وزارة الصحة

جامعة القدس

كليــة الصحــة العامــة

School of Public Health

القدس ـ فلسطين

Deanship of Graduate Studies
Al-Quds University

Non-compliance in Type 2 Diabetes Patients: Prevalence and Associated Factors in Gaza Strip

Amal Abd El Aziz Zakout

M.P.H Thesis

Jeruselem- Palestine

December - 2006

Non-compliance in Type 2 Diabetes Patients: Prevalence and Associated Factors in Gaza Strip

Prepared by:
Amal Abd El Aziz Zakout

M.B.B.Ch: Alfatah University-Tripoli-Libya

Supervisor: Dr Suzanne Shashaa , the assistant dean of the school of public health, Al-Quds University

A thesis Submitted in Partial fulfillment of requirements for the degree of Master of Public Health
Al-Quds Univesity

December 2006

Al-Quds University
Deanship of Graduate Studies
School of Public Health

Thesis Approval

Non-compliance in Type 2 Diabetes Patients: Prevalence and Associated Factors in Gaza Strip

Prepared by: Amal Abd El Aziz Zakout
Registration No:

Supervisor: Suzanne Shashaa

Master thesis submitted and accepted, Date
The names and signatures of the examining committee members are as follow:

1. Head of committee: Dr. Suzanne Shashaa	Signature…….
2. Internal Examiner: Dr. Yehia Abed	Signature…….
3. External Examiner: Dr. Ayoub El Alem	Signature…….

Jerusalem- Palestine

December / 2006

Dedication

To the soul of my father…

To My husband who has never stopped believing in me…
To My mother who has always supporting me…
To My daughter, To My Brothers and sisters for their love…

I dedicated this work to
Those who gave me every opportunity of success.

Amal Abd El Aziz Zakout

Declaration

I certify that this entire thesis submitted for the degree of Master is the result of my own research, except where otherwise acknowledged, and that this thesis (or any part of the same) has not been submitted for a higher degree to any other university or institution.

Signed

Amal Abd El Aziz Zakout

Date: December -2006

Acknowledgement

I would like to express my deepest gratitude to Dr. Basem Naeem, Minister of health, Palestine, Dr. Sari Nuseabh, President of A-Quds University, for supporting and facilitating the Master program of Public Health.

I am greatly indebated to Dr. Suzanne Shasha'a, , the assistant dean of the school of public health, Al-Quds University, my academic supervisor for her continuous support, encouragement and kind of supervision.

My full thanks to Dr. Yehia Abed, Associated Professor, Al-Quds University for his continuous support, generous help and encouragement.

I express my gratitude to the school of Public Health staff and personnel, especially Mr. Sadi Awwad for his generous kind and assistance, to Mr. Shaban Mortaja, for his support, to Miss Suzan Abed and Miss Labiqa El- Wally for their kindness.

I wish to express my appreciation and gratitude to Dr. Ali Gueder Director General of PHC-MoH for his guided and support.

My deepest thanks to Dr. Amro-Alhuseni, the assistant Director General of PHC-MoH, Dr. Moein Abu-Ramadan, Dr Bassam Al-Mohtadi for their help and encouragement.

A lot of thanks for Dr. Olfat Shaat, Deputy director of PHC-MoH in Khan Younis governerate for her support and encouragement.

I offer my thanks and gratitude to all my colleagues and to the manager of at Al-Rimal Clinic, for their encouragement advice, kindness and moral support.

I highly appreciate and acknowledge Dr. Sleman Al-Astal, Dr. Soheel Al Keshawei, and Dr. Waheeb Al-Dahoka, for their encouragement advice, and also to Mister Youssef Abo Rahma, for all his kind of help and for all persons who help and assistant me in date collection.

My thanks expanded to all those who provided helpful suggestions and useful recommendations during the preparation of research instrument especially, Dr. Abed El-Jabar Al Tibi, Dr. Abdel Aziz Thabit, and Dr. Bassam Abu Hamad.

My deepest thanks go to all who have offered assistance and support during this study especially the Eng.Khaleel Zakout for his helping, encouragement and support, and to the Eng. Faten Zakout for her support and help.

It is my pleasure to express my deepest thanks to my mother for her endless love, help and support, to my brothers Ms. Yousef, and Dr. Sami Zakout and my sisters for their assistant, encouragement, love and support.

Special thanks to my father in law, the consultant Ms. Abd El Hameed Shaat and to my mother in law for their encouragement and moral support.

Last, but far from being least, I thank my husband, Dr. Ashraf Shaat, who has helped me immeasurably in this work. Not only has he participated actively in the preparation of this thesis, but his patience and forbearance have made it possible.

Amal Zakout.

Abstract

Type 2 Diabetes Mellitus is a serious disease and a cause for growing public health concern in both developed and developing countries. Diabetes is a typical chronic disease that demonstrates the need for integrated and multifaceted approaches to achieve good control. Poor adherence to the treatment for diabetes results in avoidable suffering for the patients and excess costs to the health system. Poor adherence to recognized standards of care is the principal cause of development of complications of diabetes and their associated individual, societal and economic costs.

Aim of the study is to determine the prevalence of non-compliance among type 2 diabetes patients in Gaza- Strip and associated factors, and to suggest measures for improving compliance.

A cross-sectional study was conducted among diabetic patients from both genders with proved type-2 diabetes mellitus from different districts of Gaza Strip who registered at Al-Rimal Diabetic Central Clinic. A sample of 216 patients was chosen by convenient sampling method, Data collection was carried out using retrospective review of medical records, structured face to face questionnaire and bio-physiological measures. Compliance with the medication regimen was measured by the indirect method which included questioning the patient and bio-physiologic markers.

The prevalence of non compliance in the study population was 50.5%, farther more compliance to non- pharmacological treatment was poor, 38.9% were found not following any diet regimen and was significantly associated with non compliance and 61.6% of respondents were found not exercising at all. The result showed that 75.5% of study population had poor glycemic control measured according to HbA1c as an indicator of therapeutic outcome.

Typical reasons cited by patients for non compliance included forgetfulness (66.4%), frustration (24.3%), feeling better without treatment(19.6%), polypharmacy (14%), fear from drug side-effect (12.1%) and unavailability of drugs (8.4%).

Poor knowledge of drug side-effect, Patients' feeling (not to take their medicine or feeling in need for a rest period), negative attitude regarding taking a missed dose have a significant relationship with non compliance.

Polypharmacy, unavailability of drugs, presence of complications of diabetes in general and ophthalmic and diabetic foot complication in particular were reported to have significantly higher rates of non compliance.

Socio-demographic factors (age, gender, locality, consanguinity, marital status, family size educational level and income) were found to have no significance effect on compliance rates, while low socio-economic status, positive family history regarding the mother, associated ischemic heart disease were found to have a negative significant effect on compliance.

The majority of study population had associated risk factors; uncontrolled blood pressure(68.5%), hypercholesterolemia(64.8%), hyper triglyceridemia (68.5%), and obesity (63%). but hypertriglyceridemia and obesity were significantly increased among non compliance.

Most of the study population (88%), mentioned that they respect their appointment to the diabetic clinic, the proportion who did not omit their appointment related the causes to the increasing waiting time or to that doctors did not give them their care or attention.

Improving compliance could be achieved by identifying the barriers and overcoming factors that impede compliance. Efforts must work in the context of changing patients' self awareness of their values, needs, and goals for diabetes care, encouraging and enhancing specific training in adherence management for practitioners and staff nurses, and increasing efforts by policy makers for creation and adoption of chronic care models of service delivery, for improving access to medicines and health care, decreasing waiting time and to offer medications for all patients.

ملخص الدراسة

يعتبر النوع الثاني من الداء السكري أحد الأمراض التي تحتل مكانة هامة من بين الأمراض المزمنة كما وأنه مشكلة مؤرقة للصحة المجتمعية في كل من الدول المتطورة والنامية كما وانه يحتاج إلـي جهود متضافرة من جهات متنوعة للحصول على الضبط المعياري والمطلوب له، إن نقص مطاوعة المرضى (عدم الالتزام) للخطة العلاجية يؤدي إلي نتائج وخيمة على حياة المرضـى ويزيـد مـن الأعباء المالية الملقاة على كاهل الجهاز الصحي. إن نقص مطاوعة المرضـى للمعـايير القياسـية الصحية لهو السبب الرئيسي لظهور المضاعفات المختلفة عند مرضى الداء السكري، وما ينجم عنها من زيادة الأعباء المالية الفردية والمجتمعية.

إن هدف الدراسة هو معرفة معدل حدوث ظاهرة عدم الالتزام (والعوامل المرافقـة لهـا) عنـد مرضى ارتفاع سكر الدم من النوع الثاني في قطاع غزة، كما تهدف الدراسة إلـي التوصـل إلـي معايير خاصة تزيد من نسبة التزام المرضى.

هذه الدراسة هي دراسة مقطعية على مرضى الداء السكري من النوع الثاني من كلا الجنسين مـن مختلف المناطق في قطاع غزة والمسجلين ضمن عيادة الرمال المركزية، لقد تم جمع عينـة مـن المرضى بطريقة توافقية ويبلغ عدد هذه العينة 216 مريض، وقد جمعت المعلومـات و المقـاييس البيوفسيولوجية بالتحليل الراجع للسجلات الطبية وأيضاً من خلال الاستبيانات التي تم جمعهـا مـن خلال المقابلات المباشرة مع المرضى.

وقد وجد أن معدل ظاهرة عدم الالتزام في هذه الدراسة 50.5%، وأكثر من ذلـك فـإن الالتـزام بالعلاج غير الدوائي كان سيئا،فقد تبين أن 38.9% من العينة لا يتبعون أي برامج صحية غذائيـة

ولكل من ذلك دلالة إحصائية, ووجد أن 61.6% من الحالات المدروسة لا يتبعون أي تمارين رياضية، ووجد أن ضبط مستوى السكر في الدم كان سيئاً عند 75.5% من الحالات المدروسة وذلك عند قياس هذا الضبط بمستوى الهموغلوبين الجلوكوزي (HbA1c) كمشعر بيوفسيولوجي للحالة العلاجية.

إن الأسباب التي تم التوصل إليها بالدارسة والمسئولة عن عدم الالتزام كان66.4% منها بسبب النسيان، و24.3% من الحالات بسبب الشعور بالملل والإحباط، و19.6% نتيجة إحساسهم بالتحسن عند عدم أخذ العلاج، و14% نتيجة تعدد الأدوية التي يتناولها المريض، و 12.1% بسبب الخوف من الآثار الجانبية للعلاج, و8.4% من الحالات لا يجدون الأدوية الموصوفة لهم.

كما أن هناك جملة من الأسباب المتنوعة قد وجدت بدلالة إحصائية عند دراسة العلاقة بينها وبين عدم الالتزام: قلة المعرفة بالآثار الجانبية للدواء، المشاعر المختلفة تجاه الدواء (عدم الرغبة بأخذ الدواء أو الرغبة بأخذ قسط من الراحة)، وسلوك المريض السلبي تجاه أخذ الجرعة الدوائية المنسية. كما أن تعدد الأدوية أو عدم توفرها في المراكز الصحية، ووجود مضاعفات الداء السكري بشكل عام، وبشكل خاص المضاعفات الناجمة عن إصابة العين والقدمين، أدت إلى زيادة نسبة عدم الالتزام في العينة المدروسة وكان لها دلالة إحصائية هامة, كما وجد أن العوامل السكانية والاجتماعية (العمر ، الجنس ، المواطنة ، درجة القرابة ، الحالة الاجتماعية ، حجم العائلة ، مستوى التعليم والدخل) ليس لها أي دلالة إحصائية عند دراستها بنقص المطاوعة، بينما الأوضاع الاجتماعية الاقتصادية وكذلك وجود تاريخ مرض للعائلة للإصابة بالداء السكري من جهة الأم وترافق أمراض نقص التروية القلبية كان لها الأثر السلبي على مدى الالتزام.

ولقد وجد أن غالبية العينة المدروسة من المرضى متوافقة مع عوامل الخطر التالية: ارتفاع ضـغط الدم الشرياني (68.5%)، ارتفاع كولسترول الدم (64.8%)، ارتفاع الـدهون الثلاثيـة(68.5%)، السمنة (63%). وقد وجد أن كل من ارتفاع الدهون الثلاثية والسمنة لها دلالة إحصائية مـع عـدم الالتزام.

و قد وجد أن88%من العينة المدروسة ملتزمون بالزيارات الدورية للطبيب المشرف على العـلاج في العيادات. أما المتبقي من العينة المدروسة وجد أن عدم التزامهم بالمراجعات الدوريـة لعيـادة السكري يرجع إلي زيادة وقت الانتظار أو استيائهم من عدم اكتراث الطبيب بوضعهم الصحي.

