Type 2 Diabetes Mellitus Management and Glycemic Control: Evidence from Ramallah Governorate Clinics – Palestine

التحكم في مرض السكري-النوع الثاني والسيطرة على مستوى السكر في الدم: نتائج من دراسة عيادات محافظة رام الله- فلسطين

By Sawsan Hanna Wadi Imseeh

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This Thesis was submitted in partial fulfillment of the requirements for the Master's in Community and Public health From the Faculty of Graduate Studies at Birzeit University, Palestine.

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PREFACE

I have been intrigued by the topic of DM management for some time. As a pharmacist, DM is a disease I encounter on a daily basis. Pharmacists often educate patients and support them to practice self-care.

When I started to pursue my Master's degree in Community and Public Health at Birzeit University, I was fortunate to have the opportunity to work as a research assistant for the Diabetes Project that the Institute of Community and Public Health (ICPH) had just begun working on. This is where the story begins! During the months of fieldwork, the complexity of T2DM self-management in Palestine became evident. Yet there were few published studies on the subject. Fortunately, my supervisors provided me with access to the data set collected for the Diabetes Project so as to continue the research on this important public health issue.

ACKNOWLEDGEMENTS

I would like to express my sincere gratitude to the many people who have been involved and have contributed their time, effort, knowledge and expertise to this thesis. I am indebted to these people and wish to thank each one of them deeply.

I would first like to thank my academic supervisors Dr. Nahed Mikki and Dr. Abdullatif Husseini for their continuous guidance and support, and for providing me with the access to the dataset of the Diabetes Project. I could not have been able to conduct this study without the information they provided.

Thank you also to the staff at the ICPH, especially Professor Rita Giacaman, and researcher Rula Ghandour, as well as the Umea University team—Margareta Norberg, Lars Jerden and Hans Stenlund—for the helpful assistance, feedback and advice they have provided me in their respective areas of expertise.

I owe my loving thanks, appreciation and respect to all my family members. Especially, I would like to deeply thank my Mom & Dad who assisted me in many ways, including through their prayers and emotional support they provided me throughout this project. Without their encouragement and understanding it would have been impossible for me to finish this thesis. In the end, special thanks go out to my friends who supported me spiritually throughout my Masters Degree. Thank you Dear Lord.

Sawsan H. Imseeh

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ABBREVIATIONS

AADE	American Association of Diabetes Educator
ADA	American Diabetes Association
ADDQOL	Audit of Diabetes Dependent Quality of Life
AVH	Augusta Victoria Hospital
BMI	Body Mass Index
BST	Blood Sugar Testing
BZU	Birzeit University
CDC	Center of Disease Control
CHD	Coronary Heart Disease
CI	Confidence Interval
CVD	Cardio Vascular Disease
DCI	Diabetes Complication Index
DM	Diabetes Mellitus
DPP	Diabetes Prevention Program
DSME	Diabetes Self Management Education
DVD	Digital Video Disc
EMME	Eastern Mediterranean and Middle-East
FPS	Finnish Prevention Study
FPG	Fasting Plasma Glucose
GDM	Gestational Diabetes Mellitus
GHB/ HbA1c	Glycosylated Hemoglobin / Hemoglobin A1C
HCP	Health Care Provider
HTN	Hypertension
ICC	Intra-class Correlation Coefficient
ICPH	Institute of Community and Public Health
IDPP-1	Indian Diabetes Prevention Programme-1
IGT	Impaired Glucose Tolerance
IRR	Inter-rater reliability
LCD	Liquid Crystal Display
LM	Lifestyle Modification
LR	Logistic Regression
MNT	Medical Nutrition Therapy
MoH	Ministry of Health
MTM	Medication Therapy Management
MTM	Medication Therapy Management
NCD	Non-communicable Diseases
NGO	Non-governmental Organization
NIDDM	Non-insulin Dependent Diabetes Mellitus
NIT-DM	Non-insulin Treated-Diabetes Mellitus
OGTT	Oral Glucose Tolerance Test
OHAs	Oral Hypoglycemic Agents
oPt	occupied Palestinian territory
OR	Odds Ratio
PCBS	Palestinian Central Bureau of Statistics

PMRS	Palestinian Medical Relief Society
PRCS	Palestinian Red Crescent Society
P-value	Probability value
SCA	Self-Care Activities
SCR	Self-Care Recommendations
SD	Standard Deviation
SDSCA	Summary of the Diabetes Self-Care Activities
SDSCA(E&R)	The Summary of the Diabetes Self-Care Activities- Expanded and Revised
SDSCA (Ar)	The Summary of the Diabetes Self-Care Activities- Arabic
SMBG	Self Monitoring of Blood Glucose
STL	Standard of Living
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
UAE	United Arab Emirates
UKPDS	UK prospective Diabetes Study
UNRWA	United Nations Relief and Works Agency
US	United States
WHO	World Health Organization

ABSTRACT

BACKGROUND

Diabetes Mellitus (DM) is one of the leading causes of morbidity and mortality in Palestine. The Palestine (West Bank) STEPwise Survey (2010-2011) indicated a DM prevalence of 12.7% among adults aged 25-64 years. According to the 2011 Ministry of Health (MoH) report, DM was the fourth leading cause of death in the West Bank. Yet studies on DM management and control in Palestine are lacking. This study aimed to assess the level of glycemic control as well as the level of diabetes self-management—including patient self-care activities (SCA) and provider self-care recommendations (SCR)—and to examine the associations between glycemic control (HbA1c) and SCA, as well as between glycemic control and SCR among a sample of adult patients with T2DM in the Ramallah governorate of Palestine.

METHODOLOGY

This study was based on secondary data analysis. A cross-sectional clinic-based survey was conducted with 517 adult men and non-pregnant women (M=166, F=351) diagnosed with T2DM from 11 main primary healthcare clinics in the Ramallah governorate. These clinics are operated by the ministry of health (MoH), United Nations Relief and Works Agency (UNRWA), and by non-governmental organizations (NGO) in partnership with the MoH. Participants were identified from clinic databases and verbal consent was obtained with a response rate of 83.8%. Laboratory examinations of HbA1c levels were

completed, in addition to other laboratory tests. The Arabic translated version of the Summary of Diabetes Self-Care Activities-SDSCA (Ar) scale was used to assess diabetes self-management.

Standard responses to various aspects of self-care were obtained. These responses were organized into subscales. Each subscale was categorized based on patient's performance during the week preceding the survey. Four categories were constructed as follows: 0 (no), 1 (partially performed ≤50% of days/week), 2 (partially performed >50% of days/week) and 3 (complete performance). Data was collected by trained fieldworkers between February-June 2012, and analyzed using SPSS 18. Univariate analysis described the means and proportions of variables. Chi-square tests were used mainly to assess significant associations between glycemic control and study variables: SCA, SCR, demographic and socioeconomic characteristics (sex, age, marital status, education, standard of living (STL), locale, and refugee status), the healthcare sector, and disease-related characteristics such as duration of diabetes, type of diabetes treatment, obesity and others. A logistic regression model adjusted to classical confounders (age and sex) was conducted to determine factors associated with glycemic control.

RESULTS

The mean age was 58.1±9.8SD years and the mean duration of diabetes was 9.4±7.5SD years. The mean value of HbA1c was 8.8%±2.0SD. One in five patients (19.8%) were controlled (HbA1c<7%). 58.6% of participants did not

have a healthy eating plan. On a daily basis, 16.7% adhere to their general diet plan, 1.9% adhere to a specific diet, 1.4% exercise, 5.8% test blood sugar, 26.5% adhere to foot care practices and 77.5% adhere to medications. 16.6% did not receive dietary advice from their healthcare providers, 24.8% did not receive advice on exercise, 66% did not receive advice to test their blood sugar regularly, and 2% were not prescribed medications. Bivariate analysis of glycemic control and self-care subscales, recommendations on diet, exercise and smoking cessation demonstrated no statistically significant association. Logistic regression revealed that glycemic control was not associated with any the following variables: SCA, SCR and demographic, socioeconomic characteristics. The findings indicate significant associations between glycemic control and duration of diabetes, type of diabetes treatment, patient's perceived capability of dealing with diabetes and physician's inquiry about patient eating habits.

CONCLUSIONS

Results demonstrate low levels of glycemic control among patients and sub-optimal levels of SCA and SCR. Absence of associations between glycemic control and SCA, as well as between glycemic control and SCR raise questions regarding the quality of DM care in these clinics and probably the lack of a supportive environment to implement such recommendations. Healthcare providers were not providing all patients with SCR. These findings point to the provision of medications without sufficient health education and monitoring of patients. Self-efficacy and empowerment strategies should be initiated to achieve

better disease control. Further studies are needed to explore the barriers to diabetes management in the Palestinian society.

مـــلخـــــــص

المقدمة: يعتبر مرض السكري–النوع الثاني أحد أكثر الأمراض انتشاراً وسبباً رئيسياً من مسببات الوفاة في الأراضي الفلسطينية. وفقاً لمسح تم من قبل منظمة الصحة العالمية (STEPwise Survey) في (الضفة الغربية) فلسطين لعام 2010–2011، فقد بلغت نسبة معدل انتشار مرض السكري في الكبار الذين تتراوح أعمارهم بين 25–64 عاماً إلى 12.7%. بيّن التقرير السنوي لوزارة الصحة الفلسطينية عام 2011 أن مرض السكري هو السبب الرابع الرئيس للوفاة في الضفة الغربية. تفتقر فلسطين لوجود الأبحاث والدراسات المتعلقة بالتحكم في مرض السكري–النوع الثاني والسيطرة على نسبة مستوى سكر الدم التراكمي (HbA1c) بين المرضى.

الأهداف: تهدف هذه الدراسة إلى معرفة مستوى التحكم في نسبة السكري التراكمي في الدم (نسبة HbA1c)، ومعرفة مستوى ممارسة العناية الذاتية بين مرضى السكري، والتدخلات المتبعة من قبل مقدمي الخدمات الصحية للمرضى. ولذلك لدراسة العلاقة بين التحكم في نسبة السكر التراكمي في الدم وممارسات العناية الذاتية بين مرضى السكري وبين علاقته بالإرشادات المتبعة من قبل مقدمي الخدمات الصحية للمرضى حول العناية الذاتية للمرضى لدى عينة من المرضى الفلسطينين الذين يعانون من السكري–النوع الثاني في محافظة رام الله–فلسطين. هذه الدراسة سوف تقدم توصيات تتعلق بمستوى الخدمات الصحية المقدمة من قبل فريق الرعاية الصحية الأولية، والتي من الجدير أن تؤخذ بعين الاعتبار في صنع وتطبيق السياسات الصحية.

منهجية الدراسة: تم تنفيذ الدارسة بإجراء مسح مقطعي لعينة مكونة من 517 مريض/ة (166 ذكور، 361 إناث) يعاني/تعاني من مرض السكري–النوع الثاني (عدا النساء الحوامل ومرضى سكري النوع الأول). تم اختيار العينة من 11 عيادة رئيسية من عيادات الرعاية الصحية الأولية التابعة لكل من وزارة

الصحة الفلسطينية، وكالة الغوث وعيادات مشتركة بين وزارة الصحة ومنظمات غير الحكومية (الإغاثة الطبية الفلسطينية والهلال الأحمر الفلسطيني). تم تحديد عينة الدراسة من قواعد البيانات التابعة للعيادات المشاركة في الدراسة، علماً بأنه تم أخذ الموافقة اللفظية من المرضى، وكان معدل الاستجابة للمشاركة 83.4%. تم إجراء فحص السكر التراكمي للمرضى (كاختبار لمعرفة نسبة التحكم فيHbA1c)، إضافة إلى بعض الفحوصات الطبية الأخرى. تم استخدام أداة (SDSCA) المترجمة للعربية لتقييم مستوى العناية الذاتية والتوصيات المقدمة من طاقم الرعاية الطبية فيما يتعلق بالعناية الذاتية.

نتائج الدراسة: أظهرت نتائج الدراسة أن متوسط أعمار المرضى 58.1 سنة (الانحراف المعياري=9.8) ومتوسط المدة الزمنية للإصابة بمرض السكري–النوع الثاني 9.4 سنوات (الانحراف المعياري=7.5). بلغ متوسط تركيز السكر التراكمي في الدم (HbA1c)8.8% (الانحراف المعياري= 2.0). تبين أن 19.8% من مرضى السكري كان لديهم سكر الدم ضمن المعدل الطبيعي (HbA1c 7%). 58.6%من المرضى لم يكن لديهم خطة غذاء صحي. بشكل يومي، 16.7% من المرضى اتبعوا خطتهم الغذائية العامة، 1.9% اتبعوا تغذية محددة، 1.4% مارسوا التمارين الجسمانية، 5.8% فحصوا سكر الدم، 26.5% اتبعوا ممارسات العناية بالقدم، و77.5% التزموا بتناول الأدوية خلال الأسبوع السابق لإجراء الدراسة. كما أظهرت النتائج أن 16.6% من المرضى لم يتلقوا إرشادات حول التغذية من قبل فريق الرعاية الصحية. وحوالي ربع المرضى (24.8%) لم يتلقوا نصائح حول ممارسة الرياضة، و66%من المرضى لم ينصحوا بالفحص الذاتي لسكر الدم (بالجهاز المنزلي) و2% من المرضى لم يوصف لهم أدوية للسكري. تبين أنه لا يوجد علاقة ذات دلالة إحصائية بين السيطرة على السكر االتراكمي وممارسات العناية الذاتية والإرشادات المتعلقة بالتغذية والنشاط البدني والتدخين. بناءً على تحليل الانـــحدار اللوجستي(المعدل لتأثير الجنس والعمر)، تبين من التحليل الإحصائي أن العوامل التي تؤثر على نسبة التحكم في سكر الدم هي: فترة الإصابة بمرض السكري (7 years≤)، نوع العلاج، شعور

المريض بقدرته على التحكم بالمرض واستفسار الطبيب حول العادات الغذائية للمرضى عند آخر زيارة لهم.

الخلاصة: إن أهمية الوصول إلى نسبة أعلى من مرضى سكري النوع الثاني الذين يتحكمون بمعدل سكر الدم التراكمي تتطلب من مقدمي خدمات الرعاية الصحية وضع خطط التثقيف الصحي ضمن الأولويات الوطنية، وبذل المزيد من الجهود في تدريب الكوادر الطبية على تقديم المستوى المطلوب من الخدمات الصحية التي تتلاءم واحتياجات المرضى، وتضمن استمرارية متابعتهم من قبل الطاقم الطبي بالإضافة إلى توفير ظروف مساندة لتطبيق هذه الممارسات من قبل المرضى. البدء في تنفيذ استراتيجيات التمكين وزيادة ثقة المرضى في قدرتهم على أداء ممارسات العناية الذاتية وذلك بإتاحة فرص تبادل الخبرات وقصص النجاح بين المرضى أنفسهم.هناك الحاجة لمزيد من الأبحاث والدراسات المستقبلية حول موضوع العناية الذاتية والتحكم في مرض السكري بين المرضى الفلسطينيين الذين يعيشون في ظل الفقر والظروف السياسية والاقتصادية الصعبة.

INTRODUCTION

Diabetes Mellitus: A Global Health Epidemic

Diabetes Mellitus (DM) is a chronic metabolic disease with multiple serious complications and harmful consequences. It is thus considered to be one of the major causes of death all over the world **[1]**. The global prevalence of this epidemic is increasing at an alarming rate **[2]**. Recently published statistics by the World Health Organization (WHO) estimate that around 366 million people suffer from DM all over the world, and that by the year 2030 there will be 552 million diabetics **[3]**. Around 8.3% or 25.8 million people in the US have T2DM **[4, 5].** DM itself is considered a risk factor for heart diseases **[6, 7]**. There is evidence that macro-vascular complications of DM are causes of high morbidity and mortality **[8]**.

DM is an important health issue in the developed as well as the developing world **[9]**. People in Asia have high DM prevalence; around 110 million patients had diabetes in 2007 **[9]**. Furthermore, previously conducted studies projecting DM prevalence revealed that in the Middle Eastern Crescent the number of people with diabetes is expected to rise from about 20 million in 2000 to 53 million in 2030 **[2]**. A more recent estimate of the prevalence of diabetes for 2010 and 2030 documented that North America has the highest regional prevalence for 2010 at a prevalence rate of 10.2%, followed by the Eastern Mediterranean and Middle East (EMME) at a prevalence of 9.3%, and South Asia at a prevalence of 7.6%. This

estimate showed that the African region will have the largest proportional rise in adult diabetes by 2030 as the prevalence is expected to rise from 3.8% in 2010 to 4.7% in 2030 **[10]**.

In 2011, various countries in the Arab region had a high prevalence of DM, and some of them were ranked among the top 10 countries in the world according to the International Diabetes Federation (IDF). Estimates projected that these countries will continue to have a high prevalence of DM among adults (20-79 years) in 2030 as shown in Table 1 below **[11]**.

Table 1: The prevalence of DM in 2011 and 2030 according to Diabetes Atlas, 5th edition

Country	DM Prevalence (%)	
	Year (2011)	**Year (2030)**
Kuwait	21.1	21.2
Lebanon	20.2	20.4
Qatar	20.2	20.4
Saudi Arabia	20.0	20.6
Bahrain	19.9	20.2
United Arab Emirates (UAE)	19.2	19.8
Egypt	15.6	/
Jordan	8.92	/

Additionally, epidemiological studies reported that the populations of Qatar, UAE and Saudi Arabia suffer from an early onset of T2DM **[12]**. Specifically, DM was diagnosed at the age of 20 in both Kuwait and Oman **[13, 14]**.

Additionally, the 2011 Annual report of the United Nations Relief and Works Agency (UNRWA) revealed that the prevalence of diagnosed DM among the served refugee population aged 40 years and above was 11.4% compared to 10.5% in 2010 in the five fields of UNRWA's area of operations (Jordan, Syria, Lebanon, West Bank and Gaza Strip). The report also revealed that the West Bank field (12.5%) had the highest rates of DM, followed by the Gaza Strip (12.4%), Jordan (11.2%), Lebanon (9.9%) and Syria (9.8%) **[15].**

Diabetes Mellitus in the occupied Palestine

DM is one of the leading causes of morbidity and mortality in occupied Palestine, and all estimates demonstrate that it is a major health problem affecting the country **[16]**. In this sense, it is necessary to understand the history and time trends of DM from routine data gathered by the main service providers and from epidemiological studies conducted in the region, in an attempt to highlight the local burden of T2DM.

Studies conducted in the Ramallah governorate revealed a high prevalence of DM among adults aged 30-65 years, with higher prevalence (12.0%) in an urban area (Old Ramallah) than its prevalence (10.0%) in a rural area (Kobar), though such

difference was not statistically significant, probably due to sample size issues **[17, 18]**. In 2000, the prevalence rate of DM was estimated at 9.0% in adults aged 30 years and older **[19]**. Recent data from the Palestine (West Bank) STEPwise Survey (STEPS) 2010-2011 fact sheet indicates that the overall prevalence of diabetes is 12.7% among DM patients in the age group 25-64 years, with a prevalence of 14.2% and 11.1% among males and females respectively **[20]**. In addition, the last annual report of the MoH revealed that 490 out of 3984 (12.3%) of new cases of DM registered in primary healthcare diabetes clinics in the West Bank during 2011 were from the clinics of the Ramallah governorate **[21]**.

Overview of Diabetes Mellitus

The following section provides an overview that covers the most important issues related to the definition of diabetes, diagnosis, classification, causes, risk factors, complications and methods of prevention of Diabetes Mellitus (DM).

Disease Definition: DM is a complex metabolic disorder, initiated by multiple etiologies. High blood sugar or "chronic hyperglycemia" is the key characteristic of the disease with defects in fat, carbohydrate and protein metabolism, resulting from insulin deficiency, insulin resistance or both **[3].**

Diagnosis: The laboratory diagnosis of DM based on the American Diabetes Association (ADA) and the World Health Organization (WHO) criteria uses either

the fasting plasma glucose (FPG) test or the two-hour value in the 75g oral glucose tolerance test (OGTT) **[3]**.

T2DM may be often not detected until patients suffer from its related complications if asymptomatic during the early stages of disease development **[3, 22]**. The Hemoglobin A1c [HbA1c] test is used to assess long term diabetes control as it is an excellent indicator of chronic glycemia during the previous two to three months **[23].** In 2010, Hemoglobin A1c [HbA1c] was adopted by the ADA to confirm diabetes diagnosis with a [HbA1c] threshold of $\geq$6.5 % **[24]**.

Classification: The different types of diabetes vary in causes, clinical presentation and disease progression. Therefore, diabetes mellitus (DM) has been classified into four clinical categories: Type 1 Diabetes Mellitus (T1DM), Type 2 Diabetes Mellitus (T2DM), Gestational Diabetes Mellitus (GDM) and other specific types that occur due to genetic causes or that are induced by certain drugs or chemicals **[3]**.

Causes and Risk Factors: T2DM results usually from a combination of hereditary and environmental factors **[25].** However, people with certain characteristics may be at a higher risk of developing DM as is the case for other diseases. Such factors are divided into modifiable and non-modifiable risk factors as summarized by Figure 1 **[26]**.

Research has documented that obesity is associated with increased rates of cardiovascular disease and T2DM **[27]**. Usually most T2DM patients are obese, and there is evidence that obesity may also cause insulin resistance quite variably among patients **[24]**.

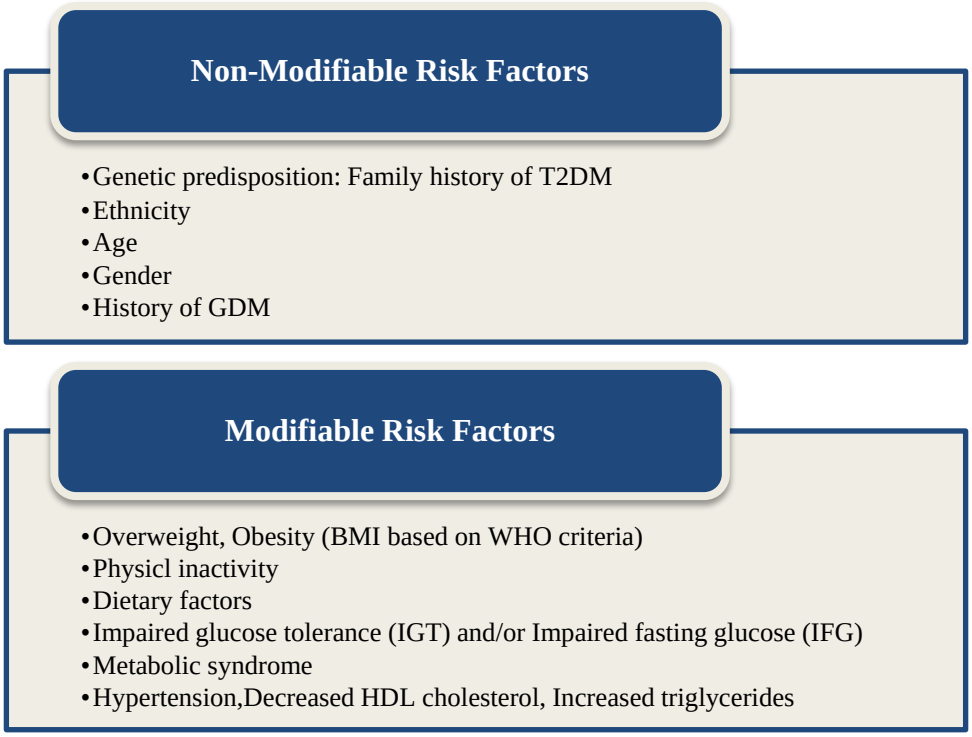

Figure 1: Modifiable and non-modifiable risk factors for T2DM

Complications of Diabetes Mellitus: Prolonged exposure to hyperglycemia in the presence of other risk factors leads to the development of acute and chronic complications **[6, 7]**. Thus, DM is associated with an increased risk of developing a wide range of micro-vascular and macro-vascular complications. These micro-vascular complications include diabetic nephropathy, neuropathy, and retinopathy, while the macro-vascular complications include coronary artery disease,

peripheral arterial disease, and stroke **[28]**. Studies estimated that micro-vascular complications exist in around 25% of individuals newly diagnosed with T2DM, demonstrating that the diagnosis is delayed six to seven years from diabetes onset in these patients **[29]**. The following section sheds light on the importance of lifestyle modification as an essential interventional behavior for the primary prevention of DM, in addition to its major impact on other levels of prevention that include prevention of diabetes-related complications, among others, in an attempt to achieve better disease control and self-management among T2DM patients.

Prevention of Diabetes Mellitus: Some important studies have examined the role of lifestyle interventions in the prevention or reduction of the incidence of T2DM among high risk populations **[26, 30-32]**. The Da Qing cohort study identified the impact of diet and exercise in preventing non-insulin dependent diabetes mellitus (NIDDM) in people with impaired glucose tolerance (IGT) in the Chinese community through encouragement of the following: weight loss for overweight subjects, dietary modification and exercise or both interventions together. The study demonstrated a significant reduction in diabetes development over six years of follow up **[31]**. In addition, the Finnish Prevention Study (FPS) was also among the first studies conducted on this topic. It examined the impact of lifestyle intervention in preventing T2DM in overweight/obese individuals with (IGT). The three year study showed a decrease in the incidence of T2DM due to intensive interventional behavior such as reducing body weight and fat intake, as well as

increasing physical activity and dietary fibers **[26, 30, 32]**. The Diabetes Prevention Program (DPP) study in the US demonstrated that lifestyle intervention was more effective than Metformin in reducing the incidence of DM among high risk groups (i.e. those with elevated fasting and post-load plasma glucose concentrations), though both interventions reduced the incidence by 58% and 31% respectively **[22]**. Based on other studies, as in the Indian Diabetes Prevention Programme (IDPP-1), diabetes was prevented among people with IGT either by lifestyle modification (LM) or Metformin, with no added value as a result of combining both interventions (LM and Metformin) **[33]**.

