mailing and reminder post-card, in accordance with the Dillman survey method, due to funding constraints. The patient survey was also moderately long, requiring approximately 15 minutes of patient's

time to complete. The potential respondent burden associated with the survey could have also contributed to the low response rate.

As with any other self-reported survey study, this study may have suffered from certain biases. Social desirability bias occurs when a respondent exaggerates, or hides a true response, because they are too embarrassed to reveal private information. In this study, the respondents were asked several questions about their attitudes, beliefs, and self-management behaviors, where their responses could have been biased. To avoid or minimize this bias, we employed standardized questionnaires validated in T2DM population, in the patient survey. The survey also captured clinical information such as the patient's most recent HbA1c level, comorbidities, and so on. This could result in recall bias. A comparison of the HbA1c levels from self-report to the HbA1c levels recorded in EMR data showed a very high correlation, suggesting that recall bias was not a threat to this study.

Future Directions

The patient sample in this study is predominantly Caucasian. Though this sample is representative of southwestern PA, the generalizability of the study findings to other, more diverse populations, is suspect. Future studies should replicate this study in larger, more diverse samples, and examine if the findings are consistent with the current study. As a natural next step to this study, a pharmacist led intervention that targets the identified predictors, and specifically focuses on improving patient knowledge of their disease, could be implemented. A cost-benefit analysis of this intervention can then be performed to assess its effectiveness, and examine if it is feasible to implement such an intervention on a larger scale.

Overall Conclusions

The findings of this study underscore the importance of DSM in the overall management of T2DM. Understanding the barriers and facilitators to DSM, common to patients and their providers, while also identifying and addressing the discordance between them regarding various aspects of patient care can improve care and outcomes. Interventions including clinical services that facilitate collaborative relationships between providers and their patients are crucial in enhancing the overall management of T2DM.

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