يمكن التوصل إلى تحسين الالتزام عن طريق تحديد المعيقات و التغلب عليها , لذلك يجب بذل كـل الجهود نحو تغيير حالة وعي المرضى تجاه الأهداف و الاحتياجات الصحية اللازمة للعناية بـداء السكري , و تشجيع عقد دورات تدريبية حول عدم الالتزام لكل من الأطباء الممارسـين و الطـاقم التمريضي , كما و يلزم زيادة الجهود المبذولة من قبل صناع القرار لعمل نماذج تسهل الحصـول السريع على الدواء و الرعاية الصحية و توفير العلاج لجميع المرضى وتقليل وقت الانتظار.

Table of Contents

List of Tables

List of Figures

Definition

Anti diabetic drug :is a drug used to treat diabetes mellitus (CDC, 2005).

Blood pressure: is the force of blood on the inside walls of blood vessels, measured by analyzing both the systolic blood pressure, the pressure when the heart pushes blood out into **the** arteries, and the diastolic blood pressure, when the heart is at rest (CDC, 2005).

Body Mass Index (BMI): a bodymass index (the weight in kilograms divided by the square of the height in meters), (CDC,2005).

Chronic diseases: Diseases which have one or more of the following characteristics: they are

permanent, leave residual disability, are caused by nonreversible pathological alteration, require special training of the patient for rehabilitation, or may be expected to require a long period of supervision, observation or care (CDC, 2005).

Compliance: The World Health Organization (WHO) has defined the compliance as "the extent to which a person's behaviour – taking medication, following a diet and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider (WHO, 2003).

Daonil : an antidiabetic sulfonylurea derivative (CDC, 2005).

Diabetes Mellitus: is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels (ADA, 2005).

Diabetic retinopathy: is diabetic eye disease that results from damage to the small blood vessels in the retina, the back part of the eye that contains the cells that respond to light. It may lead to loss of eyesight (CDC, 2005).

Exercise: is a subset of physical activity: planned, structured, and repetitive bodily movement performed to improve or maintain one or more components of physical fitness. Examples include walking, bicycling, jogging, swimming, water aerobics, and many sports (ADA, 2005).

Glucose intolerance: is a condition in which the body has blood sugar levels higher than normal, but not high enough to classify as diabetes. It is diagnosed using an oral glucose tolerance test which requires a fasting period of 8 to 12 hours and the blood sugar is measured both fasting and 2 hours after drinking a high-sugar drink (CDC, 2005).

Glycosylated hemoglobin: HbA1c is a derivative of the normal adult hemoglobin, hemoglobin A, and is formed in small amounts through the nonenzymatic glycosylation of hemoglobin A during periods of elevated plasma glucose (Pawlson, 2000).

Hyperlipidemia: The term hyperlipidemia means high lipid levels. Hyperlipidemia includes several conditions, but it usually means that you have high cholesterol and high triglyceride levels (SVS, 2006).

Insulin: is a hormone that is needed to convert sugar, starches, and other food into energy needed for daily life (CDC, 2005).

Metformin: is a medicine pill used to treat type 2 diabetes because it lowers blood sugar levels by reducing the amount of sugar produced by the liver and helping the body respond better to insulin (CDC, 2005).

Obesity: is defined as a body mass index (BMI) of =>30 kg/m2**. Overweight:** is defined as a body mass index (BMI) of 25 to 29.9 kg/m2, (CDC, 2005).

Physical activity: Physical activity is defined as bodily movement produced by the contraction of skeletal muscle that requires energy expenditure in excess of resting energy expenditure (ADA, 2005).

Smoking cessation: is generally defined as complete abstinence from the use of smoked tobacco.The duration of the studies varied from 12 weeks to 24 weeks, (CDC, 2005).

Type 2 diabetes*:* is a complex metabolic disorder characterized by hyperglycaemia and associated with a relative deficiency of insulin secretion, along with a reduced response of target tissues to insulin (insulin resistance), (Show, 2003).

ist of abbreviation

ADRs	Adverse Drug Reactions
ADA	American Diabetes Association
ASCP	American Society of Consultant Pharmacist
BMI	Body Mass Index
CDC	Centers for Disease Control and Prevention
CHOs	Carbohydrates
CVD	Cardiovascular Disease
DCCT	Diabetes Control and Complications Trial
DM	Diabetes Mellitus
FPG	Fasting Plasma Glucose
GS	Gaza Strip
GDM	Gestational Diabetes Mellitus
GDP	Gross Domestic Production
GNP	Gross National Product
HbA1c	Glycated hemoglobin A
HDL	High Density Lipoprotein
IFG	Impaired fasting glucose
IGT	Impaired glucose tolerance
IDF	International Diabetes Federation
IHD	Ischemic Heart Disease
LDL	Low Density Lipoprotein
MODY	Maturity-Onset Diabetes of the Young
MNT	Medical Nutrition Therapy
MOF	Palestinian Ministry of Finance
MOH	Ministry Of Health
MPG	Medical Practice Guidelines
NHS	National Health Systyem
NIS	New Israel Sheqalim
NGOs	Non Governmental Organizations
OGTT	Oral Glucose Tolerance Test
OHAs	Oral Hypoglycemic Agents
PCBS	Palestinian Central Bureau of Statistics
PNA	Palestinian National Authority
PHC	Primary Health Care
QIP	Quality Improvement Program
SMBG	Self-monitoring of Blood Glucose
TFR	Total Fertility Rate
UNRWA	United Nation Relief and Work Agency
UPMRC	The Union of Palestinian Medical Relief Committee
WHO	World Health Organization

Chapter 1

Introduction

Diabetes mellitus (DM), especially type 2 diabetes is a serious disease and a cause for growing public health concern in both developed and developing countries. In many countries it is now a leading cause of death, disability and a high health care cost. The World Health Report 1997 paid attention to diabetes: World Health Organization (WHO) warns that diabetes is one of the most daunting challenges posed today by virtue of its frequency, and the cost and suffering imposed by its complications. Also, diabetes is no longer a disease of the affluent, it is now a third world problem and the developing countries will bear the brunt of the diabetes epidemic in the 21st century (MOH, 2002). There is strong evidence that many patients with chronic illnesses including diabetes have difficulty adhering to their recommended regimens. A number of rigorous reviews have found that, in developed countries, adherence among patients suffering chronic diseases averages only 50%. The magnitude and impact of poor adherence in developing countries is assumed to be even higher given the paucity of health resources and inequities in access to health care.

Poor adherence to treatment of chronic diseases is a worldwide problem of striking magnitude. It is undeniable that many patients experience difficulty in following treatment recommendations.

The consequences of poor adherence to long-term therapies are poor health outcomes and increased health care costs. Poor adherence to long-term therapies severely compromises the effectiveness of treatment making this a critical issue in population health both from the perspective of quality of life and of health economics. Interventions aimed at improving

adherence would provide a significant positive return on investment through primary prevention (of risk factors) and secondary prevention of adverse health outcomes.

Diabetes is a typical chronic disease that demonstrates the need for integrated and multifaceted approaches to achieve good control (WHO, 2003).

Diabetes is a chronic illness that requires continuing medical care and patient self-management education to prevent acute complications and to reduce the risk of long-term complications. Diabetes care is complex and requires that many issues, beyond glycemic control, be addressed. A large body of evidence exists that supports a range of interventions to improve diabetes outcomes (ADA, 2006).

Diabetes is one of the foremost health challenges facing the world in the new millennium. It has the potential to overwhelm health budgets. Health administrators and health service planners need to heed the warnings as the toll from this serious disease mounts (McGill, 2001). Diabetes is highly prevalent, afflicting approximately 150 million people worldwide, and this number is expected to rise to 300 million in the year 2025. Much of this increase will occur in developing countries and will result from population ageing, unhealthy diet, obesity and a sedentary lifestyle. In developed countries, such as the United States, diabetes has been reported as the seventh leading cause of death, and the leading cause of lower extremity amputation, end-stage renal disease and blindness among persons aged 18–65 years. It has been estimated that diabetes costs the United States economy more than 98 billion dollars per year in direct and indirect costs. It has also been estimated that low-income families in the United States supporting an adult member with diabetes devote 10% of their income to his or her care, and that this figure rises to 25% in India (WHO, 2003).

This study focus on type 2 diabetes patients who are non complaints which take into consideration the factors that lead to non compliance, and suggest measures to improve compliance.

1.1 Justification of study

Diabetes is reaching epidemic proportions in many countries of the world as part of the "globalization" process, and the WHO predicts a tripling of the current prevalence rates by 2025 (McGill, 2001). According to MOH report, in the year 2000 the prevalence rate of DM in Palestine is about 9%, also data reported from Rimal-clinic in the year 2002 showed that out of total reported cases about 37,9% was among ages between 50-64 years and 11,5% among ages under 30 years (MOH, 2005). As the care of diabetes is based on self- management by the patient, who is helped and advised by those with specialized knowledge. The quest for improved glycaemic control has made it clear that whatever the technical expertise applied, the outcome depends on welling cooperation by the patient. If accurate information is not supplied, misinformation from friends and other patients will take its place. For this reason, many patients have exaggerated fears of, for example, blindness (less than one patient in 20 is blind after 30 years of diabetes), death during hypoglycemia (extremely rare), or the risk of passing diabetes on to their children (some 5% of offspring of a person with type-1 DM develop the condition, whereas about 15% of children of patients with type-2 DM develop this form of diabetes). The excess risk to diabetics compared with the general population increases as one moves down the body: Stroke is twice as likely. Myocardial infarction is 3-5 times as likely and women with diabetes lose their premenopausal protection from coronary artery disease. Amputation of a foot for gangrene is 50 times as likely (Kumar, 2002).

The consequences of poor adherence to long-term therapies are poor health outcomes and increased health care costs.

On professional level as I am a physician working in primary health care center, I observed that many diabetic patients were non compliant to therapy and exposed to complication of diabetes, so the problem is in great need to be studied.

Few local studies has been conducted to assess compliance across type 2 DM without using biological marker to compare the collected data, where it is an essential and valuable tool in the last 5 years world wide.

1.2 Objectives

General objectives

To determine the prevalence and associated factors among non-compliance in type 2 diabetes patients.

Specific objectives

1. To Estimate proportion of controlled and uncontrolled type -2 diabetes patients.
2. To assess knowledge, attitude and practice of non compliance type -2 diabetes patients towards management of diabetes.
3. To determine factors associated with non – compliance type -2 diabetes patients.
4. To suggest measures for improving compliance with management of type-2 diabetes patients.

1.3 Demographic context

Palestinian National Authority (PNA) territories comprise two geographically separated areas: West Bank and Gaza Strip. West Bank lies within an area of 5,800 sq. km^2 west of the Jordanian river.

Gaza strip is a narrow piece of land lying on the coast of the Mediterranean Sea. Gaza Strip is very crowded place with an area of 362sq. Km^2. Gaza Strip is composed of five provinces: North Gaza, Gaza City, Mid- Zone, Khan Younis and Rafah annex (3). The main income source for Gaza population was working in Israel, in addition to the poor agriculture products that have to be exported via Israel (PCBS, 2004). According to the Palestinian Central Bureau of Statistics 2006, the estimated population in the Palestinian Territory reached 3.9 million persons in mid year 2006, of which about two millions are males and 1.9 million are females. The Palestinians are distributed at 2.5 millions in the West Bank and 1.4 million in Gaza Strip. The Palestinian Territory population increased by 39% during the period 1997-2006, distributed by 45.0% in Gaza Strip and 36.7% in the West Bank. Despite the decline in the natural increase rate to 3.3% in the year 2006 compared with 3.8% in 1997 the population will continue increasing (PCBS, 2006). Ministry of health reported according to PCBS, 2004 that 42.6% of the population in the Palestinian Territory are refugees, they are estimated to 1.6 million at the end of 2004, thereof 686,000 (29.9%) in the West Bank and 892,000 (65.5%) in Gaza Strip (MOH, 2005).

According to the most recent estimation as reported by MOH, 2005, 46.3% of the population in Palestine is under 15 years; 44.4% in West Bank and 49.4% in Gaza. The percentage of Palestinians who are above 65 years in Palestine is 2%; this figure reached 2.2% in West Bank and 1.6% in Gaza (MOH, 2005). The illiteracy rate reached 7.7% of total persons aged 15 years and over in the Palestinian Territory in 2005; 3.1% among males and 11.1% among

females, moreover 7.5% of the persons aged 15 years and over have bachelor and above; 9.2% for males and 5.8% for females, its distributed by 7.0% in the West Bank and 8.4% in Gaza Strip (PCBS, 2006).