As demonstrated by the above studies, DM is a global epidemic, and addressing this healthcare problem requires urgent actions to reduce the burden of the disease globally[**34]**. Therefore, the secondary level of prevention involves the prevention of diabetic complications through achieving optimal glycemic control and the management of other simultaneous risk factors (hypertension [HTN], microalbuminurea, hyperlipidemia, cessation of smoking) **[35]**. Therefore, it is crucial to highlight the importance of self-care behavior among T2DM patients at any level of prevention, in particular the secondary prevention of its related complications, as it is an integral part of DM control and management in patients who have already developed this chronic illness.

SCOPE OF THE STUDY

Strict glycemic control is necessary to prevent or delay diabetes-related complications and achieve better diabetes outcomes **[36, 37]**. Though achieving proper glycemic control was the focus of the traditional medical management of T2DM, evidence supports a more comprehensive approach in the clinical management of the disease with the aim of minimizing its associated morbidity **[38]**.

An important aspect related to DM control is working with patients to change behavior and modify lifestyle through exercise and diet adjustment. Self-management in T2DM requires a complex multidimensional regimen, including different SCA such as diet, exercise, foot care, smoking management, blood sugar testing and adherence to medications that include the oral hypoglycemic agents and/or insulin. All previous issues have a direct influence on the attainment of proper diabetes care **[39, 40]**. The different areas of self-care are the cornerstone of T2DM management and play a crucial role in achieving diabetic control and improving patients' quality of life **[41]**.

As a major element in any healthcare system, the provision of diabetes-related services through a collaborative interdisciplinary healthcare team, that includes physicians, pharmacists, dieticians and nurses, plays a role in the proper self-management and control of DM (more details in Chapter 1). This team should put emphasis on diabetes self-management education (DSME) to facilitate diabetes

knowledge, and provide patients with the skills essential for diabetes self-care **[39]**.

Published studies on the level of diabetes control and management of T2DM among patients in Palestine are lacking. Nevertheless, some studies and information provided by service providers indicate that only a small fraction of people with diabetes are properly controlling their condition, and that there is a high frequency of diabetes-related complications **[42]**.

SIGNIFICANCE OF THE STUDY

In addition to the high morbidity related to DM, this chronic disease was the fourth leading cause of death in the West Bank, where 8.6% of the total deaths were attributed to DM in 2011 **[21].** In the same year, DM had a prevalence of 12.7% among those aged 25-64 years old, as stated previously **[20]**. Moreover, a study projected that its prevalence will increase in the coming years, with a projected prevalence of 20.8% for 2020 and 23.4% for 2030 **[43]**. Therefore, identifying factors affecting disease control and proper management, as well as addressing such factors, may reduce the local burden of DM.

Importantly; services provided to people with DM seem to be sub-optimal and fragmented as demonstrated by a baseline assessment study of diabetes services in 11 primary healthcare clinics from the different sectors in the Ramallah governorate in 2009. The assessment study also revealed that education of patients

about DM, self-management and diabetes complications were not adequately offered to patients **[44]**.

As a result, this thesis aimed to assess the level of glycemic control and diabetes self-management including patient SCA and provider SCR in a sample of Palestinian T2DM patients in the Ramallah governorate clinics. The major objective of this study was to examine the association between glycemic control and SCA, and between glycemic control and SCR. Moreover, it looked at the association of glycemic control and other study variables (including patient demographic/socioeconomic characteristics and disease-related characteristics) which will be detailed in the methodology chapter. Other associations between different variables were also studied for their importance while addressing the subject of diabetes management and control (see research questions and hypothesis: Other Research Questions).

The laboratory HbA1c test was used to assess the glycemic status (controlled vs. uncontrolled) of patients. The Arabic translated version of the Summary of the Diabetes Self-care Activities SDSCA (Ar) scale was used to assess the level of each self-care activity (diet, exercise, blood sugar testing, medication adherence, foot care and smoking) as a separate area of self-care in DM management. The application of this widely-used, reliable and valid measure/questionnaire in this study would be of interest specifically to researchers and policymakers who are concerned with diabetes control and management **[40]**. Clearly, this information would be useful for healthcare and policy decisions in terms of identifying patient

needs, matching interventions and treatments, setting priorities and allocating resources.

This study covers the issues and factors related to diabetes self-management among patients in an attempt to better understand the determinants of glycemic control among the study sample. Therefore, it is also of great importance to DM patients and their families who handle day-to-day SCA.

Such a study in the Palestinian context assesses the self-care-related services in terms of recommendations provided by the healthcare team (physicians, nurses, etc) to diabetes patients. It also addresses whether patients were asked about their self-care behavior during the previous visit to their physicians as part of diabetes education. In addition, it ended up with recommendations based on patient needs while identifying the contribution of various providers to the management of DM with the aim of working towards integrating the various service provision-systems for diabetes care.

This study will give better insight into the association between the dependent variable (glycemic control) and other studied independent variables (patient SCA, provider SCR, demographic/socioeconomic characteristics and other disease-related characteristics).

Furthermore, it illustrates the association between patient SCA and demographic/socioeconomic characteristics, and the association of patient SCA

and the healthcare sector. It also illustrates the association between provider SCR and demographic/socioeconomic factors and its association with the healthcare sector as well. It investigates the nature of the association of provider SCR and patient SCA. As a result, it appreciates the services offered by the diabetes providers and will provide recommendations for the policymakers and providers based on the results of the current study.

It is highly important to keep in mind that patient SCA and SCR provided by the healthcare team are inter-related issues and thought to be predictive of glycemic control **[41, 45]**, where people with low diabetes self-care (probably due to inadequate performance of SCA by patients or due to receiving inadequate diabetes provider SCR) are more likely to have uncontrolled glycemic levels. Additionally, the cultural context could be a barrier to care since it has a crucial impact on self-management among diabetics **[46]**. Within this context, the results of the associations between glycemic control and patient SCA, and between glycemic control and provider SCR will be analyzed, taking into consideration the demographic/socioeconomic characteristics among this sample of adult Palestinians with T2DM.

RESEARCH QUESTIONS AND HYPOTHESES

There are two main purposes of this study: First, we wanted to assess the level of glycemic control and the level of T2DM self-management including both patient SCA and provider SCR. Second, we intended to examine the associations between glycemic control and SCA and SCR in a sample of adults with T2DM in the Ramallah governorate clinics.

Primary Research Questions

- **Research Question 1**: What is the percentage of controlled patients with T2DM in the study sample?
- **Research Question 2**: What are the performance levels of diabetes SCA (diet, exercise, blood sugar testing, foot care, medication adherence and smoking status) in the study sample?
- **Research Question 3:** What is the extent to which SCR is offered to T2DM (in terms of diet, exercise, blood and urine sugar testing, recommended medications and smoking cessation) patients by their healthcare team?
- **Research Question 4:** Is there an association between glycemic control and patient SCA in the study sample?
- **Research Question 5:** Is there an association between glycemic control and provider SCR in the study sample?

Research Sub-questions

- **Research Sub-question 1:** Is there an association between glycemic control and patient demographic/socioeconomic characteristics in the study sample?
- **Research Sub-question 2:** Is there an association between glycemic control and disease-related characteristics [such as duration of diabetes, type of DM treatment and obesity] in the study sample?
- **Research Sub-question 3:** Is there an association between glycemic control and the healthcare sector providing diabetes treatment services?
- **Research Sub-question 4:** Is there an association between glycemic control and physician inquiry about patient self-care practices during the last visit?
- **Research Sub-question 5:** Is there an association between glycemic control and patient assessment of diabetes self-management (perceived capability of dealing with DM in terms of diet, exercise and medications) in the study sample**?**
- **Research Sub-question 6:** Is there an association between glycemic control and patient perception regarding diabetes knowledge (information on DM) in the study sample?

Other Research Questions

1- Is there an association between patient SCA and demographic/socioeconomic characteristics in the study sample?

2- Is there an association between patient SCA and healthcare sector providing diabetes treatment services?

3- Is there an association between provider SCR and demographic/socioeconomic characteristics in the study sample?

4- Is there an association between provider SCR and the healthcare sector providing diabetes treatment services?

5- Is there an association between provider SCR and patient SCA in the study sample?

Primary Research Hypotheses

- **Hypothesis 1:** Low percentage of T2DM patients achieves good glycemic control.
- **Hypothesis 2:** The performance level of SCA is low in the study sample.
- **Hypothesis 3:** The extent to which SCR is offered to T2DM is low in the study sample.
- **Hypothesis 4:** Glycemic control is associated with patient SCA**.**
- **Hypothesis 5:** Glycemic control is associated with provider SCR**.**

Research Sub-hypothesis

- **Sub-hypothesis 1:** Glycemic control is associated with certain demographic/socioeconomic characteristics.
- **Sub-hypothesis 2:** Glycemic control is associated with certain disease-related characteristics.
- **Sub-Hypothesis 3:** Glycemic control is associated with the healthcare sector providing diabetes treatment services.

- **Sub-hypothesis 4:** Glycemic control is associated with physician inquiry about patient self-care practices during the last visit.
- **Sub-hypothesis 5:** Glycemic control is associated with patient assessment of diabetes self-management (perceived capability of dealing with DM in terms of diet, exercise and medications).
- **Sub-hypothesis 6:** Glycemic control is associated with patient perception regarding diabetes knowledge (information on DM).

Other Research Hypotheses

1- Patient SCA are associated with demographic/socioeconomic characteristics.

2- Patient SCA are associated with healthcare sector providing diabetes treatment services.

3- Provider SCR are associated with demographic/socioeconomic characteristics.

4- Provider SCR are associated with the healthcare sector providing diabetes treatment services.

5- Provider SCR are associated with patient SCA.

CHAPTER 1

LITERATURE REVIEW

This literature review provides an overview of studies on diabetes management in relation to glycemic control among T2DM patients, including the related research in Palestine. This review draws attention to the gaps in the literature and the contribution of the current study to the healthcare field in the West Bank.

1.1 Introduction

Similar to any chronic disease, DM is a serious illness that may lead to multiple harmful complications, co-morbidities and possibly to early death **[47, 48]**. Therefore, proper care of T2DM is essential for the metabolic control of the disease. This disease necessitates lifelong management that includes proper control of blood glucose and management of co-morbidities such as hypertension, dyslipidemia and others **[3, 49]**. From this perspective, improvement in blood glucose and/or strict control of blood pressure can reduce the risk of death-related to DM as well as complications in newly diagnosed T2DM patients, as documented by the UK Prospective Diabetes Study (UKPDS-38) **[50, 51]**.

The goal of DM management is to prevent complications, attain the best treatment outcome and optimize quality of life in patients with the disease **[52]**. Moreover, lowering the healthcare costs and expenditure on treatment therapy is of great importance for the long term management of DM **[53, 54]**. The following section

sheds light on the importance of achieving good glycemic control in relation to the prevention of diabetes complications as part of DM management.

1.2 Glycemic Control

1.2.1 Importance of Glycemic Control

In the 1970s, HbA1c was first used to assess diabetes control since it is an excellent biomarker of chronic glycemia during the preceding two to three months **[23]**. Based on the ADA recommendations, good glycemic control in adults with T2DM is reflected by a value of [HbA1c] below 7% **[3]**. As a result, the HbA1c test is considered to be a standard parameter used clinically for confirming proper DM management **[23]**.

Various studies have highlighted the importance of strict glycemic control and recommended an HbA1C target of <7.0% for most DM patients, since this cut off value is considered to be necessary for the reduction of diabetes micro-vascular and macro-vascular complications **[3]**. Epidemiological studies showed a positive relationship between the HbA1c level and development of T2DM-related micro-vascular and macro-vascular complications, and also demonstrated a higher risk of such complications at levels of [HbA1c] above the normal values **[6]**. These studies indicated that diabetes-related complications can be prevented if patients are controlled and maintain good glycemic levels **[47]**. In this sense, the UKPDS-35 study demonstrated a 37% reduction in the risk of micro-vascular complications for each 1% reduction in the HbA1c level **[55]**. The UKPDS-35

also revealed that the potential risk of developing such complications may be considered to be the lowest at HbA1c levels <6%, though no HbA1c threshold of risk was determined for any clinical endpoint such as myocardial infarction and death **[55]**. Another study demonstrated that the potential of reduction in the incidence of heart failure was associated with strict glycemic control (i.e. HbA1c<7%) **[56]**.

At the local level, a large survey was conducted by the ICPH at Birzeit University in 2012 to study DM complications, management and quality of life among T2DM patients. The results demonstrated a high prevalence of diabetes complications among T2DM patients in the Ramallah governorate clinics, with a high proportion of patients having macro and micro-vascular complications. These results also showed a significantly higher proportion of poorly-controlled patients (HbA1c≥7%) having neuropathy, retinopathy and nephropathy compared to those with HbA1c <7% **[57]**.

Furthermore, the literature documented a positive association between DM self-care and glycemic control **[54]**, which will be discussed in the following sections of this chapter. Moreover, the relationship between glycemic control and health outcomes is well established in the literature **[54]**. A study investigated the benefit of glycemic control on health outcome in patients with one of diabetes-related complications, reported that HbA1c (<6.3% vs. ≥6.3%) was a significant predictor of survival in diabetics undergoing hemodialysis **[58]**. A retrospective cohort

study assessed survival as a function of HbA1c in T2DM patients and demonstrated that an HbA1c value of 7.5% (compared to low and high mean HbA1c values, 6.5% and 10.5% respectively) was associated with the lowest mortality rate and diseases of large vessels, whether in patients prescribed a combination of oral hypoglycemic agents (Metformin and sulphonylureas) or insulin based therapy **[59]**. This study implied that a wide range of HbA1c is desirable in patients with combined oral therapy, while a more narrow range is needed for patients using insulin regimens.

Consequently, it is clearly understood in the literature that the risk of diabetes-related complications increases in patients with poorly-controlled blood glucose **[55, 60]**. In other words, strict glycemic control might prevent or delay such complications and achieve better diabetes outcomes **[36, 37]**.

1.2.2 Prevalence of Glycemic Control

Several international and regional studies have measured the prevalence of glycemic control among T2DM patients from diverse populations. Most studies documented that HbA1c levels (i.e. HbA1c<7%) are still unmet among many patients with T2DM **[60-62]**.

In the developed countries, though the trend of maintaining good glycemic control (< 7% HbA1c) among US patients with DM improved from a prevalence of 37% to 55.7% between 1999 and 2004 **[63]**, recent studies continue to show a high

prevalence of poor glycemic control among patients. For example, a study of Mexican-Americans with T2DM indicated that the prevalence of poor glycemic control was 65.1% among the patients **[62]**. In the United Kingdom, a retrospective study of 10,663 patients with T2DM demonstrated that 76.0% of patients had inadequate glycemic control (HbA1c >7.0%) **[61]**.

A similar situation was found in the developing countries as well. A high proportion (46.7%) of Pakistani patients had HbA1c levels higher than 7.5% **[64]**. In the Gulf countries, the prevalence of poor glycemic control was also high. In Kuwait, HbA1c levels were above 8% in 66.7% of the population **[65]**. In Saudi Arabia, 27% of DM patients (n=404) achieved the target level of HbA1c (HbA1c<7%) **[66]**. According to a recent PhD study, the prevalence of patients with controlled blood glucose levels (HbA1c < 7%) among the Saudi Arabian population was 30% **[67]**.

Similar results were also found in the Lebanese population. A study of 313 T2DM patients showed that two-thirds had inadequate glycemic control (HbA1c >7 %) **[68]**. This study also indicated a high prevalence of diabetes-related complications. The author called for immediate action to control the situation in Lebanon.

In Jordan, a study of 917 patients with T2DM demonstrated that 65.1% of patients had HbA1c≥7% **[69]**. In 2012 a Jordanian study of 223 patients indicated a

slightly lower prevalence (56.5%) of poor glycemic control (HbA1c≥7%) in T2DM patients **[60]**.

Since both the Palestinian and Jordanian populations have similar cultural and traditional lifestyle, and given that a large proportion of the Jordanian population is of Palestinian origin, it is expected that there is a high prevalence of poor glycemic control in Palestine as well, though the health systems may differ.

A local Palestinian study assessed whether the HbA1c test can be used as a diagnostic tool for DM, showing a consistent finding with the international recommendations and supporting the use of this test among Palestinians **[70]**. A study (Master's thesis) examining the determinants of diabetic eye complications among St. John Eye Hospital community clinics (n=420 T1DM and T2DM patients) reported a mean HbA1c of 8.3%, and noted that only 22.6% of patients achieved the recommended glycemic control [HbA1c≤7%] **[71]**. The same study revealed a high prevalence of diabetic eye complications and visual impairment especially among male diabetic patients. This study also recommended achieving proper glycemic control to minimize such type of diabetes complications **[71]**.

An audit of 32 clinics operated by the UNRWA in their four fields (Jordan, West Bank, Syria and Lebanon) demonstrated that only 28.3% of patients achieved good glycemic control (HbA1c<7%) **[72]**. Specifically in the West Bank field, a clinical audit of eight UNRWA clinics that was conducted in July 2012 showed

that in a sample of 400 patients with DM (50 patients from each clinic) only 22.8% of patients achieved good glycemic control (HbA1c <7%) **[72, 73]**.

1.2.3 Factors Associated with Glycemic Control

Several factors might be associated with glycemic status. These factors can be divided into two main categories **[74]**. The first category includes patient-related factors such as demographic and socioeconomic characteristics (age, sex, education, marital status, economic status, and type of medical insurance). The second category is comprised of certain disease-related factors/characteristics, such as the duration of diabetes, type of diabetes treatment, obesity measured by the body mass index (BMI).

I. Patient-related characteristics

The investigation of factors affecting glycemic control is considered a debatable area of research. Different results have been reported by epidemiological studies. Some studies supported the association between patient demographic/socioeconomic characteristics while other studies found no significant association between these variables.

In certain epidemiological studies, it was found that male sex **[74],** elderly DM patient (>60 years) **[74, 75]**, patients with higher levels of education **[75]** had better glycemic control compared to females, younger patients (<60years) and patients with lower educational levels respectively. However, other studies

showed no association between sex, age, education, marital status and glycemic control **[76]**.

Though in some studies, patients income and employment status **[60]** or socioeconomic status **[77]** did not associate with glycemic control, others studies reported that patients with higher socioeconomic levels achieved well-controlled diabetes, since lower socioeconomic status was associated with higher rates of obesity, hyperlipidemia, and poor diabetes control **[78, 79]**.

II. Disease-related characteristics

Many studies have investigated the association between certain diabetes-related characteristics and glycemic control in T2DM patients. Longer duration of diabetes (>7 years) was significantly related to poor glycemic control in studies conducted in the US **[80]**, Netherlands**[75]** and Jordan **[69]**. Other studies did not find such association (i.e. longer diabetes duration was not associated with poor diabetes control) **[74]**.

Some studies have investigated the association between the type of diabetes treatment and glycemic control. Patients with uncontrolled glycemic status were more likely to be prescribed insulin, or a combination of oral hypoglycemic agents and insulin **[69, 75]**. This might indicate that patients were prescribed multitherapy to improve their glycemic control. However, in 2011 a systematic review reported that the use of insulin and Metformin was not associated with poor control of DM **[74]**.

A significant association between obesity (BMI≥30) and glycemic control was reported in Lebanese T2DM patients **[45]** and in elderly Mexican-American patients **[62]**. However, among DM patients in the US, BMI was not associated with the HbA1c level **[81]**.

To sum up, this section reviewed the most reported issues related to glycemic control. All aforementioned studies reported high proportions of poorly-controlled patients. Research has shed light on the importance of obtaining optimal glycemic control. A large body of literature has demonstrated that strict glycemic control is a requirement for the reduction of diabetes-related complications and the management of patients with T2DM. Glycemic control is also considered to be a prerequisite for achieving good health outcomes. The management of DM encompasses several approaches that will be addressed in detail in the following section.

1.3 Approaches to the Management of Type 2 Diabetes Mellitus

DM was a life-threatening disease before the discovery of insulin, especially among Type 1 patients **[82]**. The importance of a traditional medical approach in the management of such chronic disease and its impact on achieving good glycemic control cannot be denied. Still, medication therapy management (MTM) alone was not able to provide a magic solution to this problem and the majority of patients continued to have high levels of HbA1c despite technological and

pharmacological advancements **[83]**. Therefore, in addition to the medical regimens, patients should adapt to new lifestyle changes in order to overcome the potential of inadequate glycemic control, which often leads to early death attributed to related complications **[84]**. In this sense, Song's study suggested that self-care is as an important factor affecting health outcomes in the management of DM **[54]**. Due to this, as well as the goals of achieving the desired glycemic level (i.e. Glycosylated Hemoglobin [HbA1c] <7%) and reducing the risk of complications, patients have an active role in their own care as part of diabetes self-management. The following section will provide a better understanding of patient role in diabetes self-management.

1.4 Self-Care in Diabetes Management

Diabetes self-care can be defined as performing day-to-day self-care activities/practices with the aim of managing diabetes and optimizing health **[40, 45]**. The following terms "diabetes self-care" and "diabetes self-management" were used interchangeably in the literature. It is worth noting that other terms or concepts were also used in dealing with the topic of DM management. The concepts of "self-efficacy" and "diabetes empowerment" were used in diabetes self-care literature. In 1970s, Bandura introduced the concept of self-efficacy that was based on building patient confidence in his/her ability to successfully manage the disease **[37, 53, 60, 85]**. Moreover, Funnel and Anderson described the concept of patient empowerment as a fundamental patient-centered and

collaborative approach, where patients and the community take the control over self-care behavior, in a way that guarantees effective diabetes care **[5, 86]**.

Within this conceptual framework, the literature notes that self-efficacy may be a predictor of self-care behavior for patients with DM **[87]**. Several studies examined the concept of self-care in diabetes management in relation to patient self-efficacy, diabetes empowerment, glycemic control and health outcomes **[5, 37, 53, 54, 60]**. One of these studies provides a model of the factors that might affect self-care **[53]**. This study reported that self-efficacy enhances flexible self-care among patients, which means that diabetics who perceive themselves capable of dealing with the disease (i.e. through performing self-care behavior) have an obvious effect on their metabolic control. At the same time, this study also focused on the role of healthcare providers (HCPs) in insisting on patient knowledge, physical skills and emotional aspects while caring for diabetes, because healthy day-to-day choices are made by patients, and not by HCPs **[53]**.

Furthermore, some studies reported that the provision of patient-centered care by a health system (discussed later on in this chapter) through patient involvement or participation in diabetes management enhances the quality of medical care and improves blood sugar control among patients **[88-90]**. From this perspective, engagement of DM patients in their own care "self-care" increases their responsibilities towards the disease, and eventually improves health outcomes, satisfaction and quality of life, especially for those on an insulin regimen **[90]**.

1.5 Diabetes Self-Care Measures

To the best of my knowledge, during the early 1980s different diabetes self report measures were used to combine scores across the different components of the diabetes regimen producing a total adherence score or a total compliance score such as the Diabetes Regimen Adherence questionnaire and the Cerkoney and Hart self report measure of compliance **[91, 92]**. Moreover, the 24-hour recall interview that was developed by Johnson et al. consisted of four independent factors: "exercise, injection, diet type and eating/testing frequency" that were used for addressing 13 areas of the diabetes regimen **[93]**. Other studies provided questionnaires that assessed the frequency for five aspects of self-care behavior separately, such as the self report measure that was developed by Orme and Binik **[94]**.

In 1994, Toobert and Glasgow developed the original version of the Summary of Diabetes Self-care Activities (SDSCA) measure, which assessed five aspects of the diabetes regimen: general diet, specific diet, exercise, medication adherence and blood glucose testing. In 2000, the same authors presented an expanded & revised scale of the SDSCA (E&R), providing a total of 11 core items including items on foot care and smoking. They also provided an extension that included 14 additional questions mainly focusing on SCR that should be offered to DM patients by their healthcare team **[40]**.

1.6 The SDSCA Questionnaire in Epidemiological Studies

The English version of the SDSCA (E&R) measure has been translated into different languages such as Spanish **[95]**, Korean **[96]**, Chinese **[97]** and Arabic **[67]**. According to the author of this questionnaire, it was translated into over 21 different languages all over the world **(T. J. Deborah, personal communication, June 23, 2011)**. Moreover, it was documented that this questionnaire is a widely utilized instrument in clinical and practical research across different populations for assessing patient self-care activities and exploring the interventions of healthcare professionals **[98]**.

Several studies used the SDSCA measure to assess different aspects of SCA among the US **[99, 100]**, Canadian **[101]**, Australian **[102]**, Danish **[103]**, South Korean **[104]**, Spanish **[95]**, and Chinese populations **[97]**. Additionally, some of these studies attempted to identify possible factors such as demographic/socioeconomic and disease-related characteristics among others that might influence patient self-care behavior. However, only a few studies examined the direct association of SCA in relation to glycemic control among T2DM patients **[45, 60]**.

In the Arab countries, the literature provided evidence on the utilization of the (SDSCA) questionnaire for assessing the level of diabetes self-management among T2DM patients in Saudi Arabia **[67]**, United Arab Emirates (UAE) **[105]**, Jordan **[60]** and Lebanon **[45]**. These studies used the SDSCA measure as an

instrument to assess diabetes self-care as well as examine other associations related to different and specific research purposes.

To the best of my knowledge, this topic lacks sufficient information at the local level. The current study is the first to be conducted in the occupied Palestine which used the SDSCA (Ar) measure for assessing diabetes SCA and SCR and their associations to glycemic control. The literature documented that one study in Israel has used the SDSCA questionnaire to examine the association between the level of adherence to self-care and metabolic control among Arab (Palestinian citizens of Israel) with T2DM (see section 1.8 below for more information).

The questionnaires/instruments available in the literature for measuring the level of diabetes self-management have focused on the practices or behavior that a DM patient should engage in, or more accurately, perform daily while managing the disease. The following section will highlight the aspects/components of diabetes regimen that were addressed specifically by the diabetes self-care questionnaire used in the current study (SDSCA).

1.7 Diabetes Self-Care Activities (SCA)

Diabetes self-care consists of a wide range of challenging SCA **[40, 53]**. Such behavioral practices are considered as non-pharmacological aspects that have an added value benefit to the pharmacological treatment in the management of DM

as well as in the prevention of acute and chronic complications among patients **[28]**.

Among the lifestyle interventions, changing diet is one of the aspects that patients diagnosed with T2DM should not ignore **[3]**. Behavioral modification through change in diet and physical activity in diabetes self-management has been widely studied **[106].** Diabetes patients are also recommended to follow other aspects of self-management including blood sugar testing, and adherence to medications that include oral hypoglycemic agents (OHAs) and/or insulin **[40]**. As well, foot care and smoking cessation are considered to be required diabetes self-care behavior **[40]**. The studies reviewed in the subsequent section provide a brief overview of the impact of adherence to optimum self-care behavior (general diet, specific diet, exercise, medication adherence, blood sugar testing, foot care and smoking cessation) on the achievement of proper glycemic control indicated by the glycosylated Hemoglobin (HbA1c).

1.7.1 Diet Self-Management

According to the ADA position statement, appropriate nutrition is necessary for achieving an overall healthy lifestyle **[107]**. Therefore, engagement of people with T2DM in a healthy dietary regimen as part of diabetes self-care is highly recommended **[108]**. In addition to general diet, the literature examined each type of food (specific diet) independently. There was a debate in the literature over increasing or decreasing the consumption of specific types of food (carbohydrate,

protein, fat, fibers, etc) in the diet of T2DM patients, since food habits of people with T2DM are related to their glycemic control **[109]**. One meta-analysis showed a 0.4% reduction in HbA1c when diabetes patients consume low glycemic index diets compared to high glycemic index diets **[107]**.

1.7.2 Physical Activity/Exercise Self-Management

Exercise is another self-care tool for T2DM patients. According to many studies, it was evident that "regular physical activity enhances insulin sensitivity, increases cardio-respiratory fitness, improves glycemic control, reduces the risk of cardiovascular mortality, and enhances psychosocial well-being" **[110]**. It may also contribute to weight loss **[3]**. Therefore, physical activity/exercise is a vital therapeutic component of the diabetes management plan **[111, 112]**, because regular exercise improves glycemic control even in the absence of weight loss **[112, 113]**.

According to the ADA's recent recommendations and standards regarding the level, duration, and specific types of physical activity, a moderate aerobic physical activity of at least 150 min/week is recommended for diabetics, divided over at least three days/week with no more than two consecutive days without exercise **[3]**. To sum up, epidemiological data of various physical activity studies conducted among T2DM patients supported the evidence that there is a positive association between physical activity and glycemic control **[113]**.

1.7.3 Adherence to Medications

Though lifestyle and behavioral interventions are required in managing DM at all stages of disease progression, the traditional medical management of T2DM through insulin or/and oral hypoglycemic agents (OHAs) in almost all patients continues to be a vital component of the management plan **[114]**. It is known that insulin is optional in the treatment of T2DM patients, as it is usually used if (OHAs) have failed to achieve adequate control **[82]**.

The main goal of pharmacological treatment of DM is to achieve the target level of HbA1c, with an attempt to prevent the development of diabetes-related complications **[114]**. As recommended by the 2009 consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes, an HbA1C level of ≥7% calls for initiation, combination or change of therapy with the aim of achieving an optimal glycemic control [HbA1C level of <7%] **[114]**. However, the level of glycemic control determines whether a patient needs mono-therapy or a combination of medications, and also guides clinicians in selecting a specific treatment option, taking into consideration the duration of diagnosis with DM **[114]**. It is worth noting that clinicians may prescribe suitable treatment options for T2DM patients, but many other factors may stand in the way of achieving the targeted glycemic levels among patients. Cramer's study reported that failure to lower HbA1c levels might be related to poor self-management among other factors **[115]**. Adhering to the recommended medications is considered an essential part of diabetes patient self-management**[115]**. As a result,

medication adherence is crucial for achieving good health outcomes of diabetes care **[116]**.

1.7.4 Blood Sugar Testing (BST) / Self-Monitoring of Blood Glucose (SMBG)

Although the HbA1c test is the gold standard for estimating average blood sugar and monitoring long-term glycemic control, it does not provide on-the-spot information about "real-time" blood glucose levels **[117]**. In the 1970s and 1980s, the practice of self monitoring of blood glucose (SMBG) was highly recommended to track fasting and postprandial hyperglycemia since this test has the ability to reveal hour-to-hour blood glucose immediately and assess day-to-day control **[117]**. Moreover, this self test develops a blood glucose profile for every single patient, guiding doctors in the development of individualized treatment plans and involving patients in making decisions to adjust their daily choices of food, physical activity and medications as part of self-care **[117-119]**.

It was stated by Mbaezue that "self monitoring of blood glucose is considered to 1 of the cornerstones of diabetes self-management" **[120]**. As recommended, the frequency of SMBG was three times daily for T1DM patients, while T2DM patients were advised to monitor blood sugar at least once daily **[120]**. Clinical trials on self monitoring of blood glucose targeted different groups of DM patients, and there is evidence that SMBG in insulin treated T2DM patients has a valuable impact on their metabolic control **[117]**. Therefore, self monitoring of blood glucose in insulin treated T2DM patients is a fundamental component for

effective self-care management in those patients **[121]**. On the other hand, other studies came up with conflicting results regarding the utility of SMBG in non-insulin treated (NIT-DM) patients and its impact on metabolic control. Still however, SMBG was recommended by some studies **[117]**. In this sense, a recent study supported the use of SMBG among T2DM patient, and documented that attainment of good glycemic control depends on both medication adherence as well as on the use of SMBG, since both factors were associated with a similar reduction in HbA1c levels after achieving HbA1c baseline control **[122]**.

1.7.5 Foot Care

Patients with T2DM are more likely to have foot ulcers than people without the condition **[123]**. This complication is the most expensive complication of T2DM in terms of treatment costs, and in severe cases it leads to the amputation of the lower extremities **[123]**. Therefore, proper foot self-care is essential for reducing the incidence of such events, mainly in patients with reduced severity of neuropathy **[123]**.

According to the guidelines of the American Association of Diabetes Educators (AADE), foot care practices include daily examination of feet and inspection inside of shoes as well as washing, soaking and drying the feet **[40, 123, 124]**. Some studies have showed that poor adherence to foot care among diabetics may be due to inappropriate foot self-care practices as a result of a lack of patient knowledge. This is because healthcare practitioners may not provide adequate

foot care instructions for people with T2DM, and therefore might not perform routine foot examinations **[125]** .

With regard to glycemic control and its relationship to foot care, a study showed a significant improvement in HbA1c levels over a six month period whether among patients receiving educational presentation/lecture on foot care alone (control) or among those receiving both educational presentation and practical "on hand" foot care teaching session (experimental group) **[126]**.

1.7.6 Smoking Status and Smoking Management

There is a significant association between smoking and the risk of diabetes-related complications **[127]**. Therefore, strict glycemic control (assessed by HbA1c below 7%) is necessary for preventing or delaying diabetes complications as stated previously **[128]**. Smoking is one of the risk factors for atherosclerosis, which accelerates the risk of cardiovascular complications in diabetics **[129]**. Al Deliamy's study demonstrated that the risk of coronary heart disease (CHD) among T2DM women increased with cigarette smoking **[130]**. Smoking also triggers the deterioration of diabetic nephropathy and retinopathy **[129]**. Evidence shows that smoking enhances insulin resistance in those with NIDDM or even in those without diabetes **[128].** In 2002, a prospective cohort study documented a 0.7% reduction in HbA1c levels with smoking cessation among DM patients (a total of 34 patients, 7 T1DM patients and 27 T2DM patients) who were followed one year after smoking cessation **[128]**.

1.8 Assessment of Diabetes Self-Care Activities (SCA)

A number of studies have investigated the level of diabetes self-management and examined its association with demographic/socioeconomic factors and other disease-related characteristics that might be related to such practices. In the following studies, the SDSCA (E&R) questionnaire was used to measure SCA frequency among T2DM patients.

In the United States, a study of 192 Filipino-American T2DM patients showed that the performance of proper SCA pertaining to diet, medication adherence and blood glucose testing was suboptimal in younger patients (<65 years) with T2DM compared to elderly ones (≥65 years) **[131]**. Another study involving 211 Chinese-Americans with T2DM indicated that participants performed suboptimal levels of diet, SMBG, physical activity, and foot self-care as well **[132]**. Both studies among Filipino and Chinese-Americans demonstrate that medication adherence was performed more frequently than other self-care practices, and patients with a longer duration of diabetes were more likely to self monitor their blood glucose compared to those with shorter disease duration.

In urban southern India, DM patients reported poor dietary and exercise practices, while adherence to medications and blood sugar testing were good among these T2DM patients **[133].** This study was also consistent with the literature in terms of high levels of medication adherence compared to other diabetes SCA.

There is scarce information related to DM management in the Arab region. To my knowledge, few studies have been conducted to assess diabetes self-management practices, explore health provider interventions, investigate their associations with demographics and socioeconomic factors and other disease- related characteristics or examine the association of patient SCA with glycemic control. In Saudi Arabia, it was demonstrated by a PhD study of 210 T2DM patients that patients had low levels of compliance to most diabetes SCA **[67]**. Similar to the Western countries, in Saudi Arabia, using the translated Arabic version of the SDSCA showed that medication adherence (i.e.75% of patients took 7days/week) was among the most frequently performed self-care behavior. Moreover, diet (71% of patients control their diet three days/week), and foot-care (56% of patients performed foot care practices three days/week) were also more practiced than other SCA among the T2DM patients. However, this study also suggested that patient performance of blood glucose testing (85% of patients monitored their blood sugar four days/week) and exercise (47% two days/week) was less frequent. In addition, this study also suggested a negative association between high blood glucose levels, smoking and self-management practices; patients with uncontrolled blood glucose and smokers were more likely to perform diabetes SCA than controlled patients and non-smokers. Moreover, females and those with good income were positively associated with SCA (more likely to perform diabetes self-management) compared to males and low income patients **[67]**.

In Lebanon, a nursing dissertation examined the relationship among diabetes self-care, social support and glycemic control among people with T2DM **[45]**. This study also used the Arabic translated SDSCA (Ar), and its results indicated that none of the diabetes self-care subscales of the SDSCA (Ar) was associated significantly with glycemic control. In this study, the SDSCA subscales were categorized instead of using the continuous scales to better present the distribution of data after obtaining the author's consultation. The categorization showed that only the specific diet subscale was significantly associated with glycemic control. This means that patients who consumed an unhealthy specific diet (i.e. full fat dairy products, red meat and less fruits and vegetables) less than 3.5 days/week were more likely to have poor glycemic control. This study also demonstrated that age, male gender, type of diabetes treatment, presence of micro and macro-vascular complications (co-morbidities) and body mass index (BMI) were significantly associated with glycemic control. Similar to the Saudi Arabia study **[67]**, medication adherence rates (mean number of days=6.58±1.62 days/week) among the Lebanese with T2DM were also high compared to other diabetes SCA (the mean number of days per week of performing general diet [2.81 ±1.84 days/week], specific diet [3.07±1.92 days/week], exercise [1.36±2.09 days/week], blood sugar testing [2.49±2.48 days/week] and foot care [1.18±2.11days/week]) **[45]**.

In Jordan, a recent study used the SDSCA questionnaire to examine the relationship between diabetes self-management behavior and glycemic control **[60]**. Similarly, the majority of Jordanian patients with T2DM had suboptimal

self-management behavior that resulted in poor glycemic control. In addition, this study suggested that diet self-management was a predictor of good glycemic control, while the use of insulin was a predictor of poor glycemic control. This study also addressed other concepts of diabetes management indicating that patients' empowerment and motivation to take charge of their own disease and perform daily SCA often requires specific behavioral interventions **[60]**. It was also reported that self-efficacy perceptions and self-management behavior may predict SCA performance among T2DM patients and ultimately affect their glycemic control **[60]**. A previous study conducted in Jordan also showed low levels of self-management among patients and indicated that poor glycemic control was associated with a longer duration of diabetes (≤7 vs. >7 years), non-adherence to behavior of self-care management **[69]**.

In Israel, a study was conducted to examine the level of adherence to diabetes self-care and metabolic control in 120 T2DM patients **[134]**. All patients were over 65 years and from the Arab population who were receiving diabetes services at the Clalit clinic in Nazareth. In this study, data was gathered using standardized questionnaires including the SDSCA questionnaire, which had been translated from Hebrew into Arabic and then back-translated into Hebrew. According to this study, it was found that patient level of education was associated with the level of medication adherence. Similar to the findings of the SDSCA among the Lebanese diabetics, no significant association was found between patient reported diabetes self-care variables and metabolic control. Moreover, the findings of this study also

suggested no association between patient educational level and metabolic control, while no significant association was found between economic status and adherence to self-care and medications **[134]**. In contrast to other studies conducted on this topic, this study specifically examined the influence of religious faith and the use of traditional medicine on adherence to diabetes self-care practices among Arab elders, indicating no significant difference in medication adherence between patients who reported different levels of religiosity. Furthermore, no significant association was observed between level of religiosity and metabolic control among the study participants.

In Palestine, studies on glycemic control and DM management and glycemic control are limited. A study was conducted in 2000 to assess diabetes self-management in a rural Palestinian community **[42]**.

1.9 Diabetes Knowledge

Low health literacy was associated with poor self-care among patients with chronic diseases, given that knowledge does not necessarily predict disease outcomes **[135]**. Similarly, it was demonstrated that most diabetes patients also have limited health literacy **[135]**, and inadequate diabetes knowledge has a negative impact on patient behavior and self-care management in diabetes **[47]**. Therefore, it is necessary to fill the gap between patient SCA and awareness about diabetes, since the lack of information might stand in the face of achieving optimum glycemic control. Knowledge modification through diabetes self-

management education (DSME) programs constitutes a fundamental aspect of diabetes management planning, and is considered an essential component that enables providing patients with the needed skills to perform daily self-care behavior properly and maintain long term disease management **[3, 5]**.

1.10 Diabetes Self Management Education (DSME)

Diabetes self-management education (DSME) can be defined as the "process of teaching individuals to manage their diabetes"**[52]**. DSME has been a vital component of the clinical management of people with diabetes since the 1930s. This ongoing evidence-based process is fundamental for diabetes educators as it is needed to empower patients to better adjust to living with the disease, and it is also of great importance to support achieving quality healthcare outcomes among diabetics **[52]**.

Within the concept of self-care, there is a need of educating patients to adopt a new lifestyle through structured diabetes education programs. To achieve this objective, effective patient – educator interaction plays a crucial role in diabetes care. Given that greater diabetes self-efficacy "achieved through educational interventions" improves knowledge and enhances self-care practices among adult T2DM patients **[37]**, physician-patient interventions are vital for improving health outcomes among patients as well as in reducing disease burden **[3]**.

The fact the DM self-management requires a treatment plan that encompasses a complementary concept of care necessitates that both the healthcare providers and patients form critical elements in the management process **[3]**. Thus, both parties should play an active role in managing the disease, which eventually might be reflected on the glycemic status of patients **[3, 136]**. Teamwork collaboration in a healthcare system is essential for providing effective and efficient quality services and improving patient self-care behavior **[3]**, Therefore, a diabetes healthcare team is not limited to physicians; other healthcare professionals such as pharmacists, nurses, dietitians, mental health professionals and diabetes educators must be involved in diabetes care. As a result, this equation obligates that patients and their families or caregivers "as members of the team" are also expected to play an integral part of day-to-day diabetes care **[40]**.

Impact of DSME programs on self-care behavior and glycemic control

The literature has provided evidence for the value of the DSME for people with T2DM regarding their glycemic control; HbA1c level improved with proper DSME **[41]**. Norris et al. has reported that inappropriate diabetes self-management may lead to poor glycemic control among patients and cause premature acute and chronic complications, including retinopathy, nephropathy, peripheral neuropathy, peripheral vascular disease and cardio-vascular disease (CVD). Since all these complications have been significantly associated with higher morbidity and mortality **[41]**, the aim of diabetes management and self-

management in particular is to overcome these problems as much as possible, and this could be achieved by behavioral modification.

Many studies have insisted on the role of healthcare providers in implementing such interventions, since behavioral interventions as dietary counseling for T2DM patients are the cornerstone of global diabetes care **[137]**. A study of American diabetes patients provided evidence that a primary care physician should offer the recommended diabetes care services for older patients, which are necessary for the improvement of patient health outcomes **[138]**. Another study emphasized the role of skilled physicians in diabetes management through providing structured dietary advice and counseling **[139]**.

Furthermore, evidence was established on the efficacy of self-management education programs in enhancing self-care and clinical outcomes **[5, 41]**. A meta-analysis of 31 studies evaluated the effect of self-management education for adults with T2DM on their glycemic control and reported a decrease in HbA1c levels during or at immediate follow up, with an improved effect as the contact time between patients and educator increased **[41]**.

In Malaysia, a 90 minutes face-to-face intervention program using the Revised Self-Care Activity (RSCA) measure improved self monitoring of blood glucose (SMBG), increased total physical activity and better medication adherence,

improved diabetes knowledge and decreased HbA1c levels. This study supports the development of diabetes educational interventions in the country **[37]**.

In the southeastern US, the SDSCA scale was used to assess five aspects of the diabetes SCA: general diet (followed healthy diet), specific diet (ate fruits/low fat diet), foot care, blood glucose testing, exercise, and cigarette smoking, while the Morisky adherence score was used to assess medication adherence. This study demonstrated that diabetes empowerment interventions were associated with higher medication adherence, increased diabetes knowledge and effective self-care behavior (diet, physical activity, blood sugar testing and foot care) in 378 adults with T2DM **[5]**. Another study indicated that counseling on diet, exercise and medication over a three month period significantly improved compliance of 106 poorly-controlled DM patients **[140]**.

Similarly, a prospective study conducted at the hospital of the University of Pennsylvania utilized the SDSCA measure to examine the association of health literacy with diabetes self-management behavior in diabetes patients enrolled in diabetes education through an individual meeting with a diabetes educator and three weekly three-hour group classes **[135]**. This study demonstrated that diabetes education improved diabetes knowledge, self-management and glycemic control for patients with adequate and limited health literacy **[135]**.

The previously reviewed studies indicated that diabetes education is associated with diabetes self-care practices, diabetes knowledge, and glycemic control. A study that assessed the effect of patient diabetes knowledge and awareness levels on glycemic control among 164 T2DM patients in Turkey demonstrated that the majority of patients were not properly educated about diabetes self-care **[47]**. The findings of this study also showed better glycemic control with high diabetes knowledge and a significant association between educational level and diabetes knowledge and awareness among the studied patients **[47]**.

Other studies focused on patient education with the aim of reaching the national diabetes treatment targets or reducing the burden of diabetes complications **[141, 142]**. A Swedish study suggested that improved patient education in primary healthcare centers is needed to assist reaching the national treatment targets (HbA1c<6.5%) among diabetics in the country **[141]**. A Japanese study of 2033 men and women aged 40-70 years with T2DM showed that patients receiving a lifestyle intervention regarding dietary habits, physical activities and adherence to treatment have a significantly reduced risk of a diabetes-related complication (stroke), independently of known classic risk factors, compared to patients receiving usual or conventional treatment care **[142]**.

In Arab countries, the implementation of behavioral interventions was also supported by a number of studies. An interventional study conducted in Oman demonstrated that T2DM patients receiving practice guidelines for nutritional care

(one to three appointments with a dietitian over a six-month period) showed a significantly change HbA1c compared to those receiving usual nutritional care. A significant improvement in anthropometric measures such as waist circumference and other biomedical measures such as triglyceride and cholesterol levels and LDL cholesterol was reported in both study groups **[143]**. This study also argued that the role of a well-trained dietitian in providing continuous medical nutritional care and counseling is necessary for the long term metabolic control among T2DM patients **[143]**. In 2012, a study of the Jordanian diabetes patients reported that behavioral interventions and diabetes educational programs must be offered by healthcare providers **[60]**.

In Palestine, a study conducted at the Arab-American University-Jenin suggested the use of a more technologically advanced diabetes self-management approach such as a mobile phone SMS-based system for diabetes self-management **[144]**. This study aimed to constantly connect both patients and physicians through SMS regarding their insulin measurements and other data. With this system, patients would receive messages on self-care activities (exercise and healthcare appointments) based on the data they send to their doctors. Satisfaction of patients and their physicians was demonstrated after piloting this system for a period of two weeks **[144]**. For the future, since mobile technology is widely spread among people nowadays, even in the Palestinian community, this could be a solution of many logistical issues at clinics, especially with younger patients.

Finally, the least that could be done for the diabetes epidemic is to give people affected by diabetes the ability to manage their disease properly and live long with a good quality of life. However, it is not that easy. Diabetes management is a complex process; many obstacles or barriers may stand in the way of diabetes care among patients. Better understanding of patient and clinician perceptions, attitudes, beliefs and knowledge about diabetes may help overcome these barriers **[145]**. It is valuable to focus on issues that might impede diabetes self-management among patients. The following section will review the barriers to diabetes management.

1.11 Barriers to Diabetes Management

Since this study looks at the patient SCA and provider SCR provided by a healthcare team to patients, it would be useful to remember that barriers to diabetes management are multi-factorial, including patient-related factors, healthcare provider/clinician factors and others related to the healthcare system **[146]**. The following will provide a summary of all factors to better understand how certain factors might influence diabetes control directly or indirectly.

Some challenges facing proper diabetes management are related to patient issues such as the lack of knowledge and disease awareness among the majority of diabetics. Additionally, people with adequate knowledge of diabetes risks may not guarantee their engagement in proper self-care practices **[47, 145]**. The presence of co-morbidities, which are common in patients with DM, constitute another

barrier. People with co-morbidities may lack the physical ability to perform self-care practices, such as doing exercise, diet modification, and self monitoring of blood glucose. Negative perceptions by patients of diabetes and unawareness of the importance of diabetes self-management education may contribute to the failure of self-care management among diabetics. At the same time, non-adherence to treatment regimens, possibly due to low socioeconomic status, may also be considered an important barrier that can stand in the way of effective diabetes management **[145]**.

Some literature has indicated that all previous factors that are related to self-care behavior might be influenced by cultural issues that include race/ethnicity, language, religious belief, dietary preferences, lifestyle and perceptions about disease and health **[145]**. It is necessary to keep in mind that for a study in Palestine in particular, one should not ignore to mention the role of political issues that may lead to a lack of access to services **[147]**, as well as economic (poverty, inability to afford the needed food) **[148]** and social issues such as big family size with an average of 5.6 persons in 2012 **[149]**. Such issues might make it difficult for diabetics to prepare special foods for themselves; among others things that DM patients might need to manage their disease.

The challenges of diabetes self-care are considerable for most patients and demand a lot of time and effort from both the patients and the healthcare providers. We can't exclude that the way patients receive their diabetes diagnosis

by a physician influences the way they manage their illness. Therefore, patient diabetes care may encounter difficulties as a result of negative physician's beliefs and attitudes or due to physician's lack of knowledge about evidence based guidelines **[145]**. Though the patient–physician relationship constitutes an integral part in the management plan for DM patients, there are also external barriers that go beyond patients and their physicians related to the healthcare system in a clinic such as short staffing, staff turnover, as well as system fragmentation **[146]**. Therefore, patients may not receive integrated diabetes services due to the lack of a collaborative diabetes team with the skills necessary for effective communication **[145]**. Additionally, the cost of treatment as well as the absence of health insurance in a healthcare system is a potential barrier to quality diabetes care among patients **[145]**. In the Palestinian context, fragmentation in the health system was reported by Giacaman's study about health status and health services in the occupied Palestinian territory **[150]**. At the national level, it was reported that serious efforts have been made to implement a unified strategy for controlling and preventing diabetes in Palestine. These include surveillance and service improvement through training of physicians and nurses in diabetes care and establishing diabetes databases for diabetes patients among others, in cooperation with the Quality Improvement Project (QIP) of the MoH **[151]**.

The following study will address DM self-care and glycemic control in particular among adults with T2DM from Ramallah governorate clinics in Palestine, taking into consideration that patients are struggling while managing their chronic illnesses in the Palestinian society.

CHAPTER 2

METHODOLOGY

This study was part of a survey conducted in 2012 by the (ICPH) at (BZU) to study DM complications, control, management and quality of life of T2DM Palestinian patients in 11 primary healthcare clinics operated by the ministry of health (MoH), jointly by the MoH and non-governmental organizations (NGO) and by the (UNRWA) in the Ramallah governorate.

The major aims of the current study were to assess the level of glycemic control, and the level of diabetes self-management, including patient SCA and provider SCR, and to examine the associations between glycemic control and SCA as well as SCR among the study sample. Hence, this thesis was based on secondary data analysis of the management section of a cross-sectional clinic-based survey. The study methods that were used will be described in detail in this chapter.

2.1 Study Design

The number of main primary healthcare clinics offering services to diabetes patients in the Ramallah governorate was 14 **(annex 1)**. Of these 14 clinics, six were operated by the MoH, six were operated by UNRWA and two clinics were operated jointly by the MoH and NGOs. Three clinics were excluded from the study due to small patient loads (i.e. total number of patients needed per clinic was less than 10 patients, see annex 1**)**. One was operated by MoH, one by

UNRWA and one by PMRS. The study participants were recruited from 11 primary healthcare clinics **(annex 2)**.