The nuclear households increased by 10.9% in 2005 compared with 1997, constituting about 81.3% of the total households in the Palestinian Territory in 2005, compared with 73.3% in 1997 (PCBS, 2006). The average household size in the Palestinian Territory is 5.7 persons (MOH, 2005). The Data indicates that dependency ratio in Palestine dropped from 101.3 in 1997 to 97.5 in 2004. The ratio declined from 94.7 to 91.7 in West Bank and from 114.5 to 108.5 in Gaza at the same period. (MOH, 2005). According to the MOH reporting in 2005 the total fertility rate (TFR) in Palestine is high in comparison with other countries in the region. This may be due to early marriage especially among females, the desire to have many children, and the prevailing traditions of the Palestinian society. However, indicators show that TFR started to decline towards the end of the 20th century (MOH, 2005). Also as published by PCBS, 2006 the trend of fertility rate is declining, fertility rate reached 4.6 births per woman in the Palestinian Territory during 2004 , of which 4.1 in the West Bank and 5.8 in Gaza Strip. While fertility rate in the Palestinian Territory was 6.0 births per woman in 1997 (PCBS, 2006). Infant mortality rate in the Palestinian Territory decreased from 27.7 per 1000 live births during 1990-1994 to 24.2 per 1000 live births during 1999-2003. The life expectancy for 2006 in the Palestinian Territory is 71.7 years for males and 73.2 years for females (PCBS, 2006). The crude death rate in the Palestinian Territory in mid of 2005 is 4.0 deaths per 1000 population (4.1 deaths in the West Bank, and 3.9 deaths in Gaza Strip in mid of 2005).

1.4 Palestinian economy

As reported by MOH in 2005, according to the Palestinian Ministry of Finance (MOF), the Gross National Product (GNP) in Palestine has been subjected to high fluctuations during the last five years. The Gross National production (GNP) was 5,454 million US$ in 1999 and decreased to 3,720 million US$ in 2004. Gross Domestic Production (GDP) was 4,517 million US$ in 1999 and decreased to 3,286 million US$ in 2004 (MOH, 2005). The PCBS reported that the number of Palestinian workers in Israel decreased from 135,000 in 1999 to 50,100 in 2004. The main income source for Gaza population was working in Israel, in addition to the poor agricultural products that have to be exported via Israel. The workers in Gaza and West Bank increased from 453,000 in 1999 to 527,600 in 2004 due to the political situation and recurrent crisis (MOH, 2005). The PCBS reported that the unemployment rate reached 25.3% in the Palestinian Territory during the first quarter of 2006, distributed by 21.4% in the West bank and 34.1% in Gaza Strip. The estimated poverty rate among Palestinian households in the Palestinian Territory during the 2nd quarter 2006 reached 65.8%, distributed by 87.7% in Gaza Strip and 54.65 in the West Bank, Estimates showed that about 55.65 of households are suffering deep poverty, distributed by 79.8% in Gaza Strip and 43.2% in the West Bank (PCBS, 2006).

The total cost of antidiabetic drugs in MOH which was used in the governmental health centers was 732,561US$ in 2004, out of which 623,436 US$ for insulin and 109,125US$ for oral antidiabetic agents. The annual average cost of antidiabetic drug was 812,933 US $ during the last 4 years; equal about 5.6% of total drugs expenditure in MOH (MOH, 2004).

1.5 Health context

Over the past years, the Palestinian health care system has developed side by side along with the development of Palestinian society in general.

The four major health providers of health care services in Palestine are: The Palestinian Health Authority represented by Ministry of health (MOH), United Nation Relief and Work Agency (UNRWA), Non Governmental Organizations (NGOs), and the private sector (MOH, 2005).

Primary Health Care (PHC) is considered the backbone of the health system. It is the basic level of care provided equally to everyone. It addresses the common problem in the community by providing preventive, curative, and rehabilitative services to maximize health and well being (MOH, 2002). The total number of registered PHC centers in Palestine is 731 centers (125 centers in Gaza and 606 centers in West Bank). Distribution by provider shows that, there are 413 centers owned and supervised by the MOH with a high percentage of 56.5%, 53 centers by the UNRWA with a percentage of 7.3% and NGOs have 265 centers with a percentage of 36.3% of the total centers. In Palestine the average ratio of persons per center was 4,976 (10,698 in Gaza and 3,796 in West Bank).

The UNRWA owns and operates 53 centers in Palestine. The UNRWA offers health services free of charge for all refugees and plays a noticeable role in the vaccination program in cooperation with the MOH, in addition to curative services, antenatal and postnatal care and other specialized services. Furthermore, all refugees in Gaza and West Bank have the right of accessibility to the governmental health care services.

In Gaza: the total number of PHC centers is 125 centers in comparison with 100 centers in 2000, which indicates an increase of 25% in the last five years. Although the PHC system in Gaza is unique, well established and functioning well, the high population density and the overcrowdness of population were responsible for the high ratio of population per centre.

MOH owns and operates 56 PHC centers out of which 29 level (II), 19 level (III) and 7 of level (IV). In general, there are 10 centers working 3 shifts (24 hours, emergency services), 9 centers working 2 shifts and the rest of centers working only one shift, one of which has a delivery unit in Gaza City. The PHC centers provide special health care services in different aspects, 44 centers provide antenatal care and family planning services, in addition to 100 specialized clinics and 25 dental and oral clinics. About 34 centers have laboratories and 12 centers have x-Ray units (MOH, 2005).

The main central clinic in Gaza Strip are: Al-Rimal central clinic which is present in Gaza district. Jabalya central clinic in the South district, Dear El Balah central clinic in the Mid-zone, Khan-Younis central clinic in Khan-Younis district, and Rafah central clinic in Rafah district. There is specialized clinics for diabetes in all of them.

Central clinics provide health services to Palestinian patients and all the governmental health services are covered by governmental health insurance.

1.6 Al-Rimal clinic

Al-Rimal clinic is one of the central clinic in Gaza district, it provides health services such as specialized clinics for diabetes, hypertension, dermatology, dental and ophthalmology, as well as general health care clinic.

Central diabetic clinic in Al-Rimal provides health services for diabetic patients. All the new cases that are discovered from another PHC clinics from different districs: South, Gaza, Mid-zone, Khanyounis and Rafah, and referred to central diabetic clinic in Al-Rimal are re-evaluated by the specialist. Old cases are routinely and periodically checked.

There is a continuous improvement and development of MOH diabetic services through supplying medicine, equipment, continuous education of the medical team and establishing

clinical guidelines in 2004, through the Quality Improvement Program (QIP) Health System Project World Bank. Also improving the diabetes services through updating patient's hard and electronic files, which exists only at Al-Rimal central clinic. The newly introduced a diabetic information system (data base) contributed to the rapid improvement for the diabetic services including shortening of waiting time for patients as well as reducing the lost-time for doctors through rapid and available full data about the patient where information of the study was taken.

Ministry Of Health (MOH) in 2004 reported that the proportion of diabetic patients with obesity (BMI >=30) in Al-Rimal health center was 58.7% (43% in males and 69.5% in females) while the proportion of overweight diabetic patient was 27.4% (36.6% in males and 21.1% in females).

The distribution of diabetic (type II) cases by management in Al-Rimal health clinic is about 28.1% of all diabetics were managed by insulin treatment. About 18.7% were treated with a combined therapy (insulin and OHA). Oral anti-diabetic agents was 42.1%. Diet control (exclusively managed by lifestyle modification) was 4.7% (MOH, 2005).

Chapter 2

Literature Review

Diabetes is a typical chronic disease that demonstrates the need for integrated and multifaceted approaches to achieve good control. The control of diabetes requires more than just taking medicine. Patients with diabetes usually have co-morbidities that make their treatment regimens even more complex. In particular, other commonly associated diseases such as hypertension, obesity and depression are themselves known to be characterized by poor rates of adherence and serve to further increase the likelihood of poor treatment outcomes.

Poor adherence to the treatment for diabetes results in avoidable suffering for the patients and excess costs to the health system (WHO, 2003).

2.1 Definition of Diabetes Mellitus

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels (ADA, 2005).

2.2 Types of Diabetes Mellitus

American Diabetes Association (2005), stated that assigning a type of diabetes to an individual often depends on the circumstances present at the time of diagnosis, and many diabetic individuals do not easily fit into a single class. For example, a person with gestational diabetes mellitus (GDM) may continue to be hyperglycemic after delivery and may be determined to have, in fact, type 2 diabetes. Alternatively, a person who acquires diabetes because of large doses of exogenous steroids may become normoglycemic once the

glucocorticoids are discontinued, but then may develop diabetes many years later after recurrent episodes of pancreatitis. Thus, for the clinician and patient, it is less important to label the particular type of diabetes than it is to understand the pathogenesis of the hyperglycemia and to treat it effectively.

2.2.1 Type 1 diabetes

It is characterized by ß-cell destruction, usually leading to absolute insulin deficiency) It has two forms:

a-Immune-mediated diabetes which result form of diabetes, which accounts for only 5–10% of those with diabetes, previously encompassed by the terms insulin-dependent diabetes, type I diabetes, or juvenile-onset diabetes, results from a cellular-mediated autoimmune destruction of the ß-cells of the pancreas.

b- Idiopathic diabetes mellitus which refers to some forms of type 1 diabetes have no known etiologies (ADA, 2005).

2.2.2 Type 2 diabetes

It is ranging from predominantly insulin resistance with relative insulin deficiency to predominantly an insulin secretory defect with insulin resistance). This form of diabetes, which accounts for 90–95% of those with diabetes, previously referred to as non-insulin-dependent diabetes, type 2 diabetes, or adult-onset diabetes, encompasses individuals who have insulin resistance and usually have relative (rather than absolute) insulin deficiency at least initially, and often throughout their lifetime, these individuals do not need insulin treatment to survive. There are probably many different causes of this form of diabetes. Although the specific etiologies are not known, autoimmune destruction of ß-cells does not occur. Most patients with this form of diabetes are obese, and obesity itself causes some

degree of insulin resistance. Patients who are not obese by traditional weight criteria may have an increased percentage of body fat distributed predominantly in the abdominal region. This form of diabetes frequently goes undiagnosed for many years because the hyperglycemia develops gradually and at earlier stages is often not severe enough for the patient to notice any of the classic symptoms of diabetes. Nevertheless, such patients are at increased risk of developing macrovascular and microvascular complications. Whereas patients with this form of diabetes may have insulin levels that appear normal or elevated, the higher blood glucose levels in these diabetic patients would be expected to result in even higher insulin values had their ß-cell function been normal. Thus, insulin secretion is defective in these patients and insufficient to compensate for insulin resistance. Insulin resistance may improve with weight reduction and/or pharmacological treatment of hyperglycemia but is seldom restored to normal. The risk of developing this form of diabetes increases with age, obesity, and lack of physical activity. It occurs more frequently in women with prior GDM and in individuals with hypertension or dyslipidemia, and its frequency varies in different racial/ethnic subgroups. It is often associated with a strong genetic predisposition, more so than is the autoimmune form of type 1 diabetes. However, the genetics of this form of diabetes are complex and not clearly defined (CDC, 2005).

2.2.3 Impaired glucose tolerance (IGT) and impaired fasting glucose (IFG)

They are recognized as an intermediate group of subjects whose glucose levels, although not meeting criteria for diabetes, are nevertheless too high to be considered normal. Patients with IFG and/or IGT are now referred to as having "pre-diabetes" indicating the relatively high risk for development of diabetes in these patients. In the absence of pregnancy, IFG and IGT are not clinical entities in their own right but rather risk factors for future diabetes as well as

cardiovascular disease. IFG and IGT are associated with the metabolic syndrome, which includes obesity (especially abdominal or visceral obesity), dyslipidemia of the high-triglyceride and/or low-HDL type, and hypertension. Note that many individuals with IGT are euglycemic in their daily lives. Individuals with IFG or IGT may have normal or near normal glycated hemoglobin levels. Individuals with IGT often manifest hyperglycemia only when challenged with the oral glucose load used in the standardized OGTT.

2.2.4 Gestational Diabetes Mellitus (GDM)

GDM is defined as any degree of glucose intolerance with onset or first recognition during pregnancy (ADA, 2005). It is more common among obese women and women with a family history of diabetes. During pregnancy, gestational diabetes requires treatment to normalize maternal blood glucose levels to avoid complications in the infant. After pregnancy, 5% to 10% of women with gestational diabetes are found to have type2 diabetes. Women who have had gestational diabetes have a 20% to 50% chance of developing diabetes in the next 5-10 years (CDC, 2005).