2.2 Study Area and Population

The study was conducted in the Ramallah governorate, which is located in the center region of the West Bank. The Ramallah governorate has an area of 855km^2 and an estimated population of 310,218 inhabitants according to figures calculated in 2011 **[152]**.

Eligible participants for the study included adult men and non-pregnant women who had clinical diagnosis of T2DM in the surveyed clinics (i.e. having medical records in clinic databases) and who consented to participate in the study. Patients with T1DM, pregnant DM patients or patients unable to communicate (patients who had physical disabilities that prevented communication such as hearing or speaking difficulties, or had limited mental capacities) were excluded from the study **[153]**.

2.3 Sample Size and Sampling Frame

It was estimated that a sample of 500 adults diagnosed with T2DM would be adequate. The total estimated number of patients in the clinics included in the survey was 5212. The total sample size was calculated first based on a standard formula: **sample size (SS) = Z^2 x (p) x (1 – p)/ C^2** where Z=Z value (1.96 for 95% confidence interval); P=percentage of population picking a choice, expressed

as a decimal; C=confidence interval, expressed as a decimal (e.g., 0.05 =+/ - 5 percentage points). SS= $(1.96)^2$ * (0.5)*(0.5)/ $(0.05)^2$ = 384 participant.

Then the sample size was corrected for finite population size, and multiplied by a factor of 1.4 to account for the design effect.

Sample Size – Finite Population

New sample size (NSS) = SS/ [1 + ((SS – 1) /population]) **or**

Sample Size = n / [1 + (n/population)].

NSS= 384 / [1+ (384/5000)] = 357 participants.

This was then adjusted for design effect for clustering and others by multiplying the sample size by 1.4: 357 * 1.4 = 500 participants.

The number of patients needed from each clinic was proportional to the clinics patient load. Participants were identified from the diabetes database in each clinic and either received a phone call invitation or were referred by nurses during their doctor appointments. In certain clinics, both approaches were used in the same clinic for logistic considerations **(annex 3)**. The final sample of 517 T2DM patients was recruited from the 11 primary healthcare clinics **[153]**.

2.4 Data Collection Tools

The survey included various parts and utilized quantitative and qualitative methods. The quantitative portion of the research included a questionnaire designed to characterize diabetes complications, management and quality of life in a sample of Palestinian patients. This questionnaire included several standardized instruments to address these aspects. The diabetes complications part

was addressed using the Diabetes Complications Index (DCI). The management part was addressed using the expanded and revised scale of the Summary of Diabetes Self-Care Activities SDSCA (E&R) **(annex 4)**, and the quality of life was addressed using the Audit of Diabetes-Dependent Quality of Life (ADDQoL-19) questionnaire. Author approval was obtained to use the previously mentioned instruments. In addition, questions to cover other aspects related to patient demographic and socioeconomic characteristics, family history of diabetes, smoking status, diabetes complications and co-morbidities were added from other standardized instruments (PCBS questionnaires, Michigan Diabetes History, care profile questionnaires, Steps Non-Communicable Diseases (NCD) questionnaire and slipping slipper sign question). The quantitative portion of the survey also included clinical, anthropometric measurements and laboratory examinations [blood pressure, height, weight, waist circumference, foot examination by monofilament and tuning fork tests, blood and urine tests, and eye exam]. These measurements and examinations were done using standardized procedures.

The qualitative part of the survey included focus group discussions with T2DM patients to assess knowledge and perceptions about diabetes complications and self-care. In depth interviews with service providers and key informants from the different sectors at both the policy and the practice level were conducted to assess the health services and the needs of healthcare providers **[153]**.

2.5 Translation of the Questionnaires

The final Arabic version of the questionnaire **(annex 5)** administered to patients was based on the utilization of the available validated Arabic translation for the demographic data, educational level, employment status and smoking history from the Palestinian Central of Statistics (PCBS) surveys and Steps NCD protocol from the World Health Organization (WHO). In addition, validated Arabic translation was also available for the ADDQoL 19 **[154]** and for some parts of the SDSCA. As for the other parts (additional questions) of the SDSCA measure, only non-validated Arabic translation was available **[67]** (please see section 2.8.1 for more info). As for the DCI and the questions that were added by the research team, the first two steps (forward translation and expert panel verification of the translation) in the WHO guidelines for translation of tools were followed **[155]**. An expert panel of three health professionals (including two diabetologists) was assigned to review the translation of questionnaires from English to Arabic and to verify this translation. Some adaptations were done to clarify the questions whenever needed.

2.6 Data Collection and Fieldwork Process

During the preparation of the fieldwork, seven local fieldworkers were recruited and given intensive training for two days by the main investigator and the research coordinators. They were provided with a training manual as a guiding tool during the fieldwork. The seven fieldworkers were divided into two teams; each was composed of three-four fieldworkers.

The study was piloted on 10 patients in one UNRWA clinic (Qalandia, not included in the study) in December 2011. Following the pilot, suggestions regarding the procedures in terms of time, content and flow were discussed with the research team. Eventually, certain modifications and adaptations were applied to facilitate the process of the fieldwork and to further clarify the questions and the procedures.

The fieldwork was conducted under the supervision of the main investigator with the help of two research coordinators who organized the process of the fieldwork. The data collection for the quantitative part of the survey took place in the period between February 27th and June 7th 2012. Two focus group discussions were conducted by the main investigator and one experienced fieldworker in focus groups. Eight key informant interviews were conducted by the main investigator and one experienced researcher who was the overall supervisor of the study. The qualitative part was conducted between May and August 2012 **[153]**.

2.7 Ethical Considerations

The ethical committee at ICPH reviewed and approved the project proposal. Approval to collect data and conduct the field work was also obtained from officials among all participating healthcare providers including MoH, UNRWA, PMRS and PRCS. The main principles of research ethics were applied in this study, including obtaining informed witnessed verbal consent by two fieldworkers and assuring participants that their participation was voluntary and that they had

the freedom of not answering any question. They were also informed that they could withdraw from the study at any time and that this wouldn't affect their service provision. Confidentiality of collected data from the participants was maintained throughout the processes of data collection, data analysis and documentation. In addition, patients were provided with a copy of their laboratory and eye examination reports to be included in their medical records, through their respective clinics **[153]**.

2.8 Measures used for the current study

The following section provides a detailed description of the methods used to collect the needed data and an explanation of the variables of interest that were utilized in the analysis of the current study.

2.8.1 Data Collection Tools

Blood test: The analysis of HbA1c and other laboratory tests including lipid profile, and kidney function tests were done at (BZU) medical laboratory. The Boronate affinity method which is one of the approved methods for testing HbA1c according to the international guidelines for laboratory analysis was used [156]. A reliability study of HbA1c test was done for 30 blood samples using the high performance liquid chromatography (HPLC) method at Augusta Victoria Hospital (AVH) lab in May 2012. These blood samples were for patients from different clinics (Ramallah central clinic, Silwad, old Ramallah and Ni'lin).

Demographic/socioeconomic characteristics: The demographic and socioeconomic characteristics of the sample (sex, age, marital status, education, STL index, locale, and refugee status) were obtained by patient self reports using standardized questions from the PCBS questionnaires.

Other necessary variables added by the research team: Data on the healthcare sector (provider of diabetes services), duration of diabetes, patient assessment of diabetes self-management (perceived capability of dealing with diabetes), patient perception regarding diabetes knowledge and physician inquiry about patient self-care practices (eating habits and physical activity]) during the last visit were added by the research team to complete the needed information.

SDSCA Instrument: Data on self-care activities and self-care recommendations were obtained using the Summary of Diabetes Self Care Activities–Expanded and Revised- SDSCA(E&R) self report measure developed by Toobert, Hampson, and Glasgow in 2000. The SDSCA (E&R) measure was chosen for this research study because of its reliability, validity, and widespread use in assessing diabetes self-care across the different components of the diabetes care regimen. It has been used with over 2000 diabetic patients across the US **[40]** and according to the author, it has been translated into over 21 different languages**.**

The first Arabic translated and validated version of the SDSCA (Ar) was developed by Khalid Aljohani for his PhD Thesis in Curtin University in 2011.

This provided validated Arabic translation of the 10 core items of the SDSCA (diet, exercise, blood sugar testing and foot care but excluding smoking). The Arabic translation of the expanded SDSCA questions that included medications and the healthcare team recommendations were not validated. The translation of the SDSCA into the Arabic version SDSCA (Ar) by Aljohani went through the complete process of translation utilizing the (WHO) 2008 guidelines for translation of instruments. The full SDCA instrument was translated [i.e. including both the core items and the additional questions of the SDSCA (E&R)] and evaluated through two expert panels and content validity analyses. Only the short version of the SDSCA (first 10 core items) was pre-tested. The reliability and validity analysis of this translation revealed good clarity and representativeness of the items. According to Aljohani, the medication subscale was not validated but nevertheless it was included in his analysis due to its importance **[67]**.

The Arabic translation by Aljohani was used in the current study with very few modifications and adaptations to clarify certain questions that were suggested by the expert panel and the research team of this study.

2.8.2 Definition and explanation of study variables

1- Glycemic control

The HbA1c level was used as a continuous variable in the univariate and bivariate analysis only. In the multivariate regression analysis, it was used as a categorical variable (two categories only) to facilitate presentation and interpretation of data. Glycemic control was assessed using the HbA1c laboratory test as a measure of

glycemic control during the preceding two-three months. According to the American Diabetes Association (ADA), glycemic status was categorized as follows: good glycemic control if HbA1c <7% and poor glycemic control if HbA1c ≥ 7% **[3].**

2- Items of the SDSCA (E&R) measure

The SDSCA (E&R) questionnaire consisted of two sections. The first section was composed of essential questions about SCA such as diet, exercise, blood sugar testing, foot care and smoking. The second section (SDSCA extension) was composed of several items including additional questions about other diabetes SCA such as carbohydrate diet, medications adherence and specific foot care practices, and six additional questions addressing healthcare interventions in terms of SCR assessment with regard to diet, exercise, blood sugar testing, smoking cessation and medications. These questions were designed to get more information about the patient's healthcare context. These may be useful in clinical practice and in research.

The SDSCA (E&R) is a comprehensive multidimensional instrument, composed of 11 core items and, an expanded list of 14 additional questions. The SDSCA (E&R) measures the frequency of self-care activity during the previous seven days for each component across the regimen separately **[40]**. Each patient was asked to recall the number of days in the last week that he/she was engaged in a certain activity. If patients were sick during the past week, they were asked to reflect on the seven days before they became sick.

I. The first section of the SDSCA (E&R) measure

The SDSCA (E&R) measure consists of **11 core items** that included the following: **4 items on diet,** the first two on general diet and the others on specific diet *(1- How many of the last seven days have you followed a healthful eating plan? 2- On average, over the past month, how many days per week have you followed your eating plan? 3- On how many of the last seven days did you eat five or more servings of fruits and vegetables? 4- On how many of the last seven days did you eat high fat foods such as red meat or full-fat dairy products?);* **2 items on exercise:** *(1- On how many of the last seven days did you participate in at least thirty minutes of physical activity [total minutes of continuous activity, including walking])? 2- On how many of the last seven days did you participate in a specific exercise session [such as swimming, walking, biking other than what you do around the house or as part of your work]?*; **two items on blood sugar testing:** *(1- On how many of the last seven days did you test your blood sugar? 2- On how many of the last seven days did you test your blood sugar the number of times recommended by your healthcare provider?);* **2 items on foot care:** *(1- On how many of the last seven days did you check your feet? 2- On how many of the last seven days did you inspect inside of your shoes?);* **and 1 item on smoking:** *(e.g., Have you smoked a cigarette, even one puff, during the last seven days? If yes, how many cigarettes did you smoke on an average day?).*

II. The second section (extension) of the SDSCA (E&R) measure

The additional items of the SDSCA (E&R) included questions on self-care recommendations as stated previously. In these questions, patients were asked

whether the healthcare team (doctor, nurse, dietitian, or diabetes educator) advised the patient to follow specific self-care recommendations.

The first additional item was on self-care recommendations **about diet** and included eight questions: *1- Follow a low fat diet; 2- Follow a complex carbohydrate diet; 3- Reduce the number of calories you eat to lose weight; 4- Eats lots of food high in dietary fiber; 5- Eats plenty of fruits and vegetables (at least 5 servings per day); 6- Eats very few sweets (for example: desserts, non-diet sodas, candy bars) 7- other (specify); 8- I have not been given any advice about my diet by my healthcare team.*

The second additional item was on self-care recommendations **about exercise** and included six questions: *1- Get low level exercise (such as walking) on a daily basis; 2-Exercise continuously for at least 20 minutes at least 3 times a week; 3- Fit exercise into your daily routine (for example, take stairs instead of elevators, park a block away and walk, etc.); 4- Engage in a specific amount, type, duration and level of exercise; 5- Other (specify); 6- I have not been given any advice about exercise by my healthcare team.*

The third additional item was about **recommendations** provided by the healthcare provider regarding **self-glucose check or sugar testing** and included five questions: *1- Test your blood sugar using a drop of blood from your finger and a color chart; 2- Test your blood sugar using a machine to read the results; 3- Test your urine for sugar; 4- Other (specify); 5- I have not been given any advice either about testing my blood or urine sugar level by my healthcare team.*

The fourth additional item was about the **medications prescribed** for diabetes, and included five questions: *1- An insulin shot one or two times a day; 2- An insulin shot three or more times a day; 3-Diabetes pills to control my blood sugar level; 4- Other (specify); 5- I have not been prescribed neither insulin nor pills for my diabetes.*

The fifth additional item was on the carbohydrate diet *(On how many of the last seven days did you space carbohydrates evenly through the day?).*

The (6^{th}, 7^{th}, and 8^{th}) additional questions of the SDSCA scale were about taking the **recommended medications**: *1- On how many of the last seven days, did you take your recommended diabetes medication?; 2- On how many of the last seven days did you take your recommended insulin injections?; 3- On how many of the last seven days did you take your recommended number of diabetes pills?.* The first question was about general medication adherence, while the second and third questions were on specific **"medications adherence"**.

The (9^{th},10^{th} and 11^{th}) additional question were on specific foot care (*1- On how many of the last seven days did you wash your feet?, 2- On how many of the last seven days did you soak your feet?, 3- On how many of the last seven days did you dry between your toes after washing?*).

The SDSCA self-care recommendations about smoking status and referral to a **smoking cessation program** were also asked to patients in the current study using the 12^{th}, 13th and 14^{th} additional questions of the SDSCA (R&E) respectively: (*1- At your last doctor's visit, did anyone ask about your smoking status?; 2- If you smoke, at your last doctor's visit, did anyone counsel you about*

stopping smoking or offer to refer you to a stop-smoking program?; 3- When did you last smoke a cigarette?).

III. Items of the SDSCA (E&R) utilized by the current study

All items of the SDSCA (E&R) were used in this thesis except the five additional questions (5^{th}, 6th, 9^{th}, 10^{th} and 11^{th}) of the SDSCA (E&R) that addressed the carbohydrate diet, the general medication adherence and specific foot care. In addition, the first question of the self-care recommendation item provided by the healthcare provider regarding self glucose checks or sugar testing (*Test your blood sugar using a drop of blood from your finger and a color chart)* was removed leaving four questions instead of five of this item in this study, because this method of self testing of blood sugar is not available in Palestine.

3- Additional questions related to the management section

Two questions addressing **physician inquiry about patient self-care practices** were added by the research team to complete the needed data. These questions concerned dietary habits and physical activity: *(1-At your doctor's last visit, did anyone ask you about your eating habits?; 2-At your doctor's last visit, did anyone ask you about your physical activity?).*

4- Demographic and socioeconomic characteristics

I. **Sex of participants**: Previously conducted studies indicated that sex may have an effect on self-care management practices among T2DM patients **[157]**.

Other studies showed that sex was not significantly related to poor glycemic control **[76, 80]**. Sex (males vs. females) was included in this study to examine its association with glycemic control among the participants.

II. **Age of participants:** For the purpose of international, regional and local comparisons, age of patients was categorized as follows: category 1, 20-44 years, category 2, 45-64; and category 3, ≥65 years. Age variables were re-categorized into <65 and ≥65. The latter was considered to be the threshold for potential impaired body functions, which could affect self-care practices **[67].** Other studies used this categorization also. A study of glycemic control from 1988-2000 among US adults diagnosed with T2DM describing the changes in demographics used the previous categorization since the majority of people with T2DM are >64 years in the developed countries **[158, 159]**. In addition, the majority of patients with T2DM in developing countries are in the age group 45-64 years. Moreover, in the Palestine stepwise survey the age range 25-64 years was one of the employed categories.

III. **Marital status** of participants: this variable was categorized into four groups, constructed as follows: 'single', 'married', 'divorced' and 'widowed'. The categories single, divorced and widowed were collapsed into one category named "never married & other", while the married category remained the same.

IV. **Education:** Health literacy affects patient's adherence to self-care practices and levels of self-management **[160]**. Moreover, glycemic control was associated with education in some studies. Therefore, education was included

in the analysis to examine its association with glycemic control among the study sample. The educational level of patients was constructed into four categories that represent the hierarchical educational level in Palestine as follows: category 1, “illiterate and acquainted”; category 2, “elementary”; category 3, “preparatory and secondary”; category 4 “secondary certificate and higher”.

V. **The household standard of living (STL) index** was based on household possessions. A reliability analysis test (using Cronbach’s alpha α) was conducted to measure the internal consistency for a set of 22 items (family car, solar heater, washing machine, microwave, dish washer, central heating, clothes dryer, house library, LCD [plasma] television, DVD player, family telephone line, personal mobile phones, digital camera, computer, laptop, satellite, video, and internet connection, electrical fridge, electrical/gas stove, black and white television and colored television). However, four items (electrical fridge, electrical/gas stove, black and white television, and colored television) were excluded from the analysis as these items did not distinguish between people’s STL index. The value of α was 0.844 which was the highest value when the previously mentioned eighteen items were included. The STL index was constructed from the sum of the eighteen items; each item was given a value of 1. Three categories were constructed: “low STL index” (0- 6), “medium STL index” (7-12), and “high STL index” (13-18).

VI. The place of residence was converted into locale. **Locale classification** into urban/rural/camp was based on the 2007 Palestinian Central Bureau of

Statistics (PCBS) classification which is based on services and population size **[161]**.

VII. **Refugee status** of participants was categorized into three groups: registered refugee, non-registered refugee and non-refugee according to the PCBS classification (2006) **[162].** The first two categories were collapsed into "refugee" as there was only one person in the non-registered refugee category.

VIII. **Clinics operated by different healthcare providers (sector):** The 11 primary healthcare clinics included in the study (Al–Amari, Al-Jalazoun, Deir Ammar, Beit Ur', Ramallah central, Old Ramallah, Beit Reema, Qibya, Ni'lin, Silwad and Singil) were divided into three categories according to the service provider. Five clinics were operated by the MoH [Ramallah Central, Old Ramallah, Beit Reema, Qibya and Ni'lin]. Four primary healthcare clinics were operated by UNRWA [Al Amari, Al-Jalazoun, Deir Ammar and Beit Ur'], and two were operated jointly by MoH and NGO clinics [Silwad and Sinjel].

5- Selected Disease-Related Characteristics

I. **Duration of diabetes:** Epidemiological studies indicated that there is a positive association between the duration of T2DM and the presence of diabetes-related complications **[55, 69]**. Therefore, the main goal of DM management is to achieve optimal glycemic control (HbA1c <7%), which is necessary to prevent these complications **[52]**. Duration of diagnosed diabetes was constructed into two categories: [category 1, "equal or less than seven

years duration"; category 2, "more than seven years duration". This categorization was used in a study conducted in Jordan to determine factors associated with poor glycemic control among T2DM patients **[69]**.

II. **Obesity**: The body mass index (BMI) was classified into two categories based on the WHO definition of obesity **[163]** as follows: [category 1: comprised of a BMI less than 30, and category 2: comprised of a BMI greater than or equal to 30].

III. The **type of diabetes treatment** that was prescribed to the patients by their physicians was categorized into four groups as follows: [category 1: comprised of insulin only, category 2: comprised of oral hypoglycemic agents (OHAs) only, category 3: comprised of combined therapy of both insulin and OHAs, and category 4: comprised of no drugs].

IV. **Patient assessment of diabetes self-management (perceived capability of dealing with diabetes) and patient perception regarding diabetes knowledge:** These two questions addressed the perceived capability of dealing with diabetes *(Do you feel that you are capable of dealing with diabetes [diet, medications, physical activity]?),* and patients perceptions regarding diabetes knowledge *(Do you think you have enough information about your disease?)* among patients. They were added by the research team and verified by the translation panel. The question of patient's perceived capability of dealing with diabetes consisted of four categories originally *(1- yes in an excellent way. 2- yes, in a good way. 3- yes, to a lesser degree. 4- No, not at all).* The first two categories were collapsed into one and the latter

two categories were also collapsed into one category. The diabetes knowledge question consisted of 4 categories originally *(1- Yes, excellent information; 2- Yes, good information; 3- Yes, little information; 4- No, no information).* The first two categories were collapsed into one and the latter two also were collapsed into one category.

2.8.3 The scoring methodology of the SDSCA (E&R) scale

I. SDSCA core items: composed of the questions of the first section of the SDSCA measure (i.e. each question of the first 10 questions was considered as a core item).

II. SDSCA subscale: composed of each two inter-related core items of the first section of the SDSCA measure (i.e. the first 10 core items form five standard subscales: general diet, specific diet, exercise, blood sugar testing and foot care).

Scoring of the SDSCA core items:

Each self-care item was assessed and scored separately. The scoring of the first 10 core items (excluding the 11^{th} core item "smoking", a yes/no question) used the days per week on a continuous scale of 0–7, with a higher number of days reflecting better self-management. Based on patients frequency/distribution of performance of each self-care activity, the days per week for each scale were coded as "0 days" (non performance), "1-6 days" (partial performance); and "7

days" (complete performance) for all the 11 core items of the SDSCA and for the additional questions related to "medication adherence" of the SDSCA (E&R).

Scoring of SDSCA subscales:

Based on the scoring methodology of the SDSCA **[40]**, each standard subscale had two items; the mean number of days was calculated, resulting in an overall score for each of the six self-care aspects (i.e. general diet, specific diet, exercise, glucose self-monitoring, foot care and medication adherence). The days per week for each sub-scale were coded as "0 days" (nonperformance), "0.5 to3 days" (partial performance, but less than 50%, performance), "3.5 to 6.5 days" (partial, but more than 50%, performance), and "7 days" (complete performance).This categorization was used in other studies **[123]**. For the smoking item (the seventh aspect), the scoring consisted of assessing the smoking status (0=non smoker and 1=smoker) and the number of cigarettes smoked per day as a continuous variable.

In parallel with the scoring guidelines of the SDSCA instrument, the standard scores (score of the general diet, score of the specific diet, score of the exercise, score of blood sugar testing, score of foot care and score of medication adherence) were obtained by calculating the mean of the two core items.

The first subscale used the first two items of the SDSCA related to general diet, and measured patients adherence to a healthy eating plan followed in the last seven days preceding the survey. Such that a zero score means that a healthy eating plan was not followed in the past week and a score of seven means that healthy eating plan was followed during all the seven days of the week.

The second subscale assessed specific dietary questions related to fruit and vegetables consumption and full fat dietary products consumed in the previous week preceding the survey, whereby the responses on the latter item (full fat dietary products) reflected the consumption of high-fat dietary products. Therefore, the consumption of full fat dietary products were reverse coded, then scored accordingly.

The author of the SDSCA measure did not provide a scoring methodology for the SDSCA additional questions that addressed SCR. Therefore, all items related to SCR about diet regimen, exercise, blood sugar tests and other tests recommendations, prescribed medications for diabetes, and smoking cessation recommendation were assessed separately. Recommendations about the diet regimen (the eight questions mentioned above) provided by the healthcare team to diabetes patients were coded as: received "no advice" and received "advice" about diet regimen. The "received advice" category included those who received between one to seven recommendations about diet regimen. Recommendations about exercise (five questions mentioned above) were coded as: received "no advice" and received "advice" about diet regimen. The received advice category included those who received between one to five recommendations about exercise.

2.9 Statistical Analysis

2.9.1 Descriptive Statistics

Descriptive statistics were calculated for study variables to determine sample characteristics and evaluate variable distributions (demographics & socioeconomic data, SDSCA core items and subscales, SDSCA expanded items [additional questions], and other selected diabetes-related characteristics in terms of means and standard deviations [SD] for continuous variables and proportions [%] for categorical variables). Additionally, percentages were presented to show the proportion of those who fully or partially performed specific self-care activity or received specific self-care recommendation versus participants who did not.

2.9.2 Bivariate Analysis

The purpose of the bivariate analyses was to examine associations between the main dependent variable (glycemic control) and the independent variables (SCA, SCR and demographics/socioeconomic characteristics, and all other aforementioned variables). The Chi-square test was used to assess the statistical significance of the association between glycemic control and SCA (sub-scales: general diet, specific diet, exercise, blood sugar testing, foot care, medication adherence), SCR and other variables including demographic/socioeconomic characteristics and disease-related characteristics. The independent sample t-test and ANOVA test were used to compare the difference between means of HbA1c levels and the study variables. The statistical significance was defined as the $p=0.05$ level.

The Chi-square test and the confidence intervals were also use to examine the associations between other study variables in the current study. These associations include the following: the association of SCA (dependent variable) with the demographic/socioeconomic characteristics and the healthcare sector (independent variables); the association of SCR (dependent variable) and demographic/socioeconomic characteristics (independent variables); and the association of SCR (dependent variable) and SCA (independent variables).