2.2.5 Other types of diabetes

American Diabetes Association (ADA) in 2005 stated other types of diabetes as follow:
a-Genetic defects of the ß-cell: these forms of diabetes are frequently characterized by onset of hyperglycemia at an early age (generally before age 25 years). They are referred to as maturity-onset diabetes of the young (MODY) and are characterized by impaired insulin secretion with minimal or no defects in insulin action. They are inherited in an autosomal dominant pattern (for example MODY 1,2,3).

b-Genetic defects in insulin action: there are unusual causes of diabetes that result from genetically determined abnormalities of insulin action.

c-Diseases of the exocrine pancreas : any process that diffusely injures the pancreas can cause diabetes. Acquired processes include pancreatitis, trauma, infection, pancreatectomy, and pancreatic carcinoma.

d-Endocrinopathies: several hormones (e.g., growth hormone, cortisol, glucagons**,** epinephrine) antagonize insulin action. Excess amounts of these hormones (e.g., acromegaly, Cushing's syndrome, glucagonoma, pheochromocytoma, respectively).

e-Drug or chemical-induced diabetes: many drugs can impair insulin secretion. These drugs may not cause diabetes by themselves, but they may precipitate diabetes in individuals with insulin resistance. There are also many drugs and hormones that can impair insulin action. Examples include nicotinic acid and glucocorticoids.

f-Infections: certain viruses have been associated with ß-cell destruction. Diabetes occurs in patients with congenital rubella, coxsackie B, cytomegalovirus, adenovirus, and mumps.

g- Uncommon forms of immune-mediated diabetes.

h-Other genetic syndromes sometimes associated with diabetes: these include the chromosomal abnormalities of Down's syndrome, Klinefelter's syndrome, and Turner's syndrome (ADA, 2005).

2.3 Pathogenesis:

The American Society of Consultant Pharmacists (ASCP) in 2001 stated that the pathogenesis of DM varies with type, type1 DM may be associated with genetic, autoimmune, or viral insult, and it may become manifest at any age. The net result is a steady decrease in insulin secretion until the patient presents with the classic triad of polydipsia, polyphagia, and polyuria, usually accompanied by weight loss. Type 2 DM on the otherhand has several stages. In the first stage, obesity in middle age leads to insulin resistance and compensatory

hyperinsulinemia. Insulin, as well as both hypo- and hyperglycemia, contribute to increased appetite and craving of foods, especially carbohydrates (CHOs). This leads to additional weight gain, completing the cycle of gradual obesity, hyperinsulinemia, hyperphagia, and excessive weight gain. Increased visceral and, to a lesser extent, peripheral fat contribute to hepatic insulin resistance, impaired insulin secretion, and peripheral insulin resistance. These insulin changes, in turn, lead to DM, high blood pressure, hyperlipidemia, arteriosclerosis, and increased risks for cardiovascular and cerebrovascular disease. At some point in the DM disease process, the hyperinsulinemic state progresses to a relative insulin deficiency state due to beta cell "burnout", and exogenous insulin may be required. Formerly considered part of syndrome X, type 2 DM may indeed represent a complex metabolic syndrome that includes hypertension, hyperlipdemia, hyperinsulinemia, and insulin resistance, all of which lead to early heart, brain, eye, and kidney damage (ASCP, 2001).

2.4 Epidemiological picture

2.4.1 Global:

The epidemic nature of diabetes continues to affect ever-increasing numbers of people around the world and the number of people with diabetes is expected to double between 2000 and 2030 while public awareness remains low (Wild et al. 2004). According to International Diabetes Federation (IDF, 2003) and a recent study done by Wild et al. in 2004 and undertaken by the World Health Organization (WHO), it is estimated that 177 million people have diabetes in the adult population in the world in 2001 or about 5.2% in the age bracket 20-79, this is an increase over the 2000 estimate of 151 million and an increase from the 1995 global estimation of 135 million people with diabetes which was published in a World Health

Organization (WHO) study in 1998. Also in 2004, it is estimated that around 194 million people have diabetes in the adult population in the world.

2.4.2 In Europe

The rapid increase in diabetes in Europe is a major public health issue. Diabetes is the fourth leading cause of death in Europe, and It carries a 3-4 times higher risk of major cardiovascular complications and is now the commonest cause of heart attack and stroke and a major cause of peripheral vascular disease and peripheral neuropathy leading to a 20 fold higher risk of amputation. The cost of diabetes complications accounts for 5-10% of total healthcare spending in several countries including Belgium, France, Germany, Italy, the Netherlands, Spain, Sweden and the UK. In today's Europe, the average prevalence rate of diabetes is 7.5%, and about 60 million people live with diabetes, of whom more than 50% are unaware of their condition leaving them exposed to the risks and costly complications associated with poor control of the illness. In addition to those 60 million people who have diabetes, it is estimated that a further 120 million have pre-diabetes of which 50% will develop diabetes within 5 years. By 2025, the prevalence of diabetes is expected to double in Europe. The prevalence of Type 2 diabetes in France was 3% in 2000. In Ireland, there were around 300,000 people with diagnosed or undiagnosed diabetes. The South-East Asian Region has the highest number of people with diabetes mellitus with some 49 million, and its prevalence of 7.5% is the second highest, behind North America (7.8%), and ahead of the Eastern Mediterranean and Middle East Regions (6.4%), (IDF, 2004).

According to WHO in 1998, between 1995 and 2025 the number of the adult population affected by diabetes mellitus in developing countries is projected to grow by 170%, from 84 to 228 million people. By 2025, these countries will be home to 76% of all persons with

diabetes, as compared with 62% in 1995. In the same period, the developed world will see a 41% increase, from 51 to 72 million people. This more than twofold global increase will occur because of population ageing and growth, as well as from obesity, unhealthy diets and a sedentary lifestyle. These latter factors are closely associated with urbanization and industrialization. As they stated these figures are shocking as they represent only clinically diagnosed diabetes, and many more cases of diabetes remain undiagnosed and untreated. In addition, up to one-quarter of western populations have impaired glucose tolerance or the dysmetabolic syndrome, which are considered to represent pre-diabetic states (WHO,1998).

Type 2 diabetes is appearing increasingly in children and adolescents. The long-term complications associated with type 2 diabetes carries a crushing burden of morbidity and mortality, and most type 2 diabetic patients die prematurely from a cardiovascular event (Zimmet, 2003). Diabetes is most common among the elderly in many populations, while prevalence rates are rising alarmingly quickly among comparatively young and productive populations in the developing world. If the present trends persist and if no action is taken to address the problem, by 2025 most people with diabetes in developed countries will be aged 65 years or more, while the majority of diabetic persons in developing countries will be in the 45-64 year age group. This means that some 170 million men and women, who will reside in the developing regions of the world in less than 30 years from now, will be suffering from diabetes in their most productive years of life (WHO, 1998).

2.4.3 In United States of America (USA)

Total prevalence of diabetes in the United States of America (USA) in all ages is 7.0%. Prevalence of diagnosed diabetes in people aged 20 years or younger in the (USA) is 0.22% of all people in this age group. Although type 2 diabetes can occur in youth, the nationally

representative data that would be needed to monitor diabetes trends in youth by type are not available. Total prevalence of diabetes among people aged 20 years or older in United States of America is 9.6% of all people in this age group and is 20.9% among people aged 60 years or older. Men are 10.5% of all men aged 20 years or older and women are 8.8% of all women aged 20 years or older have diabetes (CDC, 2005). Many patients with type 2 diabetes are asymptomatic and go undiagnosed for many years. Studies suggest that the average patient with new-onset type 2 diabetes actually has had diabetes for at least 4-7 years before the diagnosis. Of patients with type 2 diabetes, 25% are believed to have retinopathy, 9% neuropathy, and 8% nephropathy at the time the diagnosis is made (ADA, 2006).

2.4.4 Regional

2.4.4.1 The prevalence of DM in Palestine

The prevalence of DM in Palestine was examined a study conducted in 2000 in cooperation with Al-Quds University and MOH. The preliminary results indicated that the prevalence of DM in Palestine is about 9% in 2000.

It is around the reported prevalence rate in Egypt and Tunisia (9%) and less than in Saudi Arabia (12%) and Oman (13%), (MOH, 2005).

In 2001, UPMRC (The Union of Palestinian Medical Relief committee) screened 2,482 people through their mobile clinics for obesity, hypertension, diabetes and dyslipidemia.

The preliminary results showed that, overweight (BMI>25) was present in 77%, obesity (BMI > 30) in 47%, hypertension in 31%, diabetes in 18% and dyslipidemia in 49%. These figures should be cautiously considered as the targeted population included men and women between 35 and 65 of age (MOH, 2005).

The prevalence of diabetes and associated factors in a cross-sectional survey of urban Palestinian population of 492 men and women aged 30–65 years were studied by Abdul-Rahim et al. in 2001, who found DM in 12.0% of the surveyed population (including 9.4% previously diagnosed). In 2004, according to the Demographic and Health Survey, which was done by the Palestinian Central Bureau of Statistics (PCBS), 2.2% of reported persons cases suffered from DM, this increased to 21.1% among elderly aged 65 years while it was 11.1% among age group of 40- 64years, and 0.4% among age group of 18-39 years (PCBS, 2004).

Also they indicated that the gap between the expected prevalence rates of DM and cases under supervision reflects under registration and underreporting, and requires special efforts to accelerate early case-finding activities in order to avoid high cost of treating the complications and disability consequences of the disease. This will give more realistic estimation of the prevalence for appropriate evaluation of the problem.

According to Ministry of Health annual report 2005, in 2004, out of total 623 new reported cases of diabetes in Al-Rimal diabetic clinic, of them 31.3% was among age group of 50-64, 31.0% was among age group of 30-49 years, 18% was among age group 20-29 years, 16.1% among age 65 years and over and 3.4% among age group of 5-19 years.

Distribution of diabetic (type II) cases by management in Al-Rimal health clinic according to the MOH annual report, 2005 was as following:

1. About 28.1% of all diabetics were managed by insulin treatment.
2. About 18.7% were treated with a combined therapy (insulin and OHA).
3. Oral anti-diabetic agents was 42.1%
4. Diet control (exclusively managed by lifestyle modification) was 4.7%

While the visits to diabetes mellitus clinics was as following in 2004, 140,578 visits were reported to the governmental PHC-specialized diabetic clinics distributed as 74,011 visits in the Gaza Strip compared with 66,567 visits in the West bank (MOH, 2005).

2.4.4.3 Mortality of diabetes mellitus: in Palestine

DM was not reported as one of the 10th leading cause of death among Palestinians. It constituted 3.6% of total population deaths. 372 persons died with mortality rate of 10.2 per 100,000 (176 males, with a rate of 9.5 per 100,000 males and 196 females, with mortality rate of 10.9 per 100,000). The average annual mortality rate of DM was 12.4 per 100,000 population in the last five years (MOH, 2005).

2.5 Compliance

Non adherence to treatment protocols is of particular interest and significance in the diabetic population. The diabetic treatment regimen is complex. It may be modified over the course of the disease, is designed for life, does not guarantee recovery, depends largely on the responsibility of the patient, and requires active attention to a variety of areas such as: diet, exercise, medication, and self-monitoring of blood glucose (Jenny, 1986).

One of the major problems that arise for persons working with patients with type 2 diabetes is the problem of non-compliance (Ferzacca, 2000).

Compliance can be defined as ‘the extent to which patient’s behavior coincides with medical advice (Hunt et al., 1998).

2.5.1 WHO historical definition of adherence

WHO report in 2003 clarified the definition of adherence according to WHO adherence meeting in June 2001. They stated that although most research has focused on adherence to medication, adherence also encompasses numerous health-related behaviours that extend beyond taking prescribed pharmaceuticals. The participants at the WHO adherence meeting in June 2001 concluded that the definition of adherence as "the extent to which the patient follows medical instructions" was a helpful starting point. However, the term "medical" was felt to be insufficient in describing the range of interventions used to treat chronic diseases. Furthermore, the term "instructions" implies that the patient is a passive, acquiescent recipient of expert advice as opposed to an active collaborator in the treatment process.

In particular, it was recognized during the meeting that adherence to any regimen reflects behavior of one type or another. Seeking medical attention, filling prescriptions, taking medication appropriately, obtaining immunizations, attending follow-up appointments, and executing behavioral modifications that address personal hygiene, self-management of asthma or diabetes, smoking, unhealthy diet and insufficient levels of physical activity are all examples of therapeutic behaviors. The participants at the meeting also noted that the relationship between the patient and the health care provider (be it physician, nurse or other health practitioner) must be a partnership that draws on the abilities of each. The literature has identified the quality of the treatment relationship as being an important determinant of adherence. Effective treatment relationships are characterized by an atmosphere in which alternative therapeutic means are explored, the regimen is negotiated, adherence is discussed, and follow-up is planned.