2.9.3 Multivariate Analysis

The last phase of the data analysis was a multivariate analysis. The aim of this analysis was to identify factors accounting for the variance in overall glycemic control in terms of demographic and socioeconomic characteristics (sex, age, marital status, education, STL index, locale, refugee status), and other selected diabetes-related characteristics (diabetes duration, obesity, type of diabetes treatment, patients assessment of their diabetes self- management (perceived capability of dealing with diabetes), and patient perceptions regarding diabetes knowledge, SCA (general diet, specific diet, exercise, blood sugar testing, foot care , smoking and medication adherence), SCR (diet regimen, exercise, medications, blood and urine sugar testing, and other tests and smoking cessation) and physicians inquiry about patient self-care practices (smoking status, eating habits, and physical activity).

Logistic regression (LR) was used to investigate/model the association between glycemic control (HbA1c≥7%) and several explanatory variables detailed in this chapter. All non significant study variables in the univariate logistic regression were excluded from the regression analyses. The significant variables that were entered into the multiple logistic regression model included: duration of diabetes, type of diabetes treatment, patients assessment of their diabetes self-management (perceived capability of dealing with diabetes), advice about testing blood sugar using the machine and physician's inquiry about eating habits adjusting also for the classical confounders: sex and age. Logistic regression models were presented using Odds Ratios (OR), Confidence Intervals (CIs) and Probabilities (P-values), as detailed in Chapter 3. P-value <0.05 was considered statistically significant. Data analysis was conducted using the Statistical Package for the Social Sciences (SPSS) version 18.0.

CHAPTER 3

STUDY FINDINGS

3.1 Response Rate and Sample Characteristics

621 DM patients were invited to participate (Figure 2), 100 did not respond, 517 patients were eligible and consented to participate, while 4 patients were ineligible for the study and excluded from the study. We invited 617 eligible patients in order to ensure that we get the calculated sample size of 500. The response rate of the study was 83.8%. Of the four ineligible patients, one patient had T1DM, three were not able to communicate because two of them had hearing problems and one had limited mental abilities. Of the 100 non-respondent patients, 62 patients refused to participate and accepted to fill the refusal form, while 25 patients refused to participate and also refused to fill this form, and 13 patients were contacted and accepted to participate but did not show up. No difference was found in sex, age categories, education, urban/rural/camp residence and refugee status of the patients who refused to participate compared to responding patients. However, all 62 non-responding patients who filled the refusal form (100.0%) had low STL index, while only (48.9%) of the responding patients had low STL index.

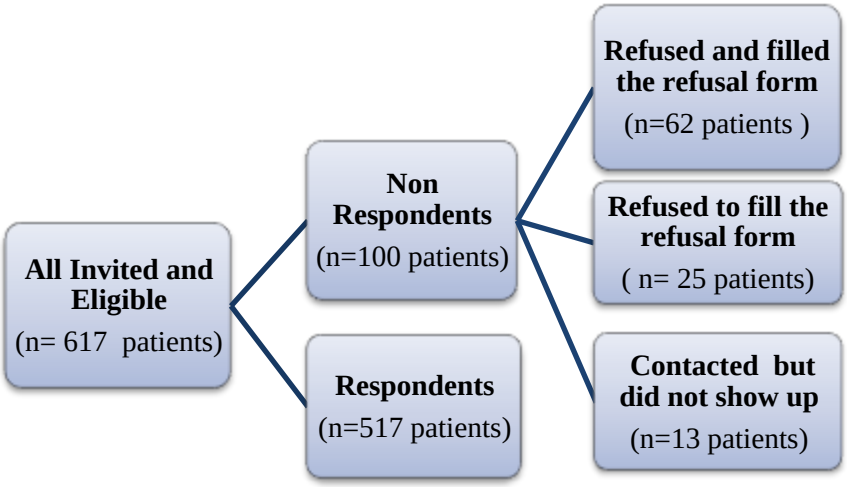

Figure 2: Patient status according to eligibility and participation in the study

3.2 General Characteristics of the Study Population

3.2.1 Demographic and Socioeconomic Characteristics

Table 2 shows the demographic and socioeconomic characteristics of the study participants for both sexes.

Sex distribution: The sample consisted of 517 patients; the majority of the respondents were females (351, 67.9%), while 166 (32.1%) were males.

Age Structure: The mean ± SD age of the participants was 58.1±9.8 years. Two-thirds of the patients were in the age group "45-64 years", followed by those aged "65 years and older" which comprised around one quarter of the study participants. Forty-two patients (8.2%) were between 20 and 44 years. In the regression analysis, age was re-categorized into <65 and ≥65 years. About three-

quarters of the patients were less than 65 years, while the remaining quarter of patients was 65 years and above.

Marital Status: Most of the patients were “married” (77.0%), followed by the widowed (17.4%). “Single and divorced” patients comprised 3.3% and 2.3% of the sample, respectively. The “single, widowed and divorced” categories were collapsed to one comprising 23.0% of the sample.

Education: One sixth of the participants were “illiterate and acquainted”, a third had an “elementary” level education and almost another third had “preparatory and secondary” level education. Around one sixth of the participants had “secondary certificates and higher”.

STL index: Around half of patients were in the “low STL” category and 40.0% were in the “medium STL” category. Only 11.0% of the patients were in the “high STL” index category.

Locale and refugee status: Around half of the patients were living in urban areas followed by one third living in rural areas. Only one fifth of the participants were living in camps. 56.0% of the patients were refugees and 44.0% were non refugees.

Healthcare sector: More than half of the patients received DM services at clinics operated by the MoH whether operated by MoH alone (43.0%) or jointly by MoH and NGOs (10.0%). The rest of the patients (47.0%) received services at clinics operated by UNRWA.

Table 2: Demographic and socioeconomic characteristics of T2DM patients (N=517)

Variable	Category	Sex N (%)		Total
		M(n=166)	**F(n= 351)**	
	mean ±SD	59.8±9.4	57.3±9.9	58.1±9.8
Age (N=515)	20-44	7(4.2)	35(10.0) ^{NS}	42(8.2)
	45-64	111(66.9)	232(66.5)	343(66.6)
	≥ 65 years	48(28.9)	82(23.5)	130(25.2)
Marital status (N=517)	Never married and other	9(5.4)	110(31.3)**	119(23.0)
	Married	157(94.6)	241(68.7)	398(77.0)
Education (N=515)	Illiterate & acquainted	6(3.6)	83(23.8)**	89(17.3)
	Elementary	46(27.8)	112(32.1)	158(30.7)
	Preparatory & secondary	62(37.3)	116(33.2)	178(34.6)
	Secondary certificate & higher	52(31.3)	38(10.9)	90(17.4)
STL* index (N=517)	Low	62(37.3)	191(54.4)**	253(48.9)
	Medium	70(42.2)	139(39.6)	209(40.5)
	High	34(20.5)	21(6.0)	55(10.6)
Locale (N=517)	Urban	93(56.0)	161(45.9)*	254(49.1)
	Rural	51(30.7)	110(31.3)	161(31.1)
	Camp	22(13.3)	80(22.8)	102(19.8)
Refugee status (N=517)	Refugee	86(51.8)	205(58.4) ^{NS}	291(56.3)
	Non-refugee	80(48.2)	146(41.6)	226(43.7)
Healthcare sector(N=517)	Ministry of Health	78(47.0)	142(40.5) ^{NS}	220(42.6)
	Joint MoH-NGO	21(12.6)	33(9.4)	54(10.4)
	UNRWA	67(40.4)	176(50.1)	243(47.0)

*STL: Variables included in the scale included private car, solar heater, washing machine, microwave, dishwasher, central heat, dryer, library, LCD TV, DVD, landline telephone, cellular phone, digital camera, computer, laptop, satellite, internet and video. Cronbach's Alpha= 0.844 (18 items). STL index categories were given equal weights: Low STL index 0-6 items, medium STL index 7-12 items, and high STL index 13-18 items.

^{NS}: not significant.*< 0.05. **<0.001

3.2.2 Glycemic Control among the Study Participants

HbA1C Test

Of the 517 patients, HbA1c values were obtained for 495 patients. The mean HbA1C of the sample was 8.8% (SD=2.0, median=8.4%), ranging between 5.2% and 14.9% and its values were not normally distributed as it was skewed to the right (see Figure 3 below). Only one in five patients (n=98, 19.8%) achieved good glycemic control, while the majority of patients had poor glycemic control (n=397, 80.2%). No statistically significant difference was found between the status of glycemic control (controlled vs. uncontrolled) and the healthcare sector providing diabetes services (p=0.132).

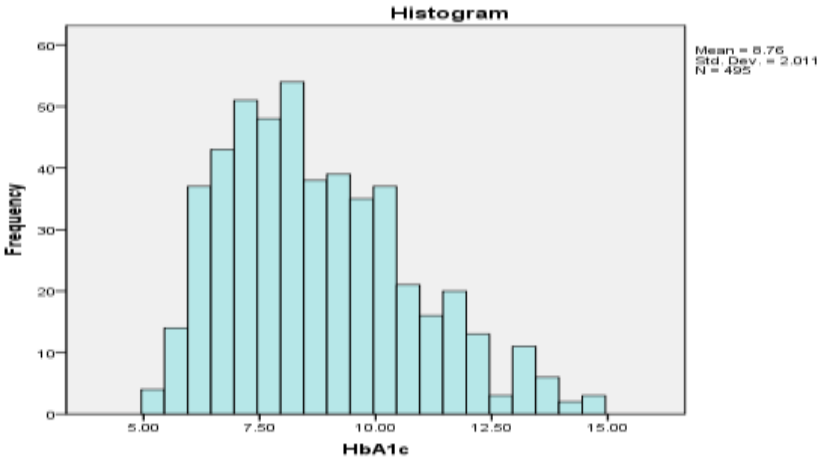

Figure 3: Distribution of HbA1c values among the study participants (N=495)

Reliability Analysis of the HbA1c test:

A sub-sample of 30 patients was randomly selected to conduct a reliability analysis of the HbA1c test. The mean of the HbA1c that was analyzed by the

(BZU) medical lab was 8.7%, while the mean of the HbA1c analysis that was conducted by (AVH) medical lab was 8.8%. One outlier case was excluded from the reliability test. The Shapiro-Wilk test of normality was constructed and demonstrated a non significant value (0.099). A paired sample T-test analysis was conducted to compare the difference between means for the sub-sample of the 29 patients whose HbA1c were measured both in (BZU) and (AVH) laboratories. The results showed no statistically significant difference between the compared HbA1c results performed in the two laboratories. On the other hand, a statistical inter-rater reliability (IRR) analysis was conducted using the intra-class correlation (ICC) coefficient to test the level of agreement between the two HbA1c assays that were obtained from (BZU) and (AVH) labs for the same patients. The ICC for the average measures was 0.989.

3.2.3 Selected Disease-Related Characteristics

The descriptive statistics of the selected diabetes-related characteristics among the study participants are presented for both sexes in Table 3.

The mean duration of diabetes was 9.4 (SD= 7.5). Around half of the patients had diabetes for seven year or less, and another half had diabetes for more than seven years. More than half of the patients were on oral hypoglycemic agents alone. 31.0% were on insulin and oral hypoglycemic. A small proportion of patients (9.0%) were on insulin alone (either one to two shots/day or three shots per day) and the smallest group of them (2.0%) was not prescribed any medication. Males

reported having twice the proportion of being on insulin compared to females ($p=0.007$).

The mean BMI was 32.3±6.1SD. The majority of T2DM patients (62.0%) were obese and only 28.0% of patients had BMI less than 30. Females reported higher proportions of obesity than males ($p<0.001$).

Patient assessment of his/her diabetes self-management (perceived capability of dealing with diabetes) in terms of medications, diet and physical activity was assessed based on patient perception as feeling capable in an "excellent, good way", "to a lesser degree or not capable at all". The majority reported being capable of dealing with their disease in an excellent or a good way (78.0%).

The knowledge of diabetes among the participants was assessed based on patient perception of having excellent, good, little or no information about DM. The majority reported having excellent or good information (79.0%).

Table 3: Selected diabetes-related characteristics of T2DM patients (N=517)

Diabetes related characteristics	Category	Sex N (%)		Total
		M(n=166)	**F(n=351)**	
Duration of diabetes (N=517)	mean ±SD	10.2±7.8	9.1±7.4	9.4 ± 7.5
	≤ 7 years	74(44.6)	179(51.0) [NS]	253(48.9)
	>7 years	92(55.4)	172(49.0)	264(51.1)
Type of diabetes treatment(N=517)	Insulin only	26(15.7)	23(6.6)*	49(9.5)
	Oral hypoglycemic agents (OHAs)only	87(52.4)	212(60.4)	299(57.8)
	Combined therapy (insulin and OAHs)	51(30.7)	107(30.5)	158(30.6)
	No medications	2(1.2)	9(2.5)	11(2.1)
Obesity* (N=508)	Obese	69(42.3)	246(71.3)**	315(62.1)
Feeling capable of dealing with diabetes(N=515)	Yes, in an excellent or good way	139(83.7)	264(75.6)*	403(78.3)
	Yes, to a lesser degree or no, not at all	27(16.3)	85(24.4)	112(21.7)
Patient perception regarding diabetes knowledge (N=515)	Yes, excellent or good information	137(83.0)	269(76.9) [NS]	406(78.8)
	Little or no information	28(17.0)	81(23.1)	109(21.2)

***Obesity was classified according to the WHO definition 2004; patients with a BMI ≥ 30 are considered to be obese.

[NS]: not significant.*< 0.05. **<0.001

3.2.4 Diabetes Self-Care Activities

The levels of diabetes self-management among the study participants (i.e. the total frequency of the SDSCA core items) demonstrated that more than half of the study participants (58.6%) did not have a healthy eating plan. Of those who reported having a healthy eating plan (n=214), only 46.3% followed their plan on a daily basis during the previous week preceding the survey. Over the month preceding the survey, only 42.5% of patients who reported having a healthy eating plan followed their plan. On a daily basis, one quarter of the sample reported eating ≥5 servings of fruits and vegetables per week during the previous week preceding the survey. Few patients (n= 35, 6.8%) did not eat a high fat food on a daily basis during the previous week preceding the survey.

More than half of the patients (53.5%) did not participate in at least 30 minutes of physical activity during the last seven days preceding the survey, while about one third (31.4%) of the participants exercised at least 30 minutes (1-6 days per week) during the week preceding the survey. Only 15.1% participated in at 30 minutes physical activity on a daily basis. Almost 94.0% of patients did not participate in a specific exercise session during the preceding week of the survey. About 62.0% checked their feet on a daily basis, while 23.3% of the patients did not check their feet at all, or checked them partially between one to six days per week during the week preceding the survey (15.1%). The majority of patients (59.5%) never tested their blood sugar during the week preceding the survey. Only 7.6% of the participants self-monitored their blood glucose levels daily, given that the

majority of study participants (69.8%) did not receive recommendations by their physician for testing blood sugar. Of the 517 patients, (n=67, 13.0%) were smokers, with an average number of cigarettes smoked per day of 19 (SD=13). Of the total sample, about 40% of the patients were prescribed insulin. 83.6% of them adhere to the prescribed insulin on a daily basis. About 87.0% of the patients were prescribed oral hypoglycemic agents, 79.0% of them adhere to these mediations on a daily basis.

The proportion of study participants performing diabetes self-management practices and the mean number of days of each item of the 11 core items of the SDSCA scale and the medication adherence questions of the SDSCA extension are displayed in Tables 4(a-c).

Table 4 (a): Performance of diet self-management among T2DM patients

Self-care activities (core items)	Proportion (%)			Mean ±SD (days/week)		
	Sex			Sex		
	M	F	Total	M	F	Total
Diet						
Do not have a healthy eating plan (N=517)	90(54.2)	213(60.7)	303(58.6)			
Have a healthy eating plan (N=214)						
Followed their healthy eating plan during the previous week (N=214)						
No performance[1]	12(15.8)	29(21.0) [NS]	41(19.2)			
Partial performance[2]	27(35.5)	47(34.1)	74(34.5)	4.9 ±2.6	4.6±2.8 [NS]	4.7±2.7
Complete performance[3]	37(48.7)	62(44.9)	99(46.3)			
Followed their healthy eating plan over the last month(N=214)						
No performance	15(19.7)	31(22.5) [NS]	46(21.5)			
Partial performance	27(35.5)	50(36.2)	77(36.0)	4.7±2.7	4.5±2.8 [NS]	4.6±2.8
Complete performance	34(44.7)	57(41.3)	91(42.5)			
Ate ≥5 servings of fruits and vegetables per day(N=509)						
No performance	50(30.5)	130(37.7) [NS]	180(35.4)			
Partial performance	64(39.0)	135(39.1)	199(39.1)	3.4±2.8	2.9±2.8*	3.0±2.8
Complete performance	50(30.5)	80(23.2)	130(25.5)			
Did not eat high fat food(N=513)						
No performance	39(23.6)	105(30.2) [NS]	144(28.1)			
Partial performance	115(69.7)	219(62.9)	334(65.1)	3.2±2.2	3.3±2.5 [NS]	3.3±2.4
Complete performance	11(6.7)	24(6.9)	35(6.8)			

[1] No performance: self-care activity never performed during the previous week preceding the survey.

[2] Partial performance: performed between 1-6 days during the previous week preceding the survey.

[3] Complete performance: self-care activity performed every day during the previous week preceding the survey.

[NS]: not significant.*< 0.05. **<0.001

Table 4 (b): Performance of physical activity/exercise, foot care and smoking self-management among T2DM patients

Self-care activities (core items)	Proportion (%)			Mean ±SD (days/week)		
	Sex			Sex		
	M	F	Total	M	F	Total
Physical activity/Exercise						
Participated in at least 30 min. physical activity (N=516)						
No performance [1]	87(52.4)	189(54.0)**	276(53.5)			
Partial performance[2]	41(24.7)	121(34.6)	162(31.4)	2.3± 2.9	1.6±2.3**	1.9±2.6
Complete performance[3]	38(22.9)	40(11.4)	78(15.1)			
Participated in specific exercise session (N= 516)						
No performance	156(94.0)	327(93.4) [NS]	483(93.6)			
Partial performance	4(2.4)	18(5.2)	22(4.3)	0.3 ± 1.4	0.2±1.1 [NS]	0.27±1.2
Complete performance	6(3.6)	5(1.4)	11(2.1)			
Foot care						
Checked feet (N=516)						
No performance	48(29.1)	72(20.5) [NS]	120(23.3)	4.4 ±3.2	4.9±2.9 [NS]	4.7±3.1
Partial performance	20(12.1)	58(16.5)	78(15.1)			
Complete performance	97(58.8)	221(63.0)	318(61.6)			
Inspected inside shoes (N=517)						
No performance	98(59.0)	196(55.8) [NS]	294(56.9)	2.5 ±3.2	2.6±3.2 [NS]	2.5±3.2
Partial performance	15(9.0)	42(12.0)	57(11.0)			
Complete performance	53(32.0)	113(32.2)	166(32.1)			
Smoking Status (N=517)						
Yes, smokers	56 (33.7)	11(3.1)*	67(13.0)			

[1] No performance: self-care activity never performed during the previous week preceding the survey.

[2] Partial performance: performed between 1-6 days during the previous week preceding the survey.

[3] Complete performance: self-care activity performed every day during the previous week preceding the survey.

[NS]: not significant.*< 0.05. **<0.001

Table 4 (c): Performance of blood sugar testing and medications adherence among T2DM patients

Self-care activities (core items)	Proportion (%)			Mean ±SD (days/week)		
	Sex			Sex		
	M	F	Total	M	F	Total
Blood sugar Testing						
Tested Blood sugar (N=516)						
No performance [1]	86(52.1)	221(63.0)*	307(59.5)			
Partial performance [2]	61(37.0)	109(31.0)	170(32.9)	1.5± 2.3	1.0±1.9**	1.2±2.0
Complete performance[3]	18(10.9)	21(6.0)	39(7.6)			
Do not have physician recommendations for testing blood sugar (N=517)	122(73.5)	239(68.1) [NS]	361(69.8)			
Tested Blood sugar the recommended times by the physician (N=156)						
No performance	31(70.5)	75(67.0)	106(67.9)			
Partial performance	9(20.4)	27(24.1)	36(23.1)	1.0±2.2	1.2±2.1 [NS]	1.2±2.1
Complete performance	4(9.1)	10(8.9)	14(9.0)			
Medication Adherence (additional SDSCA items)						
Do not take insulin (n=517)	90(54.2)	220(62.7)	310(59.9)			
Adhered to recommended insulin (n=207)						
No performance	4(5.3)	3(2.3) [NS]	7(3.4)			
Partial performance	9(11.8)	18(13.7)	27(13.0)	6.3±1.8	6.4±1.5	6.4±1.6 [NS]
Complete performance	63(82.9)	110(84.0)	173(83.6)			
Do not take OHAs (n=517)	28(16.9)	38(10.8)	66(12.8)			
Adhered to recommended OHAs (n =451)						
No performance	5(3.6)	15(4.8) [NS]	20(4.4)			
Partial performance	17(12.3)	57(18.2)	74(16.4)	6.5±1.5	6.0±2.0**	6.2±1.9
Complete performance	116(84.1)	241(77.0)	357(79.2)			

[1] No performance: self-care activity never performed during the previous week preceding the survey.[2] Partial performance: performed between 1-6 days during the previous week preceding the survey.[3]Complete performance: self-care activity performed every day during the previous week preceding the survey. [NS]: not significant.*< 0.05. **<0.001

Table 5 shows the mean scores of the diabetes self-care standard subscales during the previous week preceding the survey. As stated previously, the majority of patients do not have a healthy eating plan (n=303, 58.6%), thus only 214 patients answered the first two items of the SDSCA. A statistically significant difference was observed between women and men only in terms of the mean number of days of performing exercise and blood sugar testing subscales. The proportions of patients performing the different aspects of diabetes SCA (SDSCA subscales) are presented in Figure 4.

Table 5: Performance of patient self-care activities

Self-care Activities (subscales*)	Mean ± SD (days/week)			P-value
	Sex			
	M	F	Total	
General diet (n=214)	4.8±2.6	4.6±2.7	4.7±2.6	0.501
Specific diet (n=516)	3.3±1.7	3.1±1.7	3.2±1.7	0.159
Exercise (n= 517)	1.3±1.7	1±1.4	1.1±1.5	0.013
Blood sugar testing (n=516)	1.4±2.1	1±1.8	1.1±1.9	0.012
Foot care (n=517)	3.4±2.4	3.7±2.5	3.6±2.5	0.230
Medications adherence (n=502)	6.5±1.5	6.1±1.8	6.3±1.7	0.064

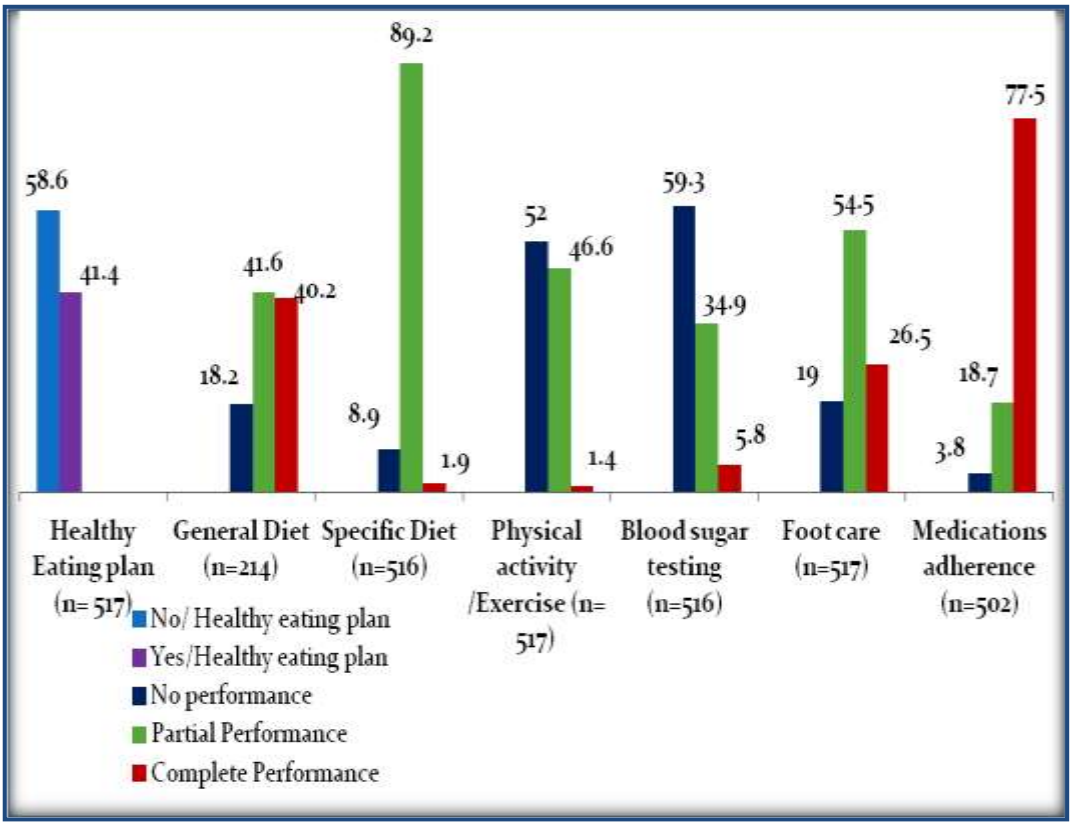

Figure 4: Proportion (%) of T2DM patients in relation to diabetes self-care subscales

In this figure, the partial performance categories (≤50% and >50 % of days per week) were combined. *General Diet category included only who reported having a healthy eating plan.