Finally they adopted the following definition of adherence to long term therapy:

"The extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" (WHO, 2003).

2.5.2 Medication compliance

It is defined as the extent to which a person's medication-taking behaviour coincides with medical advice (Haynes, 1979). Despite this definition being dated, a number of authors (Kelly, 1995; Cameron, 1996; Balkrishnan, 1998) continue to use this definition in their work. Complete medication adherence occurs when the patient follows the instructions completely. Partially compliant patients take incorrect doses of their drugs regularly or correct doses more or less often than prescribed (Deborah, 2005).

2.5.3 Patient compliance

As defined by Mark, et al. in 2006 patient compliance is the degree to which a patient follows a treatment regimen. In studies of patient behavior, only about half of patients who leave a physician's office with a prescription take the drug as directed. The most common reason given for noncompliance is forgetfulness, which may be more appropriately described as denial of illness; having to take a drug is a constant reminder of illness. Older persons may take several drugs; the regimen may be complex and hard to remember and to follow, thereby increasing the likelihood of an adverse drug interaction (Mark, et al., 2006).

2.5.4 Medical non-compliance

Following a prescribed course of treatment for a medical or psychological condition can be challenging. Many factors can make adherence difficult, including busy schedules, family stress, finances, and remembering instructions. Not following recommended treatment can be dangerous to one's health; thus, when a person does not follow a doctor-recommended treatment regimen, that individual is said to be "medically non-compliant". The most common forms of medical non-compliance are: not taking prescribed medications, not following recommendations for managing a chronic medical condition, and not following through with restorative therapy. Medical non-compliance becomes a significant problem when poor adherence to medical treatment or preventative strategies results in delaying or worsening a person's condition and/or increasing disease complications (Deborah, et al., 2005).

2.6 Rate of compliance (Adherence)

Rates of adherence for individual patients are usually reported as the percentage of the prescribed doses of the medication actually taken by the patient over a specified period. Some investigators have further refined the definition of adherence to include data on dose taking (taking the prescribed number of pills each day) and the timing of doses (taking pills within a prescribed period). Adherence rates are typically higher among patients with acute conditions, as compared with those with chronic conditions; persistence among patients with chronic conditions is disappointingly low, dropping most dramatically after the first six months of therapy. The average rates of adherence in clinical trials can be remarkably high, owing to the attention study patients receive and to selection of the patients, yet even clinical trials report average adherence rates of only 43 to 78 percent among patients receiving treatment for

chronic conditions. The ability of physicians to recognize non-adherence is poor, and interventions to improve adherence have had mixed results (Osterberg and Blaschke, 2005).

2.7 Types of non-compliance

Deborah, et al. in 2005 stated that there is many types of non-compliance such as: inconsistent medication adherence, poor appointment follow through, poor compliance with medical homework assignments, poor adherence with dietary recommendation, inconsistent adherence to exercise regiment, inconsistent medical data collection, and disease specific measures of control.

Inconsistent medication adherence (mismedication) can include: failing to initially fill a prescription, failing to refill a prescription as directed, omitting a dose(s), over dosing, prematurely discontinuing medication, taking a dose at the wrong time, taking a medication prescribed for someone else, taking a dose with prohibited foods, liquids, and other medications, taking outdated medications, taking damaged medications, storing medications improperly and improperly using medication administration devices Rajaei and Pherson in 1997 suggest that it is generally accepted that non-compliance falls into three categories:
1- Accidental: the patient forgets to take the dose or takes the medicines incorrectly because the instructions were not well understood or could not be followed.
2- Triggered: the patient starts to feel better and stops taking the medicine, or conversely, the patient feels worse, and therefore believes that the medicine is doing no good.
3-Intentional: the patient makes a conscious decision not to take the medicines as recommended (Deborah, et al., 2005).

2.8 Risk Factors of diabetes

2.8.1 Life style modifiable risk factors

Obesity increases the risk of serious co-morbidities such as type 2 diabetes, cardiovascular disease, certain cancers and reduced life expectancy. The risk of diabetes is particularly increased by obesity, and 80-95% of the increase in diabetes can be attributed to obesity and overweight with abdominal fat distribution. A study in Palestine conducted by Sha'at in 2000, regarding Diabetes Mellitus Status, where it was found that obesity reported high prevalence rates among the study population. As well another study done by Abu Ramadan in 2004, demonstrated that obesity is the major risk factor of type 2 Diabetes Mellitus. There is robust evidence from cross-sectional and longitudinal studies to support that an energy-dense, high fat diet and physical inactivity are independent risk factors for weight gain and obesity. Furthermore, interaction between dietary fat and physical fitness determine fat balance, so that the obesity promoting effect of a high fat diet is enhanced in susceptible subjects, particularly in sedentary individuals with a genetic predisposition to obesity. To prevent obesity and diabetes there are grounds for recommending the combination of increasing daily physical activity and reducing dietary fat content to 20-25 energy-% in sedentary subjects, and to 25-35% in more physically active individuals (Astrup, 2001).

The public health burden of type 2 diabetes mellitus has been dramatically increased worldwide. Not only its prevalence rate at present but the increase of its incidence in the near future can create a global health problem. The rapid increase of the total number of newly diagnosed diabetic patients proved to be associated with the increasing prevalence rate of obesity. The metabolic syndrome and type 2 diabetes can contribute to accelerated atherosclerosis and, therefore, the target organ damages can carry a serious problem for the individuals and also for the whole society. It is obvious, that the primary prevention of type 2

diabetes mellitus is of great importance. There is now substantial evidence that type 2 diabetes can be prevented or delayed by lifestyle interventions, i.e. diet and exercise should be the first choice in order to avoid weight gain when preventing diabetes. The incidence of newly diagnosed type 2 diabetes decreased parallel with weight loss (Germendy, 2003). Being overweight can be prevented by regular physical activity. A second, independent benefit of regular physical activity is improved blood sugar control in persons who already have type 2 diabetes (PHAC, 2001).

Manson, et al., in 2001 followed 84,941 female nurses from 1980 to 1996; these women were free of diagnosed cardiovascular disease, diabetes, and cancer at base line. Information about their diet and lifestyle was updated periodically. A low-risk group was defined according to a combination of variables; a bodymass index (the weight in kilograms divided by the square of the height in meters) of less than 25; a diet high in cereal fiber and polyunsaturated fat and low in trans fat and glycemic load (which reflects the effect of diet on the blood glucose level); engagement in moderate-to-vigorous physical activity for at least half an hour per day; no current smoking. During 16 years of follow-up, they documented 3300 new cases of type 2 diabetes. Overweight or obesity was the single most important predictor of diabetes. Lack of exercise, a poor diet, and current smoking were all associated with a significantly increased risk of diabetes, even after adjustment for the body-mass index. Their findings support the hypothesis that the vast majority of cases of type 2 diabetes could be prevented by the adoption of a healthier lifestyle (Manson, et al., 2001). The Palestinian annual health reports (2000, 2003) identified only one risk factor among the Palestinian diabetics, which is the obesity (MOH, 2005).

Obesity is a complex multifactorial chronic disease that develops from an interaction of genotype and the environment. Obesity is clearly associated with increased morbidity and

mortality. There is strong evidence that weight loss in overweight and obese individuals reduces risk factors for diabetes and cardiovascular disease (CVD). Strong evidence exists that weight loss reduces blood pressure in both overweight hypertensive and nonhypertensive individuals; reduces serum triglycerides and increases high-density lipoprotein (HDL)-cholesterol; and generally produces some reduction in total serum cholesterol and low-density lipoprotein (LDL)-cholesterol. Weight loss reduces blood glucose levels in overweight and obese persons without diabetes; and weight loss also reduces blood glucose levels and HbA1c in some patients with type 2 diabetes (Adrienne, 1998).

According to MOH annual report in 2005, the incidence of diabetic patients with obesity is 44.5% in males and 55.6% in females in 2000, while in 2002, the incidence of diabetic patients with obesity is 60.8% (42.3% in males and 72.4% in females).

In 2004, Al-Rimal health center (the only available data in governmental health institution) the reported proportion of diabetic patients with obesity (BMI >=30) was 58.7% (43% in males and 69.5% in females) while the proportion of overweight diabetic patient was 27.4% (36.6% in males and 21.1% in females).

Regarding the other risk factors such as older age, family history of diabetes, prior history of gestational diabetes, impaired glucose tolerance, physical inactivity etc..., there is no information or statistics available about them (MOH, 2005).

2.8.2 Older age

Age increases the risk of type 2 diabetes. In the future there will be more people aged 65 years and over (older adults). Although the exact mechanisms underlying normal ageing are not fully understood, ageing is generally associated with an increase in chronic diseases, such as cardiovascular disease, diabetes, cancer and osteoporosis (McKevith, 2005). While most diabetes occurs in older persons, it should be noted that the appearance of type 2 diabetes in children is increasingly being reported in the medical literature (PHAC, 2001).

2.8.3 Family history

The genetic link for type 2 diabetes is stronger than the genetic link for type 1. Having a blood relative with type 2 diabetes increases the risk. If that person is a first-degree relative (e.g., a parent, sibling or child), the risk is even higher (PHAC, 2001). Abu Ramadan, in 2004, found that positive family history and consanguinity were the most prevalent risk factors associated with type 2 Diabetes Mellitus. A study indicates that a genetic predisposition to type 2 diabetes, probably in association with slightly elevated glucose levels, may accelerate the development of atherosclerosis and increase the risk for coronary heart disease in glucose-tolerant individuals (Pannacciulli, 2003).

2.8.4 High blood pressure

Patients with diabetes have a much higher rate of hypertension than would be expected in the general population. Regardless of the antihypertensive agent used, a reduction in blood pressure helps to prevent diabetic complications. Most diabetic patients with hypertension require combination therapy to achieve optimal blood pressure goals. In general, only 25 percent of patients with hypertension have adequate control of their blood pressure. lifestyle

modifications such as exercise and a diet low in salt and high in potassium have clearly been shown to decrease blood pressure. Weight loss and exercise can help to lower blood pressure and may also improve glycemic control and insulin sensitivity (Sheeri, et al., 2002). A cross-sectional descriptive study was conducted at all UNRWA primary health care facilities in Lebanon Field, to assess the quality of care of diabetes mellitus and hypertension. The study reviewed 2202 records of diabetic and hypertensive patients, the major complication in that study was cardiovascular disease followed by retinopathy (Yusef, 2000).

2.8.5 Hyperlipidemia

Lipid is the scientific term for fats in the blood. At proper levels, lipids perform important functions in our bodies, but can cause health problems if they are present in excess. The term hyperlipidemia means high lipid levels. Atherosclerosis increases the risk of heart disease, stroke, and other vascular diseases. Lifestyle changes like exercising and eating a healthy diet can also lower lipid levels and are often the first step in treatment. Most hyperlipidemia is caused by lifestyle habits or treatable medical conditions. Lifestyle contributors include obesity, not exercising, and smoking. Conditions that cause hyperlipidemia include diabetes, kidney disease, pregnancy, and an under active thyroid gland (SVS, 2006). Dyslipidemia should be aggressively identified and treated to decrease cardiovascular risk (Dunn, 1992).

2.8.6 Smoking

There is a growing body of evidence to suggest that smoking is an independent risk factor for diabetes and that among people with diabetes, smoking aggravates the risk of serious disease and premature death. Macro vascular and micro vascular complications ensue more quickly in smokers with diabetes, and risk of mortality increases. The increased blood pressure and

altered lipid profiles in smokers with diabetes could encourage development of the insulin resistance syndrome, setting patients up for further cardiovascular problems (Justin, 2005).

2.9 Diagnosis of DM

Since the American Diabetes Association (ADA) issued important revisions to its guidelines on assessment and treatment of diabetes mellitus (DM) in 1997, the prevalence of diagnosed DM in long-term care settings has markedly increased. This rise in DM diagnosis is largely due to lowering of the ADA-designated threshold for acceptable fasting plasma glucose (FPG) from 139 to 125 mg/dL (ASCP, 2001).

Criteria for the diagnosis of diabetes in adults

American Diabetes Association in 2006, stated that three ways to diagnose diabetes are available, and each must be confirmed on a subsequent day unless unequivocal symptoms of hyperglycemia are present, these ways are:

1. Symptoms of diabetes plus casual plasma glucose concentration ≥200 mg/dl (11.1 mmol/l). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.

Or

2. FPG ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h.

Or

3. 2-h postload glucose ≥200 mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by World Health Organization in 2003, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.

Although the 75-g oral glucose tolerance test (OGTT) is more sensitive and modestly more specific than fasting plasma glucose (FPG) to diagnose diabetes, it is poorly reproducible and

rarely performed in practice. Because of ease of use, acceptability to patients, and lower cost, the FPG is the preferred diagnostic test. It should be noted that the vast majority of people who meet diagnostic criteria for diabetes by OGTT, but not by FPG, will have an A1C value <7.0%. The use of the A1C for the diagnosis of diabetes is not recommended at this time.

Hyperglycemia not sufficient to meet the diagnostic criteria for diabetes is categorized as either IFG or impaired glucose tolerance (IGT), depending on whether it is identified through a FPG or an OGTT:

- IFG = FPG 100 mg/dl (5.6 mmol/l) to 125 mg/dl (6.9 mmol/l).
- IGT = 2-h plasma glucose 140 mg/dl (7.8 mmol/l) to 199 mg/dl (11.0 mmol/l).

Recently, IFG and IGT have been officially termed "pre-diabetes." Both categories, IFG and IGT, are risk factors for future diabetes and cardiovascular disease (CVD). In the absence of unequivocal hyperglycemia, these criteria should be confirmed by repeat testing on a different day. The OGTT is not recommended for routine clinical use but may be required in the evaluation of patients with IFG or when diabetes is still suspected despite a normal FPG, as with the postpartum evaluation of women with GDM (ADA, 2006).

2.10 Monitoring test (**assessment of glycemic control)**

Monitoring of glycemic status, as performed by patients and health care providers, is considered a cornerstone of diabetes care. Results of monitoring are used to assess the efficacy of therapy and to guide adjustments in medical nutrition therapy (MNT), exercise and medications to achieve the best possible blood glucose control.

2.10.1 Blood glucose testing by patients

Within only a few years, self-monitoring of blood glucose (SMBG) by patients has revolutionized management of diabetes. Using SMBG, patients with diabetes can work to achieve and maintain specific glycemic goals. Given the results of the Diabetes Control and Complications Trial (DCCT) and other studies, there is broad consensus on the health benefits of normal or near-normal blood glucose levels and on the importance, especially in insulin-treated patients, of SMBG in treatment efforts designed to achieve such glycemic goals (MPG, 2006). Clinical trials using insulin that have demonstrated the value of tight glycemic control have used (SMBG) as an integral part of the management strategy. For patients using less frequent insulin injections or oral agents or medical nutrition therapy (MNT) alone, SMBG is useful in achieving glycemic goals (ADA, 2006).

2.10.2 Blood glucose testing by health care providers

Blood glucose testing (e.g., laboratory glucose or finger-stick glucose) should be available to providers for use as needed. With the availability of SMBG and glycated protein testing, routine laboratory blood glucose testing by health care providers should no longer be used to assess glycemic control except to supplement information obtained from other testing methods and to test the accuracy of SMBG. When adjusting oral glucose-lowering medication(s) in a patient not taking insulin, laboratory testing also may be appropriate (MPG, 2006).

2.10.3 Glycated protein testing

Blood and urine glucose testing and urine ketone testing provide useful information for day-to-day management of diabetes. However, these tests cannot provide the patient and health care team with a quantitative and reliable measure of glycemia over an extended period of time. Measurements of glycated proteins, primarily hemoglobin and serum proteins, have added a new dimension for assessment of glycemia. With a single measurement, each of these

tests can quantify average glycemia over weeks and months, thereby complementing day-to-day testing (MPG, 2006).

2.10.4 Hemoglobin A1c (HbA1c) testing

GHb, commonly referred to as glycated hemoglobin, glycohemoglobin, glycosylated hemoglobin, HbA1c, or HbA1, is a term used to describe a series of stable minor hemoglobin components formed slowly and nonenzymatically from hemoglobin and glucose. The rate of formation of GHb is directly proportional to the ambient glucose concentration. In the normal person, about 3–6% of HbA is glycated, in the diabetic, the percentage of HbA1c may double or even triple depending upon the degree of hyperglycemia. With normalization of blood sugar in the diabetic, HbA1c values will gradually approach normal levels (Gonen, et al,1997).

-The values of measuring HbA1c

HbA1c accumulates within red blood cells and exists in this form throughout the life span of the cells. A single HbA1c value taken every 2 to 3 months serves as an integrated index of blood glucose control over those months and thus provides an objective view of the patients glycemic control between checkups. The circulating erythrocyte has an average half-life of 60 days, so HbA1c levels do not change quickly. HbA1c values will begin to reflect radical changes in diet or changes in other modes of therapy approximately 3 to 4 weeks after initiation of the change. Numerous investigators have shown a correlation between HbA1c and glycemic control as assessed by traditional glucose assays.

The landmark nine-year Diabetes Control and Complications Trial (DCCT), completed in 1993, showed that the risk for development and progression of the chronic complications of diabetes is closely related to the degree of glycemic control, as measured by HbA1c

determinations. DCCT results revealed that intensive therapy provides the means of preventing or postponing long-term complications such as neuropathy, retinopathy, and nephropathy. People with diabetes who follow an intensive glucose management regimen could experience up to a 76% reduction in eye problems, a 35–56% reduction in severe kidney problems, and up to 60% reduction in crippling nerve related disorders (Gonen, et al.,1997). Similarly, the results of the United Kingdom Prospective Diabetes Study show that lowering blood glucose levels, as measured by HbA1c determinations, reduces the incidence of microvascular complications in Type 2 diabetes (Gonen, et al., 1997).

A cross-sectional study was conducted in US by which published in 2005 in Diabetes Care journal studied the relationship between HbA1c level and peripheral arterial disease, they found that an association exists between higher levels of HbA1c and peripheral arterial disease, even among patients without diabetes. Individuals with HbA1C levels ≥5.3% should be targeted for aggressive risk factor reduction, which may reduce the burden of subclinical cardiovascular disease even among those without diabetes (Paul, et al., 2005).

A retrospective evaluation was performed by Rhee, et al. in 2005 for 1560 patients with type 2 diabetes who presented for a new visit to the Grady Diabetes Clinic between 1991 and 2001 and returned for a follow-up visit and HbA1c after 1 year of care, they stated that keeping more appointments and taking diabetes medications as directed were associated with substantial improvements in HbA1c. Efforts to enhance glycemic outcomes should include emphasis on these simple but critically important aspects of patient adherence (Rhee, et al., 2005). Preconception care of women with diabetes entails specialized monitoring. The American Diabetes Association in 2006 recommends lowering glycohemoglobin levels to achieve maximum fertility and optimal embryo and fetal development. Initially, HbA1c levels

are assessed on a monthly basis. When appropriate glycemic control is achieved, HbA1c levels are then measured at 6 to 8 week intervals until conception. Recent studies indicate that many patients with diabetes do not receive the recommended number of HbA1c tests. This is surprising given that experts agree that regular HbA1c testing and appropriate therapeutic intervention can minimize the complications of the disease (Gonen, et al., 1997). In general, for every 1% reduction in results of HbA1c blood tests (e.g., from 8.0% to 7.0%), the risk of developing microvascular diabetic complications (eye, kidney, and nerve disease) is reduced by 40% (CDC, 2003).

-Frequency of testing

The American Diabetes Association (ADA) in 2006, certified that HbA1c testing should be performed routinely in all patients with diabetes, first to document the degree of glycemic control at initial assessment and then as part of continuing care. The ADA recommends HbA1c testing at least twice per year in patients who are meeting treatment goals (and have stable glycemic control) and 4 times per year in patients whose regimen has been modified or are not meeting their glycemic control goals (Gonen, et al., 1997). For any individual patient, the frequency of HbA1c testing should be dependent on the clinical situation, the treatment regimen used, and the judgment of the clinician (ADA, 2006).

The HbA1c test is subject to certain limitations. Conditions that affect erythrocyte turnover (hemolysis, blood loss) and hemoglobin variants must be considered, particularly when the HbA1c result does not correlate with the patient's clinical situation (ADA, 2006).

-Glycemic goals regarding HbA1c:

American Diabetes Association in 2006 summarized the glycemic goals as: The HbA1c goal for patients in general is an HbA1c goal of <7%, Lowering HbA1c has been associated with a reduction of microvascular and neuropathic complications of diabetes. The HbA1c goal for the individual patient is an HbA1c as close to normal (<6%) as possible without significant hypoglycemia. Less stringent treatment goals may be appropriate for patients with a history of severe hypoglycemia, patients with limited life expectancies, very young children or older adults, and individuals with co-morbid conditions. Aggressive glycemic management with insulin may reduce morbidity in patients with severe acute illness, perioperatively, and following myocardial infarction (ADA, 2006).

2.10.5Microalbumin

Diabetic nephropathy develops in up to 45% of type I diabetes and up to 35% in type II patients. Microalbuminuria is the increased, but low urinary albumin excretion of >30-300 mg/L indicating early changes in glomerular permeability. Current dipstick technology is usually sensitive to albumin levels of 200-300 mg/L. Increasing levels of albumin in urine indicates a progressive decline of glomerular function leading to end-stage renal failure. Therefore, early detection by monitoring microalbumin in both type I and II diabetic patients is advocated. "Detecting Hidden Renal Disease". The earliest clinical evidence of renal dysfunction in diabetic patients is the appearance of microscopic amounts of albumin in the urine (microalbuminuria). In the past, this condition often went untreated or undetected. Today, however, it is widely accepted that microalbuminuria often advances to overt albuminuria (>300 mg/day). This then leads to progressive decline in renal function and finally to end-stage renal disease (MPG, 2006).

2.11 Management of diabetes

2.11.1 Management strategies of type 2 diabetes

Optimal control or 'tight control' reduces complication rates if hypoglycemia can be averted and the patient/family members are willing to participate in the necessary regimen. These goals are achieved through a medically monitored program of diet, medication, exercise and education. However, education with continuing reinforcement are important in maintaining even suboptimal control for some patients (CDC, 2005).

2.11.2 Non- pharmacological treatment

Diet and exercise are the cornerstones of treatment for persons with type 2 diabetes mellitus, yet patients find these areas of self-management to be the most difficult (Shultz, et al., 2001).

a-Diet

Diet is the initial treatment of type 2 diabetes. No patient should be commenced on oral medication before they have been given an adequate trial of diet (6–12 weeks). If patients are unwell and needing urgent treatment insulin should be considered (NHS, 2006).

b- Exercise (physical activity)

This should be encouraged. The more the better. It will help lower blood glucose but not necessarily achieve weight loss. A minimum target should be 30 minutes moderate intensity physical activity most days of the week (NHS, 2006).

Physical activity promotes weight reduction and improves insulin sensitivity, thus lowering blood glucose levels. Together with dietary treatment, a programme of regular physical activity and exercise should be considered for each person. Such a programme must be tailored to the individual's health status and fitness.

People should, however, be educated about the potential risk of hypoglycaemia and how to avoid it (Alwan, 1994).

2.11.3 Pharmacological treatment (medications)

Oral medications are required for type 2 diabetes when the disorder is inadequately controlled by diet and exercise programs alone, metformin is drug of choice in patients above ideal body weight (BMI>25) with inadequate glycaemic control, gastrointestinal side effects common but usually dose and duration related and about 10% of patients will not tolerate**.** Sulphonylureas indicated for patients who are of normal body weight, where diet alone has failed, may be added to patients inadequately controlled on metformin, sulphonylureas are potentially dangerous drugs with significant risk of hypoglycaemia. The other additional medication includes thiazolidenediones (glitazones), a new class of oral hypoglycaemic agent reducing insulin resistance and increasing glucose uptake into peripheral tissue and acarbose, it is occasionally useful in the overweight patient where metformin is contraindicated (NHS, 2006).

2.11.4 Combined therapy

Combination of metformin and insulin can be effective especially in overweight patients with poorly controlled diabetes. Can achieve better control with less weight gain than adding sulphonylureas. Combination with sulphonylurea and insulin rarely used. Achieves similar levels of glycaemic control with insulin alone but with lower dose of insulin. Occasionally useful in the elderly where once daily insulin in addition to their oral medication can improve control (NHS, 2006).

2.11.5 Insulin therapy

There are a few absolute indications for insulin in type 2 diabetes and a discussion of its use with the hospital clinic is recommended. In the appropriate patient, where the problem is predominantly insulin deficiency, (poor control in a lean patient or with weight loss) insulin is a good treatment for type 2 diabetes.

Optimal control or 'tight control' reduces complication rates if hypoglycemia can be averted and the patient/family members are willing to participate in the necessary regimen (NHS, 2006).