3.2.5 Diabetes Self-Care Recommendations

The SCR on diet and exercise regimens provided to patients by their healthcare team are summarized in Figures 5 and 6. The proportion of patients who did not receive diet, exercise recommendations were 16.6%, 24.8% respectively.

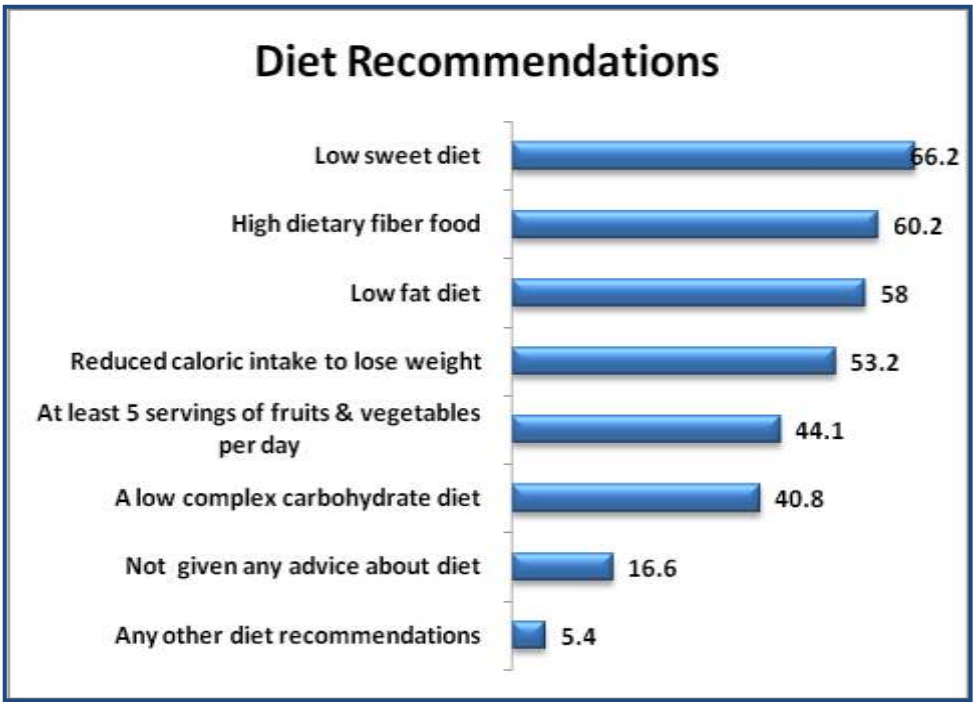

Figure 5: Proportions (%) of T2DM patients reported receiving the following dietary advices by their healthcare team during the last 6 months (N=517)

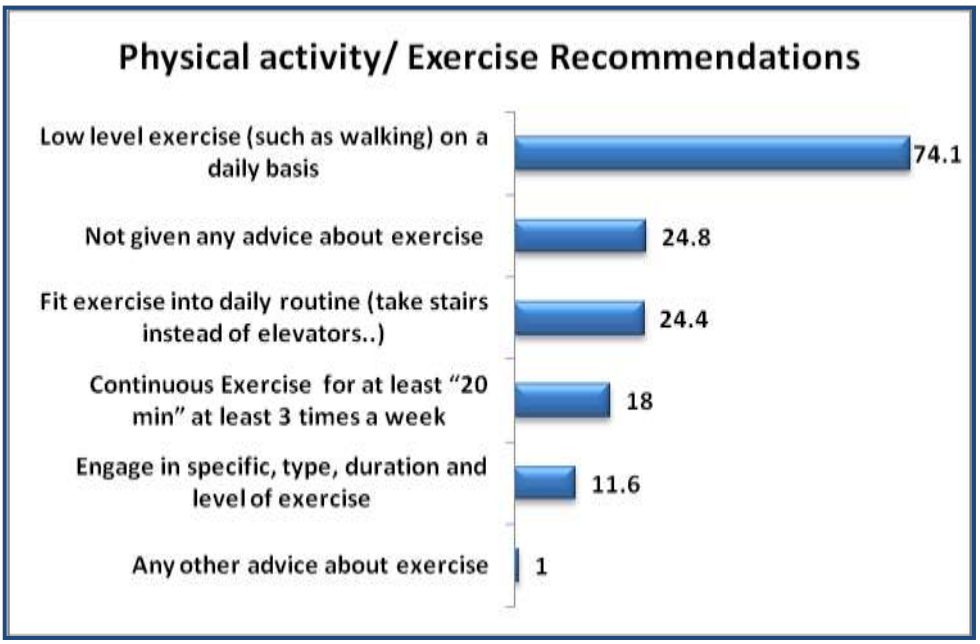

Figure 6: Proportions (%) of T2DM patients reported receiving the following exercise advice by the healthcare team during the previous six months (N=517)

The proportion of patients who reported being advised to self-monitor their blood glucose (test their blood sugar) using the glucometer and being advised to do other tests (urine sugar, other blood tests or examinations) in addition those that received recommendations regarding smoking cessation were presented in Table 6. Only one third of the patients received advice on self-testing blood sugar using the machine. 16.4% received advice on testing urine sugar, while 3.3% of patients reported being advised to perform any other tests. More than half of the patients (59.0%) reported not being given recommendations for testing blood or urine sugar level by their healthcare providers. During the last doctor's visit, less than one quarter of the sample (18.4%) reported being asked about their smoking status. Of smokers, about half of them reported not being advised by their physicians to stop smoking.

Table 6: Proportions (%) of T2DM patients reported receiving self-care recommendations by their healthcare

Self-care recommendations during the last six months	**N(%)**
Advice on blood sugar testing	
Yes, received advice (n=517)	176 (34.0)
Advice on urine sugar testing	
Yes, received advice (n=517)	85 (16.4)
Inquiry about smoking status (n=516)	
Yes, being asked about smoking status during the last doctor's visit	95 (18.4)
Recommendations on smoking cessation (n=63)	
Yes, being counseled about stopping smoking or offered to be referred to a stop-smoking program	32 (50.8)

3.2.6 Physician Inquiry about Patient Self-Care Practices

One of the additional questions of the SDSCA extension assessed whether patients were being asked about their smoking status by their physicians during the last visit. Similar questions were added about eating habits and physical activity by the research team. The majority of patients were not being asked about their smoking status, eating habits and physical activity (81.6%, 78.8% and 71.1%) respectively.

3.2.7 Patient Self-Care Activities & Demographic/Socioeconomic Characteristics

No statistically significant difference was found in age, sex, marital status and STL index of patients who partially (both categories) or fully performed their general or specific diet compared to those who did not perform such behavior.

The age of patient was significantly related to the performance of physical activity/exercise (p=0.016). Patients aged 65 years and older were less likely to exercise compared to those 65 years and older. At the same time, no association was found between other demographic characteristics (i.e. sex, education, STL index, marital status, healthcare sector) and exercise.

Among patient demographic and socioeconomic characteristics, education and STL index (p-value=0.001 and p-value <0.001 respectively) were significantly associated with blood sugar testing. “Illiterate and acquainted” patients were less likely to test blood sugar than patients who had “secondary education certificates

and higher". Patients who attained "elementary" educational level were more likely to partially (≤50% of days/week) test their blood sugar than "illiterate and acquainted" patients. Patients who had a "secondary certificate and higher educational levels" were more likely to completely (seven days/week) test their blood sugar than those with elementary educational level. Patients from the low STL index were less likely to test their blood sugar compared to patients from medium and high STL index. In other words, patients from high STL index were likely to test blood sugar daily compared to patients from medium and low STL index. Moreover, patients that ranked as medium on the STL index were more likely to test blood sugar compared to those from low STL index.

An association was observed between the healthcare sector providing diabetes services and the performance of specific diet among the patients. Patients from the MoH clinics were more likely to follow a specific diet (according to the SDSCA subscale) than patients from the UNRWA clinics, though not statistically significant.

Furthermore, a statistically significant difference was found between blood sugar testing and the healthcare sector providing diabetes services (p-value <0.001). Patients from the MoH clinics were more likely to self-monitor their blood sugar on a daily basis compared to those from UNRWA. However, sex, age and marital status did not show this association with SMBG.

None of the demographic and socioeconomic characteristics; age, sex, education, marital status, STL index and the healthcare sector was significantly related to the performance of foot self-care among patients. All these variables were also not significantly related to patient medication adherence practice.

All demographic/socioeconomic characteristics showed no association with smoking, except when it came to the sex of the participant, where males have higher proportions of smoking than females ($p<0.001$). The association between the demographic, socioeconomic characteristics and patient SCA are presented in Table 7(a), and between SCA and the healthcare sector providing diabetes services are presented in Table 7(b).

Table 7 (a): The association between patient self-management practices and demographic and socioeconomic characteristics

		Proportion (95% Confidence Interval)			
Variable	**Categories**	**Not performed**	**Partially performed (≤50 % of days/week)**	**Partially performed (>50 % of days/week)**	**Completely performed**
		Physical activity/exercise			
Age	<65 years (n=385)	48.3(43.3-53.3)	48.3(43.3-53.3)	2.1(0.7-3.5)	1.3(0.2-2.4)
	≥65years (n=132)	62.9(54.7-71.1)	35.6(27.4-43.8)	0.0(0.0-0.0)	1.5(0.0-3.6)
Education		**Blood sugar testing**			
	Illiterate & acquainted(n=89)	71.9(62.6-81.2)	19.1(10.9-27.3)	4.5(0.2-8.8)	4.5(0.2-8.8)
	Elementary(n=158)	57.6(49.9-65.3)	34.8(27.4-42.2)	5.1(1.7-8.5)	2.5(0.1-4.9)
	Preparatory & secondary(n=177)	61.6(54.4-68.8)	29.9(23.2-36.6)	3.4(0.7-6.1)	5.1(1.9-8.3)
	Secondary certificate & higher(n=90)	44.4(34.1-54.7)	34.4(24.6-44.2)	6.7(1.5-11.9)	14.4(7.2-21.7)
STL index		**Blood sugar testing**			
	Low(n=252)	69.0(63.3-74.7)	25.4(20.0-30.8)	2.4(0.5-4.3)	3.2(1.0-5.4)
	Medium (n=209)	54.1(47.3-60.9)	35.4(28.9-41.9)	5.3(2.3-8.3)	5.3(2.3-8.3)
	High(n=55)	34.5(21.9-47.1)	32.7(20.3-45.1)	12.7(3.9-21.5)	20.0(9.4-30.6)

Table 7 (b): The association between patient self-management practices and the healthcare sector providing diabetes services

		Proportion (95% Confidence Interval)			
	Categories	**Not performed**	**Partially performed** (≤50 % of days/week)	**Partially performed** (> 50 % of days/week)	**Completely performed**
Healthcare sector			**Specific diet**		
	MoH (n= 220)	4.5(1.8-7.2)	60.5(54.0-66.9)	32.7(26.5-38.9)	2.3(0.3-4.3)
	UNRWA (n=243)	12.8(8.6-17.0)	55.6(49.4-61.9)	29.6(23.9-35.3)	2.1(0.3-3.9)
	Joint MoH-NGO (n=53)	9.4(1.5-17.3)	69.8(57.4-82.2)	20.8(9.9-31.7)	0(0.00-0.00)
			Blood sugar testing		
	MoH (n=220)	45(38.4-51.6)	37.3(30.9-43.7)	7.3(3.9-10.7)	10.5(6.5-14.6)
	UNRWA (n= 242)	69.4(63.6-75.2)	26.0(20.5- 31.5)	1.7(0.1-3.3)	2.9(0.8-5.0)
	Joint MoH-NGO (n= 54)	72.2(60.3-84.2)	20.4(9.7-31.2)	7.4(0.4-14.4)	0.0(0.0-0.0)

Specific Diet subscale: composed of two self-care items including eating ≥5 servings of fruits and vegetables per day and not eating high fat food during the previous week preceding the survey.

3.2.8 Provider Self-Care Recommendations (SCR) & Demographic/Socioeconomic Characteristics

None of the demographic and socioeconomic characteristics (age, sex, education, STL index, marital status) of patients were associated significantly with the diet or exercise recommendations provided by the healthcare team.

Though no association was observed between the healthcare sector and the diet recommendations, a significant relation was found between the healthcare sector and exercise recommendations provided by the healthcare team to the patients (p-value<0.001). Patients from the MoH clinics were more likely to receive recommendations on exercise than patients from the UNRWA clinics. However, no difference was found between patients from the MoH clinics and those from joint MoH-NGO clinics. Moreover, no difference was found between patients from UNRWA clinics and joint MoH-NGO clinics.

About half of the patients (50.3%) and 60.9% of patients do not have glucometer and glucometer strips respectively. Regarding provider advice on blood sugar testing using the machine, only patient STL index was significantly associated with blood sugar testing recommendations (p-values <0.001). Patients from the high STL index were more likely to receive advice on blood sugar testing (using the machine) by the healthcare team compared to patients from the low STL index. Moreover, patients from the medium STL index were more likely to receive advice on blood sugar testing than patients from the low STL index.

Only sex was associated with physician inquiry about smoking status during the last visit ($p<0.001$). Males were more likely to be asked by their physicians about their smoking status during the last visit. No association was found between any of the demographic and socioeconomic characteristics and physician recommendations on smoking cessation.

3.2.9 Provider Self-Care Recommendations and Patient Self-Care Activities

Diet and exercise recommendations offered by the diabetes healthcare team did not make a difference in diabetes patient self-care dietary behavior (performing a general or specific diet) or exercise behavior. However, a statistically significant difference was observed between patient adherence to self-monitoring of blood glucose ($p<0.001$), and physician recommendations for testing blood sugar using the machine.

3.3 Glycemic control and the Study Variables

3.3.1 Glycemic Control and Self-Care Activities

Cross-tabulation of glycemic control (main dependent variable) and the different aspects of SCA (general diet, specific diet, exercise/physical activity, blood sugar testing, medication adherence, foot care and smoking) showed no statistically significant association between these variables. The proportion of patients and the mean HbA1c level with each category of the seven aforementioned aspects as presented in Table 8.

Table 8: The relation between glycemic control/ HbA1c and patient self-care activities (subscales)

Self-care Activities	Category	Good glycemic control	Mean ±SD HbA1c
		Proportion (95% Confidence Interval)	
General diet(495)	Have no healthy eating plan (n=290)	18.6 (14.1-23.1) [NS]	9.2±2.2 [NS]
	Never performed[1] (n=39)	17.9(5.9-29.9)	8.5±2.3
	Partially performed≤ 50 % of days[2] (n=27)	29.6(12.4-46.8)	8.4±1.8
	Partially performed>50% of days[3] (n=59)	20.3(10.0-30.6)	8.6±1.8
	Performed every day[4] (n=80)	21.3(12.3-30.3)	8.8±2.1
Specific diet(N=494)	Never performed (n=45)	24.4(11.9-36.9) [NS]	9.0±2.2 [NS]
	Partially performed≤ 50 % of days (n=294)	18(13.6-22.4)	8.7±1.9
	Partially performed>50% of days (n=146)	21.2(14.6-27.8)	8.7±2.1
	Performed every day(n=9)*	33.3(2.5-64.1)	8.4±1.9
Exercise/physical activity(N= 495)	Never performed (n=261)	17.6(12.9-22.2) [NS]	8.9±2.1 [NS]
	Partially performed≤ 50 % of days (n=220)	22.7(17.2-28.2)	8.6±1.9
	Partially performed >50% of days (n=7)*	0.0(0.0-0.0)	9.2±1.3
	Performed every day(n=7)*	28.6(0-62.1)	8.7±1.9
Blood sugar testing (N= 494)	Never performed (n= 297)	20.5(15.9-25.1) [NS]	8.7±2.1 [NS]
	Partially performed≤ 50 % of days (n= 148)	21.6(14.9-28.2)	8.8±2.0
	Partially performed>50% of days (n= 22)*	9.1(0.0-21.1)	8.7±1.4
	Performed every day(n=27)*	7.4(0.0-17.3)	8.6±1.7
Medication adherence (N=480)	Never performed (n=18)	33.3(11.5-55.1) [NS]	8.8±2.8 [NS]
	Partially performed≤ 50 % of days (n=28)*	14.3(1.3-27.3)	8.7±2.2
	Partially performed>50% of days (n=62)	12.9(4.6-21.2)	9.4±2.2
	Performed every day (n=372)	19.6(15.6-23.6)	8.7±1.9
Foot care(N= 495)	Never performed (n=93)	20.4(12.2-28.6) [NS]	8.8±2.1 [NS]
	Partially performed ≤ 50 % of days (n=224)	19.2(14.0-24.4)	8.7±1.9
	Partially performed >50% of days (n=47)	17(6.3-27.7)	8.7±2.3
	Performed every day(n=131)	21.4(14.4-28.4)	8.8±2.0
Smoking status(N=495)	No (n=434)	19.4(15.7-23.1) [NS]	8.7±1.9 [NS]
	Yes, smoking at least one puff/week (n=61)	23(12.4-33.6)	8.8±2.3

[1]Never performed: self-care activity is not performed (0 days) during the previous week preceding the survey. [2]Partially performed ≤50 % of days: self-care activity is performed from 0.5–3.5 days during the previous week preceding the survey. [3]Partially performed >50% of days: self-care activity is performed from 4-6.5 days during the previous week preceding the survey. [4] Performed every day: self-care activity is performed daily (7 days) during the previous week preceding the survey. P-value for X^2 test, ANOVA or independent-test (smoking) was not significant [NS].*Please interpret cautiously as n was less than 5 cases which may affect the precision of CI values.

3.3.2 Glycemic Control and Self-Care Recommendations

Table 9 shows no statistically significant association between patients who received diet, exercise and smoking cessation recommendations and those who did not receive these recommendations in terms of glycemic control. However, receiving advice to test blood sugar using the machine was significantly associated (p-value =0.003) with good glycemic control. On the other hand, receiving advice to test urine sugar showed no statistically significant association (p-value =0.498) with glycemic control.

Table 9: The association between glycemic control/HbA1c and provider self-care recommendations

Self-care Recommendations	Good glycemic control Proportion (95% Confidence Interval)	Mean ±SD HbA1c (%)
Diet recommendations (N=495)		
Received no advice (n=83)	22.9(13.9-31.9) [NS]	8.5±2.0 [NS]
Received advice (n=412)	19.2(15.4-23.0)	8.8±2.0
Exercise recommendations (N=495)		
Received no advice (n=122)	22.1(14.7-29.5) [NS]	8.9±2.2 [NS]
Received advice (n=373)	19.0(15.0-22.9)	8.7±1.9
Advice to test blood sugar using the machine		
Received no advice (n=327)	23.5(18.9-28.1)*	8.7±2.1 [NS]
Received advice (n=168)	12.5(7.5-17.5)	8.8±1.8
Advice to test urine sugar		
Received no advice (n=413)	20.3(16.4-24.2) [NS]	8.7±2.0 [NS]
Received advice (n=82)	17.1(8.9-25.3)	8.9±1.9
Smoking cessation recommendations (N=63)		
Received no advice (n=28)	32.1(14.8-49.4) [NS]	8.4±2.2 [NS]
Received advice (n= 29)	17.2(3.5-30.9)	9.3± 2.4

*P-value for the chi-square test (x^2) < 0.05. [NS]

3.3.3 Glycemic Control and Physicians Inquiry about Patient Self-Care Practices

Physicians inquiry about patient eating habits during their last doctor's visit was associated with achieving good glycemic control (p=0.003). However, no statistically significant association was observed between glycemic control and physician inquiry about patient physical activity or smoking status as illustrated below in Table 10.

Table 10: The association between glycemic control/HbA1c and physician inquiry about patient self-care practices

Variable	Good glycemic control Proportion (Confidence Interval %)	Mean ±SD HbA1c (%)
Smoking status (N= 494)		
Not being asked(n=403)	18.4(14.6-22.2) [NS]	8.8± 2.0 [NS]
Being asked (n= 91)	26.4(17.3-35.5)	8.6±2.1
Eating habits (N=493)		
Not being asked (n=388)	22.7(18.5-26.9)*	8.7±2.0 [NS]
Being asked (n= 105)	9.5(3.9-15.1)	9.0±1.9
Physical activity (N=494)		
Not being asked (n=349)	21.5(17.2-25.8) [NS]	8.7±2.0 [NS]
Being asked (n= 145)	15.9(9.9-21.9)	8.8±2.0

*P-value < 0.05. [NS] not significant

3.3.4 Glycemic Control and Demographic/Socioeconomic Characteristics

None of the demographic and socioeconomic factors of the study participants was significantly associated with glycemic control as displayed in Table 11.

Table 11: The association between glycemic control/HbA1c and patient demographic/socioeconomic characteristics

Variable	Category	Good glycemic control	Mean ± SD HbA1c
		Proportion (95% Confidence Interval)	
Sex (N=495)	Male (n=154)	17.5(11.5-23.5) [NS]	8.9±2.0 [NS]
	Female (n=341)	20.8(16.5-25.1)	8.7± 2.0
Age(N=495)	< 65 years (n= 375)	19.7(15.7-23.7) [NS]	8.8±2.0 [NS]
	≥ 65 years (n=120)	20(12.8-27.2)	8.6± 1.9
Marital status (N= 495)	Never married &other (n= 114)	17.5(10.5-24.5) [NS]	9.1±2.2*
	Married (n=381)	20.5(16.5-24.6)	8.7±1.9
Education (N=493)	Illiterate & acquainted (n=82)	20.7(11.9-29.5) [NS]	8.7±2.1 [NS]
	Elementary (n=153)	18.3(12.2-24.4)	8.8±2.0
	Preparatory & secondary (n= 171)	19.3(13.4-25.2)	8.7±2.0
	Secondary certificate & higher (n=87)	21.8(13.1-30.5)	8.7±1.9
STL index(N=495)	Low STL index (n=243)	19.3(14.4-24.3) [NS]	8.6±1.8 [NS]
	Middle STL index (n=199)	21.1(15.4-26.8)	8.8±2.2
	High STL index (n=53)	17(6.9-27.1)	9.2±2.0
Locale(N=495)	Urban (n=244)	20.5(15.4-25.6) [NS]	8.5±1.8*
	Rural (n=151)	17.9(11.8-24.0)	8.9±2.1
	Camp (n= 100)	21(13.0-30.0)	9.1±2.3
Refugee status (N= 495)	Refugee (n=283)	22.3(17.5-27.2) [NS]	8.7±2.1 [NS]
	Non Refugee (n=212)	16.5(11.5-21.5)	8.9±1.9
Healthcare sector(N=495)	MOH (n=206)	18.4(13.1-23.7) [NS]	8.6±1.8 [NS]
	Joint MOH NGO (n=236)	22.9(17.5-28.3)	8.8±2.2
	UNRWA (n=53)	11.3(2.8-19.8)	9.2±2.0

**p-value <0.001, * <0.01, [NS] not significant

3.3.5 Glycemic Control and Disease-Related Characteristics

The cross-tabulation of glycemic control and the duration since diagnosis with T2DM showed that there is a statistically significant association between glycemic control and duration of diabetes (≤7 years vs. >7 years). Glycemic control was associated with the particular type of diabetes treatment. The proportion of patients on insulin or combined insulin and OHA who had poor glycemic control was higher than those on OHAs or on no drugs. Glycemic control was associated with "feeling capable of dealing with diabetes". The proportion of patients and the mean HbA1c within each category of the selected diabetes-related characteristics are presented in Table 12.

Table 12: The association between glycemic control/HbA1c and disease-related characteristics

Variable	Category	Good glycemic control	Mean ±SD HbA1c (%)
		Proportion (95% Confidence Interval)	
Duration of diabetes (N=495)	≤7years (n= 246)	28.9(23.2-34.6)**	8.2±1.9**
	>7 years (n=249)	10.8(6.9-14.7)	9.3±1.9
Obesity (N=488)	Non obese (n=180)	18.3(12.7-24.0) NS	8.9±2.1 NS
	Obese (n=308)	20.8(16.3-25.3)	8.6±1.9
Type of diabetes treatment (N=495)	insulin only (n=46)	6.5(0.0-13.6)**	9.9±2.1**
	Oral hypoglycemic agents only (n=289)	27.7(22.5-32.9)	8.3±1.9
	Combined “insulin &OHAs” (n=149)	5.4(1.8-9.0)	9.5±1.8
	No medications (n=11)	63.6(35.2-92.0)	6.6± 0.9
Perceived capability of dealing with diabetes(N=493)	Yes, in an excellent / good way (n=385)	22.3(18.1-26.5)*	8.6±2.0*
	to a lesser extent or not at all (n=108)	11.1(5.2-17.0)	9.2±2.0
Diabetes knowledge (N=493)	Yes, excellent/ good information (n=392)	18.6(14.8-22.5) NS	8.7± 1.9 NS
	Little or no information (n=392)	23.8(15.5-32.1)	8.9±2.2

**p-value <0.001, * <0.01, NS not significant

3.3.6 Logistic Regression Model

Univariate Logistic regression (LR)

In the univariate logistic regression, none of the demographic and socioeconomic characteristics of the participants was found to be a statistically significant predictor of glycemic control. However, duration of diabetes, type of diabetes treatment and patient assessment of diabetes self-management (perceived capability of dealing with diabetes) were statistically significant predictors of glycemic control. In addition, none of the diabetes self-care subscales (general diet, specific diet, exercise/physical activity, blood sugar testing [BST], foot care, medication adherence and smoking) were a significant predictor of glycemic control. Only one of the self-care recommendations provided to patients by their healthcare team (advice about BST using the machine) was significantly associated with glycemic control. Among the items related to physician inquiry about patient self-care practices during the last visit, "being asked about eating habits" was the only statistically significant predictor of glycemic control.