2.12 Optimal control of type-2 diabetes:

According to the MOH, Palestinian guidelines DM in 2004 obtained control of type 2 divided into:

1-Maintain fasting glucose levels below 120 mg% (80 to 140 mg% on most tests); less than 180 mg% 1.5 to 2 hours post-prandial, bedtime glucose 100 to 140 mg%, and maintain the average glucose <150 mg%. In patients with a history of hypoglycemia, these targets should be increased on an individualized basis.

2-Maintain glycohemoglobin (HbA1c) levels within 1.0 unit of the upper limit of the normal range.

3-Maintain weight, adjusted for height, frame and sex. weight control is a key issue for lipid and glucose control in the non-insulin dependent diabetic.

4-The primary goal of therapy for adults should be to decrease blood pressure to < 130/80 mmHg (MOH, 2004).

Blood pressure control can reduce cardiovascular disease (heart disease and stroke) by approximately 33% to 50% and can reduce microvascular disease (eye, kidney, and nerve disease) by approximately 33%. In general, for every 10 millimeters of mercury (mm Hg) reduction in systolic blood pressure, the risk for any complication related to diabetes is reduced by aggressive management of hypertension, particularly using ACE inhibitors, will delay the onset of nephropathy and other microvascular-related disorders by 12% (CDC, 2005).

5-Control of blood lipids : In diabetic patients, test for lipid disorders at least annually and more often if needed to achieve goals. Total serum cholesterol should be maintained less than 200 mg/dl, LDL should be maintained at $\leq$ 100 mg/dL. A secondary goal is to increase HDL cholesterol to >35 mg/dL in men and > 45 mg/dL in women, triglyceride should be maintained less than 150 mg/dl. lipid assessments may be repeated every 2 years. Improved control of cholesterol or blood lipids can reduce cardio-vascular complications by 20% to 50%.

6-Smoking cessation is a mandatory recommendation for all smokers; avoid ‘second-hand’ smoke.

7-An exercise program should be a clear and specific recommendation (CDC, 2005).

2.13 Complication of diabetes

Diabetes mellitus, especially if poorly controlled, is a major contributory cause for blindness, heart attacks, amputations, strokes, kidney failure and impotence (Anthony, et al., 2004). Acccording to diabetes fact sheet, diabetes is the main cause of new blindness, kidney failure and amputations. It is also a major risk factor for heart disease, stroke and birth defects. Diabetes is the sixth leading cause of death from disease. Diabetes doubles the risk for death 8 and shortens the average life span by up to 15 years (ADA, 2003). A study was done by Abu Mousa about the Magnitude of Diabetes Mellitus in Gaza Strip in 1999, he stated that although complication associated diabetes were under reported, 65.5% were found to suffer from one or more of the common complications; cardiovascular, retinopathy, nephropathy and neuropathy (Abu Mousa, 1999).

2.13.1 Heart disease and stroke

Heart disease is the leading cause of diabetes-related deaths. CVD is the major cause of mortality for individuals with diabetes. Adults with diabetes have heart disease death rates about 2 to 4 times higher than adults without diabetes. The risk for stroke is 2 to 4 times higher among people with diabetes. About 65% of deaths among people with diabetes are due to heart disease and stroke (CDC, 2003). It is also a major contributor to morbidity and direct and indirect costs of diabetes. Type 2 diabetes is an independent risk factor for macrovascular disease, and its common coexisting conditions (e.g., hypertension and dyslipidemia) are also risk factors (ADA, 2006).

2.13.2 High blood pressure

Hypertension, which also increases the risk of atherosclerosis, is twice as common in patients with type 2 diabetes as in persons without diabetes. Patients with diabetes must have their hypertension treated aggressively to lessen their risk of developing serious atherosclerosis (Scott and Anne, 2004). About 73% of adults with diabetes have blood pressure greater than or equal to 130/80 mm Hg or use prescription medications for hypertension (CDC, 2003).

2.13.3 Blindness

Diabetic retinopathy depends on the duration of their diabetes as well as the level of glycemic control maintained. Importantly, since the diagnosis of type 2 diabetes often is delayed, 20% of these patients have some degree of retinopathy at the time of diagnosis (Scott and Anne, 2004).

Diabetes is the leading cause of new cases of blindness among adults aged 20-74 years. Diabetic retinopathy causes 12,000 to 24,000 new cases of blindness each year (CDC, 2003).

2.13.4 Kidney disease

All patients with diabetes should be considered to have the potential for renal impairment unless proven otherwise (Scott and Anne, 2004). Diabetes is the leading cause of end-stage renal disease, accounting for 44 percent of new cases. In 2001, 42,813 people with diabetes began treatment for end-stage renal disease. And a total of 142,963 people with end-stage renal disease due to diabetes were living on chronic dialysis or with a kidney transplant (CDC, 2003).

2.13.5 Nervous system disease

About 60% to 70% of people with diabetes have mild to severe forms of nervous system damage. The results of such damage include impaired sensation or pain in the feet or hands, slowed digestion of food in the stomach, carpal tunnel syndrome, and other nerve problems. Severe forms of diabetic nerve disease are a major contributing cause of lower-extremity amputations (CDC, 2003).

2.13.6 Amputations

Between 50% and 70% of all nontraumatic lower-extremity amputations occur in diabetic patients. The insensate, poorly perfused foot is at risk for ulcers from pressure necrosis or inflammation from repeated skin stress and unnoticed minor trauma. Either can evolve into cellulitis, osteomyelitis, or nonclostridial gangrene and end in amputation (Scott and Anne, 2004).

2.13.7 Dental disease

Periodontal (gum) disease is more common among people with diabetes. Among young adults, those with diabetes have about twice the risk of those without diabetes.

Almost one-third of people with diabetes have severe periodontal diseases with loss of attachment of the gums to the teeth measuring 5 millimeters or more (CDC, 2003).

2.14 Prevention of diabetes

2.14.1 Primary prevention:

The prevention of type 1 and type 2 diabetes requires different strategies, as they have quite different causes. Primary prevention efforts are focused on the reduction of obesity and physical inactivity, which are the known modifiable risk factors for type 2 diabetes only (Show and Chisholm, 2003). Type 1 diabetes currently cannot be prevented. It is an

autoimmune disorder, and is not caused by poor health behaviors. Type 2 diabetes can be a result of poor health behaviors, such as being overweight or obese. Maintaining a healthy diet, weight and exercising regularly may help protect against the development of Type 2 diabetes. For people with "pre-diabetes" (elevated blood sugar), losing weight and doing physical activity can prevent or delay progression to actual diabetes (ADA, 2002).

2.14.2 Secondary prevention:

Secondary prevention involves early identification of diabetes through screening to prevent or delay the progression of the disease (Show and Chisholm, 2003).

According to the American Diabetes Association in 2002, at least one-third of people with type 2 diabetes go untreated because they do not know they have the condition. Many of these people will be diagnosed with diabetes only after they have developed serious complications, such as heart attack, kidney disease, poor circulation, or impaired eyesight.

People with type 2 diabetes may be able to control their blood sugar through diet and exercise. Others may need to take oral diabetes medicines alone or in combination to lower their blood glucose levels. If this does not work, insulin may be necessary to add to the regimen. Preventing complications from diabetes is an important focus of diabetes management. Maintaining glucose control (as measured by the blood HbA1c level) is the critical aspect of diabetes management and prevention of complications.

Even a minimal reduction in HbA1c has a dramatic impact: for every 1 point reduction in HbA1c, the risk of developing eye, kidney and nerve disease is reduced by 40% (ADA, 2002). In addition to HbA1c control, people with diabetes need to take care of their eyes, skin and heart to prevent diabetes complications. Detection and treatment of diabetic eye disease (through a yearly eye exam) can reduce severe vision loss by 50-60%. Comprehensive foot

care (careful washing and drying of the feet and checking for blisters or cuts that might not heal) can reduce the amputation rate by 45-85%. Detection and treatment of early kidney disease can reduce the development of kidney failure by 30-70%. Blood pressure control can reduce risk of heart disease and stroke by 33-50% and eye, kidney and nerve disease by 33%. Control of cholesterol can reduce the risk of cardiovascular complications by 20-50%. Screening for and treating depression is an important part of diabetes care. Depression rates are much higher in individuals with diabetes.

The symptoms of depression can affect the course of the illness, as well as the person's ability to follow the treatment recommendations. Working with their health care providers, people with diabetes can learn to manage their diabetes. Following a treatment plan for medication, monitoring (self-monitoring of blood glucose, daily foot exams), and lifestyle changes (diet, exercise) are essential. People with diabetes should see their doctor at least every 3 months, and receive all recommended health screenings and services, including: quarterly HbA1c blood screening, annual dilated eye exam, annual lipid/cholesterol screening, foot exam at every visit, annual screening for kidney disease, dental exams at least twice a year, blood pressure screening (at every visit). Other important aspects of diabetes care include smoking cessation (ADA, 2002).

2.14.3 Tertiary prevention:

Tertiary prevention is aimed at delaying or preventing the development of complications in people who already have diabetes. Tight control of blood sugar and blood pressure reduces the rate of microvascular disease and macrovascular disease (heart disease or stroke) in people with type 2 diabetes. The treatment of hyperlipidemia also prevents the development of macrovascular disease in people with diabetes. For all people with diabetes, regular foot and

eye examinations with proper preventive treatment can prevent amputations and progression of retinopathy. Diabetes education of health care professionals and those affected by diabetes plays a key role in the tertiary prevention of the disease (Show and Chisholm, 2003).

Persons with diabetes must understand their disease and be empowered to avoid obesity, smoking and unhealthy diets, and encouraged to exercise, and control blood glucose. Good health education, health promotion and access to professional care are essential for persons with diabetes mellitus (Anthony, 2004).

2.15 Consequences of non-compliance

There is strong evidence that many patients with chronic illnesses including diabetes, have difficulty adhering to their recommended regimens. This results in less than optimal management and control of the illness. Poor adherence is the primary reason for suboptimal clinical benefit. It causes medical and psychosocial complications of disease, reduces patients' quality of life, and wastes health care resources.

Rapoff in 1999 summaries the consequences of poor adherence as: increased office visits, decreased responsiveness to medication, exacerbation of side effects, exacerbation of acute illness, increased risk of future health problems, increased risk for future inappropriate medical recommendations, and Impaired provider-patient relationship. The problems that may result from non-adherence not only include the personal costs to the patient and provider, but also have a negative impact on an already overwhelmed health care system. Taken together, these direct consequences impair the ability of health care systems around the world to achieve population health goals. For these reasons, difficulties with adherence should be assumed and each patient should be questioned as though the provider understands how difficult it can be to follow medical recommendations (Christophersen and Mortweet, 2005).

World Health Organization in 2003, reported that the consequences of poor adherence to long-term therapies are poor health outcomes and increased health care costs. Adherence is a primary determinant of the effectiveness of treatment because poor adherence attenuates optimum clinical benefit. Good adherence improves the effectiveness of interventions aimed at promoting healthy lifestyles, such as diet modification, increased physical activity, non-smoking, and of the pharmacological-based risk-reduction interventions. It also affects secondary prevention and disease treatment interventions.

In studies on the prevention of diabetes type 2, adherence to a reduced-fat diet and to regular physical exercise has been effective in reducing the onset of the disease. For those already suffering the disease, good adherence to treatment, including suggested dietary modifications, physical activity, foot care and ophthalmologic check-ups, has been shown to be effective in reducing complications and disability, while improving patients' quality of life and life expectancy. Level of adherence has been positively correlated with treatment outcomes in depressed patients, independently of the anti-depressive drugs used.

In addition to their positive impact on the health status of patients with chronic illnesses, higher rates of adherence confer economic benefits. Examples of these mechanisms include direct savings generated by reduced use of the sophisticated and expensive health services needed in cases of disease exacerbation, crisis or relapse. Indirect savings may be attributable to enhancement of, or preservation of, quality of life and the social and vocational roles of the patients. The development of resistance to therapies is another serious public health issue related to poor adherence, among other factors. In addition to years of life lost due to premature mortality and health care costs attributable to preventable morbidity, the economic consequences of poor adherence include stimulating the need for ongoing investment in research and development of new compounds to fight new resistant variants of the causative

organisms. The “chronic” investment in research and development could be avoided if adherence rates were higher, and the resources could be better used in the development of more effective and safer drugs, or by being directed to the treatment of neglected conditions. There is growing evidence to suggest that because of the alarmingly low rates of adherence, increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments (WHO, 2003).