Multiple Logistic Regression Model

All statistically significant predictors of glycemic control from the study variables in the univariate LR were included in the logistic regression model to investigate their associations with glycemic control. Sex and age were entered in the regression model in addition to the previously significant variables.

Table 13 shows the unadjusted and adjusted odds ratios for the development of glycemic control (reference “good glycemic control”). Both the unadjusted and the age-sex adjusted model showed that predictors of glycemic control were duration of diabetes, type of diabetes treatment, and perceived capability of dealing with diabetes and physician inquiry about patient eating habits. This data shows that there was no significant confounding effect of sex and age on glycemic control in the adjusted model.

From the adjusted model, patients who reported having T2DM for 7 years or less have higher odds (more likely) of being "controlled" compared to those reported having T2DM for more than 7 years (OR=2.006, 1.126-3.575). The regression model also showed that the type of diabetes treatment is associated with glycemic control. Patients who reported being prescribed OHAs only have higher odds (more likely, but barely significant) of being "controlled" compared to those prescribed insulin only (OR= 3.489, 0.989-12.307). Patients who reported being prescribed OHAs have higher odds (more likely) of being "controlled" compared to those prescribed combined "insulin and OHAs" (OR= 4.196, 1.853-9.498). Patients who reported being prescribed OHAs have lower odds (less likely) of being controlled compared to those not prescribed medications for diabetes (OR= 0.187, 0.045-0.769). Patients who reported feeling capable of dealing with diabetes in terms of diet, physical activity and medications in an excellent or good way have higher odds (more likely) of being controlled compared to those feeling less capable or not capable at all (OR=2.436, 1.220-4.866). The regression model also demonstrated that patients who reported not being asked about their eating

habits during the last doctor's visit have higher odds (more likely) of being controlled compared to those being asked about their eating habits during the last doctor's visit (OR= 2.615; 1.235-5.536). In this analysis, healthcare team advice about use of self-monitoring of blood glucose was not a significant predictor of glycemic control in the presence of other predictors. The five independent variables in the adjusted logistic regression model together account for 20% of why a T2DM patient may has controlled glycemic status or not.

Table 13: Unadjusted and adjusted logistic regression model for glycemic control.

Predictor	Unadjusted OR	95 % CI	P-value	Adjusted OR	95 % CI	P-value
Duration of diabetes						
≤7years *	1			1		
>7years	1.914	1.091-3.358	0.024	2.006	1.126-3.575	0.018
Type of diabetes treatment						
OHAs only*	1			1		
insulin only	3.637	1.042-12.688	0.043	3.489	0.989-12.307	0.052
Combined “Insulin &OHAs”	4.349	1.930-9.801	<0.001	4.196	1.853- 9.498	0.001
No medications	0.190	0.046-0.781	0.021	0.187	0.045-0.769	0.020
Perceived capability of dealing with diabetes						
Yes, in an excellent or good way*	1			1		
Yes, to a lesser degree / no, not at all	2.455	1.229-4.904	0.011	2.436	1.220-4.866	0.012
Advice about testing blood sugar using the machine						
No*	1			1		
Yes	1.189	0.668-2.117	0.556	1.198	0.672-2.134	0.541
Physician’s inquiry about eating habits during the last visit						
No*	1			1		
Yes	2.597	1.227-5.496	0.013	2.615	1.235-5.536	0.012

Odds ratio, 95% Confidence Intervals (CIs), and probability values for predictors of glycemic control in the type 2 diabetes mellitus patients. Columns 2 through 4 present results from the unadjusted model; columns 5 through 7 show results from the age and sex adjusted model. Glycemic control (dummy variable: 0=controlled glycemic status (reference), 1= uncontrolled glycemic status; other predictors: category*: reference group.

CHAPTER 4

DISCUSSION

In this part, I will start with discussing the methodological section, and then I will focus on the findings of this study in reference to the proposed research questions. My participation as a fieldworker for the primary survey facilitated my interpretation of the study findings as I was involved with many issues raised by the patients during the data collection process. Further discussion will elaborate on implications for the practice of healthcare providers in terms of health education recommendations for future research in diabetes management among T2DM patients in the Ramallah governorate and other governorates of Palestine.

4.1 Methodological Discussion

To the best of my knowledge, this is the first study which used a standardized instrument (SDSCA) to assess the level of diabetes self-management in Palestinian patients with T2DM in the Ramallah governorate, though the cultural differences which might have an effect on the self-care behavior between Palestinians living in different governorates were not addressed. The topic of self-management was, however, previously studied by Al-Sabbah for her 2000 Master's thesis to assess diabetes self-management in a rural community **[42]**.

The current study used the Arabic translated version of the SDSCA scale [SDSCA (Ar)] that was provided by a PhD study, which translated the English version of the SDSCA into Arabic to be used in the Saudi Arabian population. Since this

available translation provided reliable and valid results for the first 10 core items of the SDSCA (first section of the SDSCA measure), it was a good decision to use this instrument in the Arab Palestinian population, given that this instrument was tried previously in the Lebanese, Jordanian, and Saudi Arabian populations. Moreover, comparing the results of our study with international and regional studies is also of great importance for research purposes and implementation of policy decisions in different settings. Though this Arabic translation does not provide a validation to the SDSCA extension (second section) that addressed diabetes provider SCR as well as patient medications adherence, the full scale (first and second sections of the instrument) was used in the current study because of the importance of these aspects in diabetes management. This is similar to other studies which used these items for the same purpose.

The use of this instrument in research and clinical practice can be of great benefit for patients and clinicians as well as for policymakers to support problem solving, informed decision making and active collaboration with the healthcare team in order to improve the disease's clinical outcomes, patient health status and quality of life **[39]**. Moreover, it would be helpful for researchers to generalize their study results on the target population and to allow comparison, as the SDSCA can be generalized to different diabetes subpopulations; including insulin status, sex, number of co-morbid conditions and diabetes duration **[40]**.

The Ramallah governorate is a highly urbanized area compared to other governorates in Palestine. The main reason behind selecting this area and

population was to build on previous studies on the topic of DM that were carried out either in urban or rural communities of Ramallah (these studies were reviewed earlier in Chapter 1). This study will enhance understanding of the situation in this governorate. The current study cannot be generalized to all West Bank governorates although they share same service providers. Further studies including the North and South region of the West Bank are needed as the socioeconomic status and other factors such as access to services may differ between governorates.

The design of the current study used a clinic-based survey, where T2DM patients with severe conditions and complications (such as amputations, etc) who can't access these clinics were not included. This would possibly lead to underestimating the real problem and may not reflect the exact situation among the Palestinian patients. However, for sample selection and sampling framework considerations, the methodology utilized by this study is suitable and accepted in research.

The recruitment of participants for the current study was limited to the main primary healthcare clinics (n=11) operated by the MoH, jointly by the MoH and NGOs and by UNRWA which provides care for DM patients in the Ramallah governorate. The exclusion of patients from the other clinics operated by the previous healthcare sectors, as well as patients from the private clinics, limited the generalizability of this study. Given that the majority of DM patients receive

diabetes treatment mainly in the clinics of the following sectors (MoH, UNRWA and joint MoH-NGO), a small fraction of patients can afford treatment in the private sector (these may be from the high STL index which reflects the minority). The selection of clinics with high patient loads was due to issues of the budget and timeframe allocated for the completion of the current study, rather than issues related to the study design.

The sampling detailed in the methodology chapter was based mainly on two approaches. In some clinics, patients were approached while they were waiting to be seen by their doctor and were invited to participate in the study. However, in other clinics a combination of methods was used because there was not enough of a patient load due to lack of lab equipment, tests and medicines at that time, mainly in the Palestinian MoH primary healthcare clinics. Therefore, the nurse prepared a list of the T2DM patients and these were contacted by phone and invited to participate. The response rate for the participation was 83.8%, an acceptable rate with a good percentage with no non-response bias.

All non-respondents had low SLT index, while approximately half of the respondents had the same socioeconomic level. This may be possibly due to issues related to the time needed for participation rather than to their socioeconomic level itself. Many of the patients reported leaving work for one to two hours to visit the physician, and they wanted to go back to work and did not have enough time to participate.

4.2 Discussion of Study Findings

The main purpose of the current study was to assess the level of glycemic control, and the level of diabetes self-management including patient SCA and provider SCR, as well as to examine the significance of these SCA and the SCR on glycemic control in Palestinian T2DM patients. The study findings indicated that only one fifth (19.8%) of the participants had controlled HbA1c levels, suggesting low level of glycemic control (HbA1c<7%), similar to what was reported in a study of diabetes control in three villages of Palestine **[164]**. Our results were also similar to those of a recent unpublished (2012) clinic audit conducted in the UNRWA health clinics (22.8%, n=400 patients) in Palestine, and very close to the result of a study submitted for a Master's degree (22.6%, n=420 patients) among Palestinian adults with T2DM in 2009 **[71]**.

The finding of a high prevalence of poor glycemic control among Palestinian T2DM patients was also similar or worse compared to the results found in other Arab countries. The prevalence of poor glycemic control (HbA1c ≥7%) in Jordanian DM patients was 56.5% **[60]**. In Kuwait, HbA1c levels were above 8% in 66.7% of the population **[65].** In Saudi Arabia, a study in 2001 indicated that only 27.0% of DM patients achieved the target level of HbA1c **[66]**. A most recent study also confirmed this finding in Saudi Arabia, showing that 30.0% of T2DM patients had controlled HbA1c levels **[67]**.

Our finding on the prevalence of glycemic control was also compatible with international studies of T2DM patients. This major study finding was consistent with the finding of the ADA study that less than half of patients with T2DM achieve ideal glycemic control (HbA1c<7%) **[165]**. The prevalence of poor glycemic control (HbA1c≥7%) among Mexican-American T2DM patients was 65.1% **[62]**. Around half of Pakistani patients (46.7%) had HbA1c levels higher than 7.5% **[64]**.

As discussed below glycemic control might be affected by the self-care behavior of patients with T2DM. However, other possible obstacles might affect the HbA1c levels such as obesity, the presence of co-morbidities among other issues and low levels of health education provided to diabetics, as was also suggested by the UNRWA's clinical audit recently **[73]**, in addition to availability of and adherence to medications. Further prospective (longitudinal) research examining other possible predictors of glycemic control (such as presence of complications etc) may be needed to examine these associations over time.

Another major finding of this study was that patients reported suboptimal levels of self-care activities/practices for most of the components of diabetes regimen (discussed below). This finding was similar to a study of Jordanian T2DM patients, in which the majority of patients had suboptimal self-management behavior **[60]**.

Of the 517 patients in the current study, 303 DM patients (58.6%) did not have a healthy eating plan. Among the remaining 214 patients who reported having a healthy eating plan, the mean number of days of performing this plan was 4.7±2.7, and 46.3% of patients adhere to their healthy eating plan on a daily basis, while 34.5% of patients adhere partially between 1-6 days per week. 19.2% did not adhere at all. Though the political situation in Palestine during the period of fieldwork of the current study was better than the previous years, this finding of the current study was similar to a previous finding regarding Palestinians during a crisis condition **[147]**, which also showed no difference between women and men in terms of following the healthy eating plan when dealing with diabetes. The lack of a healthy eating plan and the low level of performance for such a plan, if available, among the majority of DM patients might be due to the low level of patient education, or due to patient unawareness of diet self-care in diabetes management. Moreover, this might be due to the negative perceptions of patients regarding healthy dietary regimens or due to psychological issues such as depression, which is often associated with eating disorders. However, this may be also attributed to economic barriers, since 48.9% of the patients were from the low STL index. Still, however, these patients might be unable to afford healthy food due to financial constraints as well as other possible barriers such as social and cultural considerations, which might affect the dietary practices of these patients which were not addressed by the current study. All the aforementioned possible barriers were reported by a previous study conducted in Palestine examining the inter-linkage between diabetes health education and patient self-

management practices. This study used qualitative methods, including two focus group discussions and interviews with 152 DM patients (35-65 years) in different diabetes clinics in the Ramallah and Al-Bireh governorates (Al-Bireh governmental clinic and Al-Amari UNRWA clinic) to better understand the situation **[166]**. It demonstrated that some patients were more familiar with a healthy diet than others, and that the main barriers to a proper diet were not being able to afford healthy food and patient perceptions that eating the right food for diabetes requires buying special expensive food (such as special bread, saccharine). Others had difficulty changing their diet (moving away from delicious food), shyness to tell others that they have diabetes, and depression **[166]**.

The items of the specific diet (fruits and vegetables and fat food) subscale demonstrated that there is a statistically significant difference between women and men in terms of eating ≥5 servings of fruits and vegetables/per day, with a mean number of days of 3.4±2.8 in men compared to 2.9±2.8 in women, while no difference between them was observed in terms of not eating high fat food. Moreover, only 30.5% of males and 23.2% of females ate ≥5 servings of fruits and vegetables per day. The STEPS (West Bank) survey demonstrated that 80.3% of males and 81.0% of females ate less than five servings of fruits and/or vegetables on average per day in a typical week. This means that our finding was consistent with the STEPS result as males (19.7%) have higher percentages than females (19.0%).

The current study also indicated low levels of physical activity/exercise (1.9±2.6 days/week) among T2DM patients in this sample. During the week preceding the survey, only 15.1% of patients participated in at least thirty minutes of physical activity (such as walking) on a daily basis, with a higher proportion of men (22.9%) compared to women (11.4%, p=<0.001). The majority of patients (93.6%) did not participate in specific exercise sessions (such as swimming) during the previous week preceding the survey. One possible explanation is that around one quarter (25.2%) of the sample was classified as elderly (≥65 years), and might have impaired body functions or other co-morbidities that resulted in low levels of physical activity practices. In addition, the collection of data started at winter, therefore the low levels also might be due to the cold weather and the difficulty of engagement in specific exercise activities during this time of the year. In the previously mentioned study, the analysis of the interviews with Palestinian diabetes patients revealed that walking is the most performed type of exercise, as it is only possible to practice and does not place an economic burden on the patients like other types of exercise (such as attending exercise sessions). In addition, other types/habits of exercise (such as jogging) were not well accepted by people in the Palestinian context especially for women **[166]**. This was also similar to what was reported by a previous Palestinian study in which walking was the most common type of physical activity, and men had higher proportion of performing physical activity/exercise than women **[147]**. Regarding the low levels of exercise, this finding was consistent with other regional studies in Lebanon and Jordan (reviewed earlier in Chapter 1). One possible explanation offered by these

studies was that exercise was recommended without providing clear instructions on the characteristics such as type of exercise, duration and frequency. Also providers were not following up with patient practices and documenting their exercise behavior. Moreover, patients may have difficulty reporting skill deficiency in contrast to non-adherence to a specific diabetes regimen **[45]**.

Our study found that more than half of the patients (59.5%) did not test their blood sugar, with a mean number of days of (1.2±2.0 days/week) during the previous week preceding the survey, indicating a significant difference between women and men ($P<0.05$). The majority of the respondents were not given the necessary recommendations by their physicians for testing blood sugar (n=361, 69.8%); which may possibly contribute to the low performance level of such self-care behavior among T2DM patients. Still, however, among those who were given recommendations by their physicians, the proportion of patients who daily tested their blood sugar was extremely low (9.0%). This can be partially explained by the finding that 50.3% and 60.9% of patients do not have glucometer and glucometer strips respectively. Other possible explanations might be due to financial limitations and/or due to the lack of patient's education on how to perform this self-test. Additionally, as shown by this study, the majority did not receive recommendations for testing blood glucose by the physician or the healthcare team. The low levels of blood sugar testing among these T2DM patients might be attributed to all issues mentioned previously. This was compatible with Jilleh's finding that most patients did not have glucometer.

According to Jilleh's study, one of the patients reported that: "*I do not have a blood check machine, it is expensive, and the sticks are also expensive, so sometimes when I visit my friend, she checks my blood with her machine."* Jilleh's study also demonstrated that patients usually test their blood glucose once a month when they come to the clinic **[166]**. This is similar to what patients told us during the data collection process of the current study. Another study conducted after the second Palestinian Intifada and during the incursions period, demonstrated that the reason for patient non-performance of self-monitoring of blood glucose "though some of them have glucometer" is due to the unavailability of glucometer strips, an expired glucometer, lack of knowledge on how to use this machine and not being able to afford the strips since prices were expensive and not being covered by any health insurance in the West Bank **[147]**.

Our study indicated that the most frequently performed self-care activity was medication adherence, adherence to recommended insulin (6.4±1.6 days/week) and adherence to recommended oral hypoglycemic agents (6.2± 1.9 days/week). The mean number of days of adherence to OHAs was higher among men compared to women ($p<0.001$). Our finding was compatible to that reported by the literature in which patient adherence to medication use was higher than for lifestyle change **[167]**. The mean number of days of medication adherence among patients of this study was very close to a study among Jordanian T2DM patients (adherence to insulin was 6.01±1.8 days/week and adherence to OHAs was 6.11±1.8 days/ week) **[60]**.

One possible explanation of finding such a high medication adherence among the patients is that the Palestinian healthcare system adopts a biomedical model rather than a more comprehensive approach in disease prevention and management and physicians emphasize taking the recommended medications more than other self-care activities/practices. Even if physicians provided the necessary self-care recommendations to their patients, patients themselves might ignore the importance of self-care in the management of chronic diseases such as DM, as a result of the lack of cultural awareness through comprehensive health education programs.

Though medication adherence was high among patients, the shortage of medical supplies (including drugs, needles and disposables), was one of the problems facing patients visiting the governmental clinics during the fieldwork. This was partially due to the financial crisis facing the Palestinian National Authority in general and the Ministry of Health (MoH) specifically during the crisis conditions and afterwards **[147]**. Similar problems related to political and financial crises were also suggested in Jilleh's study (as the fieldwork of her study started in 2001).

This study showed that 79.2% of the study participants fully adhere (seven days/week) to the recommended OHAs. However, a cross-sectional study (n=131 patients) examining the adherence to oral hypoglycemic medications (using the Morisky Medication Adherence Scale) among diabetic patients in Nablus (another

Palestinian governorate) demonstrated that 38.5% had a high adherence, (44.6%) had a medium adherence and (16.9%) had a low adherence rate. This study suggested improving patient treatment satisfaction to improve medications adherence **[168]**.

Other aspects of diabetes self-care (foot care and smoking) that were addressed by the current study demonstrated that the majority (61.6%) of patients reported checking the feet on a daily basis (with a mean number of days of (4.7±3.1) per week. According to what was reported by the patients, this self-care activity was performed in parallel with a religious practice of washing hands and feet called *wado*, before starting Islamic prayers.

We found that some of the SCA subscales were related to STL index, education, and age as shown in the previous chapter. Patients aged 65 years and older were less likely to exercise compared to those 65 years and younger. This may be partially explained because younger patients may have better general health, and less co-morbidity compared to elderly patients. We also found that less educated patients were less likely to test blood sugar than patients who had higher educational levels. Highly educated patients may have better access to health education materials (books, internet, etc), and be more well informed about their disease. This may be also attributed to the better socioeconomic status of some patients (STL index), since the glucometer device and the strips are expensive and not all patients can afford them. Moreover, patients from the low STL index were

less likely to test their blood sugar compared to patients from medium and high STL index. This may be due to the high cost of the materials (glucometer and strips) needed to perform this self-test as mentioned above.

We also found that patients from the MoH clinics were more likely to self-monitor their blood sugar on a daily basis compared to those from UNRWA. Regarding provider SCR, patients from the MoH clinics were more likely to receive recommendations on exercise than patients from the UNRWA clinics. A possible explanation is that overcrowding in the UNRWA clinics might lead to short consultation time. Patients from the high STL index were more likely to receive advice on blood sugar testing (using the machine) by the healthcare team compared to patients from the low STL index. One possible explanation is that physicians limited the advice of self-monitoring of blood glucose (using the machine) to patients of high socioeconomic status (higher STL index) who can afford the expensive machine and strips.

Males were more likely to be asked about smoking status during the last doctor visit. This is possibly because physicians expect that smoking is more common among males in our society, as was found in the current study. However, males did not differ from females in receiving smoking cessation recommendations.

Most importantly, a major study finding indicated that glycemic control was not associated with any of the patient SCA (general diet, specific diet, exercise, blood sugar testing, foot care, smoking and medications adherence). Moreover,

comparing the means of HbA1c between the categories of self-care subscales indicated no significant difference. These findings were similar to what was found in the Lebanese T2DM patients (with the exception of the specific diet subscale) **[45]**. However, these findings were different from those reported in Jordan in which non-adherence to diabetes self-care management behavior was associated with poor glycemic control **[69]**. In addition, this finding was in contrast to another Jordanian study, which reported that diet self-management was among the most statistically significant predictors of good glycemic control **[60]**. Despite that Jordanians and Palestinians might have similar dietary practices and be expected to have similar results, other unknown factors may contribute to this finding.

The lack of an association between glycemic control and patient SCA must be addressed carefully. One possible explanation is that these SCA were independent of each other since diabetes regimens are multidimensional and adherence to one component of a regimen may be unrelated to adherence in other aspects of a regimen,**[167]**. Moreover, each self-care behavior requires specific knowledge, skills and patient education by the healthcare team. In addition, patient perception of the importance of performing these different aspects of diabetes self-care activities is also considered a critical issue **[60]**. Moreover, as reported by Clarke, Snyder and Nowacek in 1985, HbA1c levels do not necessarily presume whether the patient is adherent or not **[169]** and HbA1c levels might often be a poor indicator of patient behavior **[45, 170]**. Our finding was consistent with a Lebanese study **[45].** Other factors such as the duration since diagnosis with

diabetes might affect the glycemic status. Adherence to diabetes self-management practices is one important contributor to achieving a good glycemic control. However, adherence/performance of these activities does not necessarily reflect glycemic control, since it cannot be evaluated by just looking at the lab results, given that many other factors may contribute to control such as inadequate prescriptions, incompatible self-management actions, co-morbid conditions, timing of the HbA1c measure, inappropriate dosing, idiosyncratic factors, among many others **[45, 170]**.

Furthermore, in terms of SCR offered to patients by the healthcare team, this study revealed that a number of patients did not receive any advice about diabetes self-care practices, diet, exercise, blood sugar testing and smoking cessation. One out of every six patients were not given any advice from the healthcare team (doctors, nurses, dietitians, diabetes educators) about diet regimen, while approximately one out of every four patients were not given any advice about an exercise regimen. Only 34% of patients were advised to test their blood sugar using the machine (glucometer), while 16.4% were advised to test urine sugar. Few patients (3.3%) were advised to perform other tests. More than half of the patients were not given any advice to test blood or urine sugar level. Among smokers, half of patients (50.8%) did not receive counseling about smoking cessation. Although these study findings were self reported and patients might have recall difficulties, they indicated that not all patients were offered adequate diabetes care or sufficient education by their healthcare providers. A possible explanation of this finding is due to the high patient loads at these clinics, and the

physician might not have enough time to give patients the needed health education. Even if the doctors provided the diabetics with the necessary information and education to practice diabetes self-care activities, they did not ensure that patients were following their recommendations through continuous monitoring and follow up of patients. This finding on the low level of health education among diabetics was similar to what was found by the UNRWA **[73]**, and similar to a previous Palestinian study **[166]**. On the other hand, the literature reported that the diabetes program of the PMRS as a community based quality improvement intervention, including different techniques (such as attending health education sessions, patient support groups, regular medical visits and laboratory tests) resulted in an improvement in diabetes control in three Palestinian villages (Abud, Singil and Ithna) **[164]**. This study also demonstrated that the degree of patient participation in this intervention was correlated with improvement in their disease control. Therefore, there is a need to focus on health education among T2DM patients in order to improve the control of diabetes **[164]**.

Our study found that diet and physical activity/exercise recommendations offered by their healthcare team were not significantly associated with patient performance of general diet, specific diet and physical activity/exercise. Provider advice on blood sugar testing was associated with patient performance of BST self-care activity ($p<0.001$). Provider recommendations regarding physical activity/exercise were related to the healthcare sector ($p<0.001$). Patients from the MoH clinics were more likely to receive recommendations on exercise. Moreover,

recommendations regarding blood sugar testing were related to the patient's STL index ($p<0.001$). Patients from the high STL index were more likely to receive advice on BST using the machine.

Our study has shown that patients with T2DM who received SCR about diet, exercise regimens and smoking cessation did not differ from those who received no recommendations by their healthcare team in terms of glycemic control. These findings on self-care advice should not reflect that provider recommendations have no impact on patient glycemic control. Rather, this raises questions to the quality of services given to those patients, and possibly the lack of a supportive environment to implement such recommendations. However, a recent study conducted for a Master's degree at Al-Najah University investigated the effect of a diabetes educational program as an "intervention for T2DM patients in the Tulkarm governorate directorate of health **[171]**. The findings of this study demonstrated that changes in lifestyle involving dietary, exercise and diabetes self-management resulted in a significant decrease in weight, fasting blood glucose (FBS), HbA1c, cholesterol and triglyceride and improvement in patient knowledge. Specifically, the mean HbA1c significantly declined to 7.95±1.42 after the educational intervention from 8.57±1.21 before educational intervention **[171]**. To overcome the problem of the lack of continuous monitoring and follow up of patients at the clinics, the use of a more technologically advanced diabetes self-management approach such as a mobile phone SMS-based system for diabetes self-management could be the solution as suggested by a local study

(detailed in Chapter 1) **[144]**. Moreover, the healthcare system is facing many shortcomings such as data fragmentation. Additionally, the system may lack a complementary approach needed for providing effective diabetes care; possibly because it was observed there was no active collaboration between diabetes healthcare team (physicians, nurses, pharmacists, dieticians, diabetes educators). Since treatment of diabetes and its complications entails huge costs and burdens on the health system, especially in a country with limited resources such as Palestine, healthcare providers should emphasize proper diabetes self-management education (DSME) to facilitate the knowledge and the skills for diabetes self-care among patients. Otherwise, the growing epidemic continues unabated with increasing disease prevalence, morbidity and mortality.

The bivariate analysis revealed a difference between T2DM patients who reported receiving advice to test blood sugar using the machine (glucometer) and those who had not been given such advice. However, the regression model showed that this association was no longer significant at the presence of other predictors of glycemic control (i.e. including all significant variables together in the regression model) and might be confounded by other factors. This association should be further investigated.

Our analysis showed an association between glycemic control and physician inquiry about patient eating habits during the last visit, where patients with T2DM who received such service (being asked about their eating habits during the last doctor's visit) were less likely to have good glycemic control (more likely to be

uncontrolled). Possible explanations of this finding include the following: services were individualized and based on the current status of the patient, and that diabetes education is not systematically applied, similar to the findings of Jilleh's study **[166]**. This suggested that patients with worse condition (higher HbA1c levels) received better diabetes services than those controlled. On the other hand, no association was observed between glycemic control and physician inquiry about physical activity and smoking status during the last visit. Another possible explanation of these findings was that physicians might focus on diet regimens especially for those with poor glycemic control, as it is easier to adhere to dietary regimens and because they knew that patients had difficulty adhering to other self-care practices such as exercise and smoking cessation. This is in accordance with the literature; the adherence rates observed for diet were 65% but only 19% for exercise **[167]**.

Our study has demonstrated that more women than men attend the surveyed clinics. This finding was similar to the results found in a study of UNRWA's clinics **[172]**, suggesting that the reason for this phenomena is not related to the disease itself, but rather because these clinics work during the morning and men had difficulty leaving their work at this time of the day **[172]**.

The study findings indicated that none of the demographic and socioeconomic characteristics of patients (sex, age, marital status, education, STL index, locale and refugee status) were statistically significant predictors of glycemic control.

Our findings on **sex** were compatible with those reported by studies of US adults with T2DM in which sex was not significantly related to glycemic control **[76, 80]**, but different from those reported by Sanal and colleagues in their systematic review in which males had better control of disease compared to females **[74]**.

This study's findings on **age** were consistent with what was reported by a study of data from Michigan Diabetes in Communities II (DIC II), showing no significant association of glycemic control with age **[76]**. But this finding was different from that reported by a study in the Utrecht region of the Netherlands, which found an association of glycemic control and younger age. It also differed from what was reported according to a systematic review and meta-analysis, in which elderly people (>60 years) with normal BMI had better diabetes control [74, 75].

No association between **marital status** and glycemic control in our study was in line with a previous study of middle-aged and older adults with T2DM from Hispanic and African-American communities, which reported that marital status was not associated with HbA1c levels **[80]**.

In the present study, findings on **education** were consistent with that reported by a study of Mexican and Mexican-American patients with T2DM, which did not find an association of glycemic control and education among these patients **[62]**, and to that reported by the Ching and colleagues study mentioned above **[80]**. A survey among family medicine patients with T2DM also reported no statistically significant association between education and glycemic control **[173]**. Nevertheless, this finding was different from those reported in the Netherlands

(Utrecht) study, which demonstrated that a lower level of education was associated with poor glycemic control **[75]**.

The economic status or the level of wealth among the study participants was measured by the **standard of living (STL)** index. We found that the STL index was not a predictor of glycemic control. This finding is in line with a study in Jordan which reported that both patient income and employment status, variables that might reflect economic status, did not associate with glycemic control **[60]**. Similarly, a study of non-Hispanic blacks, non-Hispanic whites and Mexican-Americans reported no significant association between socioeconomic status and glycemic control **[174]**. A study of whites and Mexican-Americans in Texas did not find an association of socioeconomic status and glycemic control **[175]**. However, the lack of a relationship between STL index and glycemic control in our study contradicts a previous study conducted in Israel, in which patients from higher socioeconomic levels more often achieved well-controlled diabetes since lower socioeconomic status was also found to be related to higher rates of obesity, hyperlipidemia, and poor diabetes control **[78, 79]**.

We found that controlled and uncontrolled diabetes patients did not differ with respect to **locale** (urban, rural and camp residence), or **refugee status** (refugees and non-refugees). However, half of the refugees were living in urban areas and the difference between refugee status and locale was statistically significant.

We found no association between glycemic control among T2DM patients and the **healthcare sector** offering diabetes services. Almost all patients (96.7%) were

insured and covered to use MoH, joint MoH-NGO and UNRWA clinics services. This is in line with previous studies. Harris and colleagues did not find an association between medical insurance and glycemic control **[174]**. However, this study finding contradicts a study in San Diego which demonstrated that patients who were uninsured had higher levels of HbA1c over time **[176]**. The majority of refugees (78.6%) were receiving diabetes services in the UNRWA clinics, and the association between refugee status and sector was significant ($p<0.001$ respectively). The healthcare system in Palestine is a mixture of governmental (public), non-governmental, UNRWA and private service delivery. Private clinics were not included in our study, since the three aforementioned sectors were the most predominant service providers and took over responsibility for healthcare provision.

Our study found that **longer duration of diabetes** (≤7 years) was significantly associated with poor glycemic control. Moreover, it was consistent with previous studies in which longer duration of diabetes was significantly associated with poor glycemic control, or shorter duration of diabetes was associated with lower HbA1c levels respectively **[69, 75, 80]**. A study of Jordanian T2DM patients found that increased duration of diabetes (> 7 years vs. ≤7 years) was associated with poor glycemic control, suggesting that insulin secretion is impaired progressively with time **[69]**. This could be a possible explanation to our results too. However, this study finding was contradictory to a systematic review and meta-analysis, which reported that longer diabetes duration was not associated with poor diabetes control **[74]**.

In the present study, we found that patients who were prescribed combined therapy (OHAs & insulin) were more likely to have poor glycemic control compared to those prescribed OHAs only. This may indicate that patients with poor glycemic control were more likely to be prescribed a "combination of oral hypoglycemic agents and insulin" in an attempt to achieve better disease control. Physicians were probably trying multi-therapy as suggested by the Jordanian study **[69]**. This finding was similar to the Goudawaard et al. and Khattab et al. studies **[69, 75]**. A study of Iranian T2DM patients also found an association between medication type and glycemic control. Moreover, the Benoit et al. study reported that poor glycemic control was associated with insulin use or use of multiple oral agents **[176]**. This might indicate that patients were prescribed multi-therapy to improve their glycemic control. Moreover, this reflects the fact that with time the disease deteriorates and patients experience more progressive disease that requires more aggressive treatment (including insulin) **[69]**. However, this finding is not consistent with Sanal et al. systematic review, in which use of insulin and Metformin were not associated with poor control of DM **[74]**.

We found that patient assessment of diabetes self-management **(perceived capability of dealing with diabetes)** in terms of diet, physical activity and medications was associated with glycemic control. Those who perceived themselves not being capable (or capable to a lesser degree) of dealing with their disease were more likely to have poor glycemic control. In other words, those who perceived themselves capable of dealing with the disease in an excellent or a good way were more likely to have good glycemic control. This is consistent with

a study evaluating patient assessment of their diabetes self-management in relation to their actual glycemic control **[177]**. This study reported that a higher evaluation of self-management was associated with lower HbA1c levels. This might indicate that perceived capability may serve as a proxy for self-care practices which may lead to improved glycemic control.

The lack of a relationship between **patient perception regarding his/her own diabetes knowledge** (through having information about the disease) and glycemic control in our study contradicts the finding of Padma et al., in which patients who were more self-aware about the disease achieve better glycemic control and better diabetes management **[178]**. This means that controlled and uncontrolled patients do not differ with respect to their perceptions of having diabetes information and knowledge. This might be attributed to patient non-adherence to diabetes regimens, though knowledgeable, or might indicate that patients who perceived themselves knowledgeable about their disease, in fact have insufficient diabetes knowledge. Moreover, other factors such as education and diabetes duration were associated with knowledge ($p<0.001$, $p=0.007$ respectively). In the current study, patient perceptions regarding diabetes knowledge was associated with marital status, education, and diabetes duration. These previous findings were similar to those reported a study which demonstrated that educational status, marital status and duration of diabetes were associated with diabetes knowledge **[179]**.

As diabetes is a progressive disease with increasing deterioration of glycemic control, and medications usually are increased with increasing duration, it is

evident that diabetes duration and type of medication are related to glycemic control.

4.3 Strength and Contributions of the Study

To the best of my knowledge, this study is the first that has used an international standardized instrument (SDSCA), though it is the second to be conducted on diabetes management, specifically self-management among adult T2DM patients, in the Ramallah governorate of Palestine. Therefore, this study can act as a starting point for further research in the field of T2DM management and glycemic control.

4.4 Limitations of the Study

Like most related studies, the following limitations were inherent in the study, and the study results were interpreted in this light. First, this study was based on a cross-sectional design confined to a specific point in time. This precludes the causal inference regarding observed associations, which means this type of study (i.e. cross-sectional) hampered the ability to assess a cause and effect relationship between glycemic control and patient SCA and provider SCR due to an inability to establish temporality. Therefore, a longitudinal study is needed to assess the relationship between those variables over time. Second, a limitation concerns the study sample, in which patients were recruited from 11 primary healthcare clinics only, while other clinics that provide diabetes services in the Ramallah governorate, including private clinics were not included in the current study. As a result, this study is limited by selected sample of clinics with high loads of T2DM

patients, which affected the generalizability of these findings beyond this study sample, as severely ill patients that cannot visit the clinics also were not addressed. Third, data about patient SCA and provider SCR were self reported. Patients were asked to recall the number of days that they engaged in a certain self-care activity during the week preceding the survey, and to recall the different SCR that had been given to them by their healthcare team during the previous six months. This might be affected by recall bias and/or social desirability biases, in addition to the fact that the majority of patients were elderly, and had difficulty understanding certain questions. Therefore, the actual performance of self-care behavior could not be confirmed. Another possible limitation is that the qualitative part of this survey has not yet been completed. Therefore, the use of quantitative methods alone in this study may not sufficiently fill the gap in knowledge, and may obscure better interpretation of the results that will be provided in the qualitative part (in parallel with the quantitative part). The quantitative method might not give the reader a more holistic picture of the situation. Moreover, we do not assess the influence of this relationship on long term diabetes complications. Unlike other studies, we show that self-care activities/practices are unrelated to HbA1c levels. While we used an Arabic translated version of the SDSCA and a validated measure for most parts of the SDSCA to assess diabetes self-management, the findings of this study might vary from those of other studies due to variations in the instruments used across studies. Other possible predictors of glycemic control such as presence of diabetes-related complications **[55]** and depression **[179]** were not addressed by

the current study. Despite the previously stated limitations and the fact that our study may not be representing all Palestinian T2DM patients, it yielded a number of important findings with implications that should be taken into consideration by the patients, clinical researchers and healthcare policy makers for improving future practice.

CHAPTER 5

CONCLUSION, IMPLICATIONS AND RECOMMENDATIONS

5.1 Conclusion

This study has shown that only a few patients with T2DM visiting primary healthcare clinics in the Ramallah governorate were controlled, while the majority of them were poorly-controlled, similar to that reported by other country studies. The low or suboptimal performance of important diabetes self-care practices among T2DM patients may indicate the presence of barriers to optimal self-management practices. This finding might be a warning sign that urges immediate actions. The lack of an association between demographic and socioeconomic characteristics, diabetes self-care practices, and healthcare provider recommendations and glycemic control is due to factors beyond the control of disease. Duration of diabetes, type of diabetes treatment, patient assessment of self-management (perceived capability of dealing with diabetes in terms of diet, physical activity and medications), and physician inquiry about patient eating habits were all associated with glycemic control. There were no significant differences between the different healthcare providers concerning glycemic control among patients. This raises questions as to the quality of care and services offered to T2DM patients at these clinics.

These findings should be carefully addressed by health policymakers and healthcare providers. There is a need for extensive changes in the available

healthcare system and an improvement in DM services offered to patients at the MoH, joint MoH- NGO, and UNRWA primary healthcare clinics.

Despite that medication adherence was highly performed among T2DM patients, medications alone were not sufficient to manage diabetes. It would be of great importance to highlight the benefit of lifestyle modifications through health education. A better understanding of the factors contributing to glycemic control in adult Palestinian patients with T2DM should be a priority to achieve better self-management outcomes for T2DM patients. This research has shown many questions in need of further investigation.

5.2 Study Implications

This study has a number of implications for diabetes self-management practices in relation to primary healthcare clinics in the Ramallah governorate.

The key findings of this study suggest the following:

I. The importance of maintaining good glycemic control (HbA1c<7 %) among Palestinian T2DM patients, as the majority had poor glycemic control.

II. The use of an Arabic version of the SDSCA (Ar), a reliable and valid instrument for assessing the level of diabetes self-care practices and self-care recommendations among Palestinian diabetes patients, is an initiative step in this field.

III. The low levels of performing the different aspects of a diabetes regimen (e.g. self-care practices related to general diet, specific diet, exercise, blood sugar testing, foot care, smoking and medication adherence) calls for incorporating

patients in their own disease management through the initiation of self-efficacy and empowerment based strategies to achieve better disease control. To improve diabetes mellitus outcomes, it is necessary to build patient confidence in their ability to play an active role in controlling their diabetes.

IV. The biomedical model adopted by the Palestinian healthcare system will continue to have no impact on DM control, unless healthcare professionals start to emphasize on other aspects of self-management in diabetes care.

V. The evidence that the status of glycemic control was not associated either to demographic and socioeconomic factors or to self-care practices. Rather, other predictors of glycemic control are often beyond the control of the patients.

VI. The need for a comprehensive delivery of health services in terms of the quality of care and monitoring of patients with T2DM, rather than the delivery of conditional and individualized health services to highly uncontrolled patients.

5.3 Recommendations for Future Research and Practice

A number of recommendations in relation to T2DM management and future clinical practice have been reached based on evidence from this study. In general, future local studies should assess and identify the needs of T2DM patients, allocate the appropriate resources and improve services offered to DM patients in the Ramallah governorate as well as other governorates of Palestine.

This study suggests the following issues for future research:

I. Training of the healthcare team in the selected primary healthcare clinics on introducing self-care topics to DM patients and following up with them.

II. Maintaining active collaboration and coordination between different health care providers in terms of availability of resources and materials to unify self-care and education messages, taking into consideration the importance of initiating a comprehensive health education program through patient counseling, skills building and behavioral interventions.

III. Improving the healthcare system to incorporate all relevant healthcare professionals including physicians, nurses, pharmacists, dietitians and diabetes educators in diabetes care, and adopts a participatory approach: an active collaborative role of both patients and healthcare providers.

IV. Improving the quality of care offered to T2DM patients by their healthcare providers in the clinics operated by the MoH, joint MoH- NGO and UNRWA sectors.

V. The adaptation of other instruments that could fill the gaps in both patient self-care practices and healthcare provider recommendations and the comparison with the findings of this study which utilized the SDSCA instrument.

VI. The need for further exploration of the barriers to effective diabetes self-management practices among T2DM patients in Palestine.

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ANNEXES

Annex 1

The main primary healthcare clinics offering services to diabetes patients (N=14)

Clinic	Health care Provider	active diabetic patients	Number of patients needed per clinic
Al Am'ari Camp	UNRWA	1400	132
Al Jalazun Camp	UNRWA	600	57
Deir 'Ammar	UNRWA	190	18
'Ein 'Arik	UNRWA	60	6
Budrus	UNRWA	50	5
Beit 'Ur at Tahta	UNRWA	120	11
Ramallah central clinic	MoH	1300	123
Old Ramallah clinic	MoH	481	45
Beit Reema	MoH	150	14
Qibya	MoH	190	18
Ni'lin	MoH	148	14
Silwad	PRCS	308	29
Sinjel	PMRS	230	22
Mghayer	PMRS	60	6
Total		**5287**	**500**

Annex 2

The primary health care clinics that were included in the study (N=11)

	Clinic	Health care Provider	Estimated Active diabetes patients	Estimated Number of patients needed Per clinic	Number of patients in the final sample
1	Al Am'ari Camp	UNRWA	1435	138	142
2	Al Jalazun Camp	UNRWA	643	62	66
3	Deir 'Ammar	UNRWA	188	18	20
4	Beit 'Ur	UNRWA	139	13	14
5	Ramallah central clinic	MoH	1300	125	126
6	Old Ramallah clinic	MoH	481	46	46
7	Beit Reema	MoH	150	14	14
8	Qibya	MoH	190	18	22
9	Ni'lin	MoH	148	14	13
10	Silwad	MoH and PRCS	308	30	31
11	Sinjel	MoH and PMRS	230	22	23
	Total		**5212**	**500**	**517**

Annex 3

The sampling methodology of the study

	Clinic name	Health care provider	Description of the clinic	Sampling methodology	Number of diabetes patients					field work days
					Invited by phone	Exclusions	Refusal refused to fill refusal form	Refusal filled the refusal form	Participants	
1	**Al-amari**	UNRWA	Located in Amari camp, diabetes clinic daily	Patients were approached while they were waiting to be seen by their doctor and were invited to participate in the study. Witnessed verbal consent was taken (by two fieldworkers). Refusal forms were filled. During the first four days, the NCD nurse referred the consenting patients herself so no refusal forms were filled out	Not applicable	2	Not recorded	20	142 pts	15 days
2	**Jalazune**	UNRWA	Located in Al Jalazoun Camp, diabetes clinic daily.	Patients were approached while they were waiting to be seen by their doctor and were invited to participate in the study. Witnessed verbal consent was taken (by two fieldworkers). Refusal forms were filled.	Not applicable	0	Not recorded	3	66 pts	6 days
3	**Deir Ammar**	UNRWA	Located in Deir Ammar (rural), Diabetes clinic daily.		**26** patients were contacted (19 patients participated + 5 contacted patients refused to participate + 2	0			20	2 days

					accepted but did not come)					
4	**Beit Ur**	UNRWA	Located in Beit Ur (rural clinic), has diabetes clinic on two days per week; Tuesday and Saturday.	Patients were approached while they were waiting to be seen by their doctor and were invited to participate in the study. Witnessed verbal consent was taken (by two fieldworkers). Refusal forms were filled.	Not applicable	0	Not recorded	0	14 pts	1 day
5	**Central Ramallah**	MoH	Located in Al bireh , Al balou', Ramallah city.(urban clinic), has diabetes clinic on five days per week; Monday, Tuesday, Wednesday, Thursday and Sunday	During the first 8 Days of the study, patients were approached while they were waiting to be seen by their doctor and were invited to participate in the study. Witnessed verbal consent was taken (by two fieldworkers). Refusal forms were filled. (70 patients were recruited using this method)		1	Not recorded	16	126 pts	
				During the rest of the fieldwork, and because there was no enough patients load due to lack of lab tests at the clinic, the nurse prepared a list of the diabetes patients and these were contacted by phone and invited to participate	**80**patients were contacted (56 patients participated + 14 contacted patients refused to participate + 10 accepted but did not come)					
6	**Old Ramallah**	MoH	Located in Ramallah city, has diabetes clinic on two days per week;	Patients were approached while they were waiting to be seen by their doctor and were invited to participate in the study. Witnessed verbal consent was	Not applicable	1	25	16	46 pts	6 days

			Sunday and Thursday	taken (by two fieldworkers). Refusal forms were filled, some patients refused to participate and refused to fill the refusal forms						
7	**Beit Rima**	MoH		Patients were approached while they were waiting to be seen by their doctor and were invited to participate in the study. Witnessed verbal consent was taken (by two fieldworkers). Refusal forms were filled.	Not applicable	0	Not recorded	2	14 pts	1 day
8	**Qebia**	MoH	Located in Qebia (rural clinic), has diabetes clinic one day per week; Monday.	Patients were approached while they were waiting to be seen by their doctor and were invited to participate in the study. Witnessed verbal consent was taken (by two fieldworkers). Refusal forms were filled.	Not applicable	0	Not recorded	3	22 pts	2 days
9	**Ni'lin**	MoH	Located in Ni'lin (rural clinic), has diabetes clinic one day per week; Tuesday.	Patients were approached while they were waiting to be seen by their doctor and were invited to participate in the study. Witnessed verbal consent was taken (by two fieldworkers). Refusal forms were filled.	Not applicable	0	Not recorded	0	13 pts	2 days
10	**Silwad**	PRCS and MoH	Located in Silwad (rural clinic), has diabetes clinic two days per week ; Tuesday and Sunday	The first 18 patients were selected using the methodology where patients were approached while they were waiting to be seen by their doctor and were invited to participate in the study.	The other 13 patients were taken using a mixed methodology of phone invitation and the previously mentioned method on the last day of the fieldwork.	0		2	**31**(the needed sample from this clinic is 30 patients)	Total **4** days (3 days using this methodology)

									10 contacted patients participated (out of 13 contacted pts, 3 patients were contacted and did not show up) + 3 patients approached while they were waiting to be seen by their doctor on that day.	1 day using this methodology
11	Sinjel	PMRS and MoH	Located in Singel (rural clinic), has diabetes clinic one day per week; Tuesday.	A list of 186 active diabetes patients was provided by Sinjel clinic. a systematic random sample of 22 patients was needed; where every sixth patient was selected and called to be invited to the study; however as many phone numbers were not functioning, this process was repeated several times until 24 patients were invited.	24 patients were invited by phone to participate in the study (1 patient was contacted and did not show up).	0			23	2 days

Annex 4

The English version of the Summary of Diabetes Self-Care Activities the SDSCA-(E&R) scale developed by Toobert et al, 2000

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

Diet

1- How many of the last SEVEN DAYS have you followed a healthful eating plan?

0 1 2 3 4 5 6 7

2- On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?

0 1 2 3 4 5 6 7

3- On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?

0 1 2 3 4 5 6 7

4- On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?

0 1 2 3 4 5 6 7

Exercise

5- On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).

0 1 2 3 4 5 6 7

6- On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

0 1 2 3 4 5 6 7

Blood Sugar Testing

7- On how many of the last SEVEN DAYS did you test your blood sugar?

0 1 2 3 4 5 6 7

8- On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?

0 1 2 3 4 5 6 7

Foot Care

9- On how many of the last SEVEN DAYS did you check your feet?

0 1 2 3 4 5 6 7

10- On how many of the last SEVEN DAYS did you inspect the inside of your shoes?

0 1 2 3 4 5 6 7

Smoking

11- Have you smoked a cigarette—even one puff—during the past SEVEN DAYS?

0. No

1. Yes. If yes, how many cigarettes did you smoke on an average day?

Number of cigarettes: ----------.

Additional Items for the Expanded Version of the Summary of Diabetes Self-Care Activities

Self-Care Recommendations

1A.Which of the following has your health care team (doctor, nurse, dietitian, or diabetes educator) advised you to do?

Please check all that apply:

a. Follow a low-fat eating plan

b. Follow a complex carbohydrate diet

c. Reduce the number of calories you eat to lose weight

d. Eat lots of food high in dietary fiber

e. Eat lots (at least 5 servings per day) of fruits and vegetables

f. Eat very few sweets (for example: desserts, non-diet sodas, candy bars)

g. Other (specify):

h. I have not been given any advice about my diet by my health care team.

2A. Which of the following has your health care team (doctor, nurse, dietitian or diabetes educator) advised you to do?

Please check all that apply:

a. Get low level exercise (such as walking) on a daily basis.

b. Exercise continuously for at least 20 minutes at least 3 times a week.

c. Fit exercise into your daily routine (for example, take stairs instead of elevators, park a block away and walk, etc.)

d. Engage in a specific amount, type, duration and level of exercise.

e. Other (specify):

f. I have not been given any advice about exercise by my health care team.

3A. Which of the following has your health care team (doctor, nurse, dietitian, or diabetes educator) advised you to do?

Please check all that apply:

a. Test your blood sugar using a drop of blood from your finger and a color chart.

b. Test your blood sugar using a machine to read the results.

c. Test your urine for sugar.

d. Other (specify):

e. I have not been given any advice either about testing my blood or urine sugar level by my health care team.

4A. Which of the following medications for your diabetes has your doctor prescribed?

Please check all that apply.

a. An insulin shot 1 or 2 times a day.

b. An insulin shot 3 or more times a day.

c. Diabetes pills to control my blood sugar level.

d.Other (specify):

e. I have not been prescribed either insulin or pills for my diabetes.

Diet

5A. On how many of the last SEVEN DAYS did you space carbohydrates evenly through the day?

0 1 2 3 4 5 6 7

Medications

6A. On how many of the last SEVEN DAYS, did you take your recommended diabetes medication?

0 1 2 3 4 5 6 7

OR

7A. On how many of the last SEVEN DAYS did you take your recommended insulin injections?

0 1 2 3 4 5 6 7

8A. On how many of the last SEVEN DAYS did you take your recommended number of diabetes pills?

0 1 2 3 4 5 6 7

Foot Care

9A. On how many of the last SEVEN DAYS did you wash your feet?

0 1 2 3 4 5 6 7

10A. On how many of the last SEVEN DAYS did you soak your feet?

0 1 2 3 4 5 6 7

11A. On how many of the last SEVEN DAYS did you dry between your toes after washing?

0 1 2 3 4 5 6 7

Smoking

12A. At your last doctor's visit, did anyone ask about your smoking status?

0. No
1. Yes

13A. If you smoke, at your last doctor's visit, did anyone counsel you about stopping smoking or offer to refer you to a stop-smoking program?

0. No
1. Yes
2. Do not smoke.

14A. When did you last smoke a cigarette?

\1. More than two years ago, or never smoked
2. One to two years ago
3. Four to twelve months ago
4. One to three months ago
5. Within the last month
6. Today

Annex 5

The Arabic version of the questionnaire administered to Type 2 DM patients