2.16 Measures of compliance

Adherence to medication regimens has been monitored since the time of Hippocrates, when the effects of various potions were recorded with notations of whether the patient had taken them or not. Even today, patients' self-reports can simply and effectively measure adherence. The methods available for measuring adherence can be broken down into direct and indirect methods of measurement as mentioned by Osterberg and Blaschke in 2005. They stated that each method has advantages and disadvantages, and no method is considered the gold standard. Directly observed therapy; measurement of concentrations of a drug or its metabolite in blood or urine, and detection or measurement in blood of a biologic marker added to the drug formulation are examples of direct methods of measures of adherence. Direct approaches are expensive, burdensome to the health care provider, and susceptible to distortion by the patient. However, for some drugs, measuring these levels is a good and commonly used means of assessing adherence.

Indirect methods of measurement of adherence include asking the patient about how easy it is for him or her to take prescribed medication, assessing clinical response, performing pill counts, ascertaining rates of refilling prescriptions, collecting patient questionnaires, using electronic medication monitors, measuring physiologic markers, asking the patient to keep a

medication diary, and assessing children's adherence by asking the help of a caregiver, school nurse, or teacher. Questioning the patient (or using a questionnaire), patient diaries, and assessment of clinical response are all methods that are relatively easy to use, but questioning the patient can be susceptible to misrepresentation and tends to result in the health care provider's overestimating the patient's adherence (Osterberg and Blaschke, 2005).

Also they stated that the most common method used to measure adherence, other than patient questioning, has been pill counts (i.e., counting the number of pills that remain in the patient's medication bottles or vials). This method is subject to many problems, because patients can switch medicines between bottles and may discard pills before visits in order to appear to be following the regimen. For these reasons, pill counts should not be assumed to be a good measure of adherence. A medical system that uses electronic medical records and a closed pharmacy can provide the clinician or research scientist with readily available objective information on rates of refilling prescriptions that can be used to assess whether a patient is adhering to the regimen and to corroborate the patient's responses to direct questions or on questionnaires (Osterberg and Blaschke, 2005).

Electronic monitors capable of recording and stamping the time of opening bottles, these devices provide precise and detailed insights into patients' behavior in taking medication, but they are still indirect methods of measuring adherence; they do not document whether the patient actually ingested the correct drug or correct dose. Patients may open a container and not take the medication, take the wrong amount of medication, or invalidate the data by placing the medication into another container or taking multiple doses out of the container at the same time.

At present, there is no ‘gold standard’ measure of medication adherence. Various objective methods have been employed to assess adherence (Osterberg and Blaschke, 2005).

2.17 Identifying poor adherence

World Health Organization report in 2003 focused on that poor adherence should always be considered when a patient's condition is not responding to therapy.

The simplest and most practical suggestion for physicians is to ask patients non judgmentally how often they miss doses. Patients generally want to please their physicians and will often say what they think their doctor wants to hear. It can be reassuring to the patient when the physician tells them, "I know it must be difficult to take all your medications regularly. How often do you miss taking them?" this approach makes most patients feel comfortable in telling the truth and facilitates the identification of poor adherence. A patient who admits to poor adherence is generally being candid. Patients should also be asked whether they are having any side effects of their medications, whether they know why they are taking their medications, and what the benefits of taking them are, since these questions can often expose poor adherence to a regimen (WHO, 2003).

2.18 Barriers to adherence

Research on adherence has typically focused on the barriers patients face in taking their medications. As found in that research common barriers to adherence are under the patient's control, so that attention to them is a necessary and important step in improving adherence. Physicians contribute to patients' poor adherence by prescribing complex regimens, failing to explain the benefits and side effects of a medication adequately, not giving consideration to the patient's lifestyle or the cost of the medications, and having poor therapeutic relationships with their patients. More broadly, health care systems create barriers to adherence by limiting access to health care, using a restricted formulary and having prohibitively high costs for drugs, co-payments, or both. To improve the patient's ability to follow a medication regimen, all potential barriers to adherence need to be considered. An expanded view that takes into account factors under the patient's control as well as interactions between the patient and the health care provider and between the patient and the health care system will have the greatest effect on improving medication adherence (WHO, 2003).

2.19 Improving compliance:

The “state-of-the-art” adherence interventions target the patient, the provider, and the health care system.

Several programs have demonstrated good results using multilevel team approaches. Researches on interventions to promote adherence has focused largely on modifying patient behaviour. According to several published reviews on adherence, no single intervention targeting patient behaviour is effective, and the most promising methods of improving adherence behaviour use, a combination of the strategies which include:

patient education , behavioural skills , self-rewards, social support , and telephone follow-up. Various combinations of these techniques have been shown to increase adherence and improve treatment outcomes.

2.19.1 Patient interventions

The interventions reported by Kem, et al. in 2003 to improve adherence was adherence aids, written and oral education/counseling, simplification of the dosage regimen, refill and follow-up reminders, contracts with patients, and comprehensive management, including special training regarding disease state or medication consumption and contracts with patients. The description of these aids was as follow:

a- **Adherence aids**

Adherence aids are devices such as medication calendars, medication organizers, and electronic devices that help patients organize and take their medications appropriately. Some are low-technology and low-cost (e.g., a pill box or medication calendar).

Others use more sophisticated technology at a higher cost (e.g., electronic caps, alarms, Internet-based devices).

The ideal adherence device would be described as being “closed loop.”

Closed-loop devices operate online and in real time, assuring the highest levels of adherence and outcomes monitoring capabilities. These devices help patients in real time with active monitoring, they help patients remember to take their medication through the use of alarms and verification checks, they help patients remember whether they have taken a particular dose by giving information about what has taken place, they reduce the complexity of the medication regimen by grouping doses for patients to take at a given time and displaying the action required by the patient.

b- Refill and follow-up reminders

Refill and follow-up reminders are printed, electronic, or telephone messages that notify patients when it is time to refill their medication or follow up with a health care provider. These reminders may be triggered by a pharmacy or patient management computer system.

c- Simplification of the dosage regimen

Simplification of the dosage regimen may include conducting a drug utilization review to decrease the number of medications a patient is taking, decreasing the number of daily doses by switching to extended-release formulations, or using some form of adherence packaging.

d- Written and oral education

Written and oral education can take many different forms, such as pharmacist counseling, patient specific education sessions focusing on the disease and its treatment, point-of-care educational pamphlets, or point-of-care technology that helps pharmacists show patients how to use medications appropriately. Online compendia are available to support pharmacists' decision making regarding patient care.

Counseling or education sessions that are tailored to individual patients have been shown to improve adherence.

e- Comprehensive management

This category includes patient education on disease state or medication use in combination with one or more of the following: contracts with patients, adherence aids, reminder systems, or dosage simplification. This form of intervention also goes beyond a one-time interaction with the patient to include some form of follow-up (Kem, et al., 2003).

The most effective adherence-enhancing interventions directed at patients aim to enhance self-regulation or self-management capabilities. Self-management programmes offered to patients with chronic diseases can improve health status and reduce health care utilization and costs.

Several strategies appear to be effective, at least in the short term. These include: self-monitoring, corrective feedback, behavioural contracting, commitment enhancement, creating social support, reinforcement; and relapse prevention. A meta-analysis of 28 studies revealed that the key intervention components were providing reinforcement (WHO, 2003).

2.19.2 Interventions directed to providers

Because providers have such a significant role in adherence, designing interventions to influence their behaviour seems a reasonable strategy. Training providers in patient-centred methods of care may be effective, but the strongest effects of such training appear to be on patient satisfaction with treatment (WHO, 2003).

2.19.3 Education of health providers

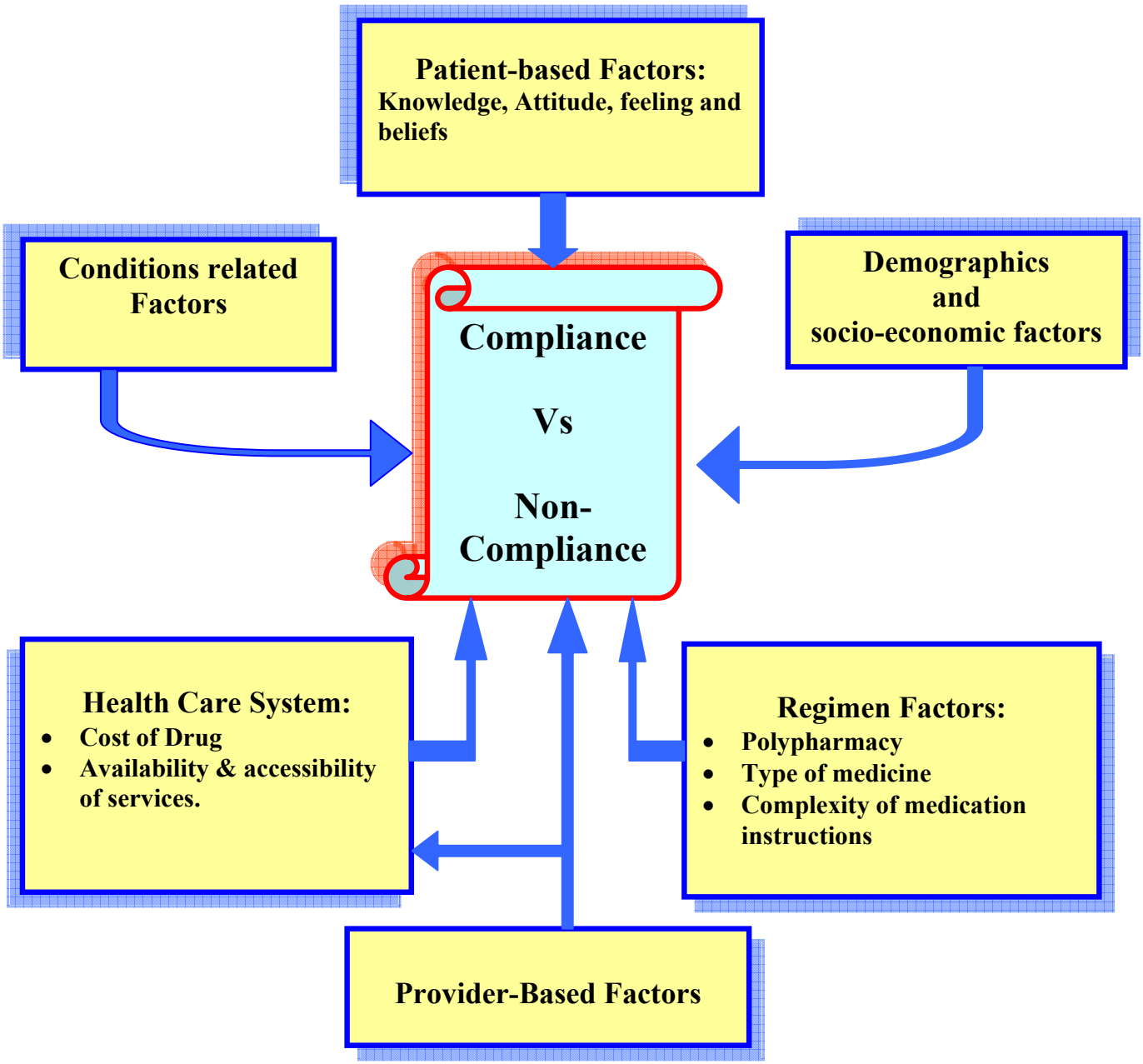
Diabetes care at secondary and tertiary levels is ideally provided by a multidisciplinary team consisting of a doctor, nurse, dietitian, pharmacist, chiropodist and others, although it is recognized that some of these may not be available in many countries of the Region. At the primary care level, absence of trained health care professionals makes it difficult to provide diabetes care; therefore, one of the main priorities of the diabetes control programme should be to respond to this gap by promoting knowledge and skills of primary health care providers in diabetes care and strengthening community participation in this respect (Kem, et al., 2003).

2.19.4 Interventions in the health system

Interventions in the health system are higher order interventions affecting health policy; organization and financing of care and quality of care programs. Creation and adoption of chronic care models of service delivery, which, at least in patients with diabetes, have been shown to result in better patient outcomes (WHO, 2003).

Chapter 3

Conceptual framework of factors affecting compliance among Type 2 Diabetes Mellitus



The major factors known to affect medication compliance

Health care providers often believe that patients with diabetes do not follow medication and other self-care recommendations due to a lack of self-discipline, limited intelligence, or an unreasonably fearless attitude towards the consequences of diabetes. In fact, data suggest that the major factors influencing compliance are not broad personality characteristics, but rather are situational and specific in nature. Such influences are so specific that, for example, patients taking multiple medications are likely to be selective about which of their medications they take carefully, which they skip from time to time, and which they quit altogether.

The common belief that patients are solely responsible for taking their treatment is misleading and most often reflects a misunderstanding of how other factors affect people's behaviour and capacity to adhere to their treatment. The ability of patients to follow treatments in an optimal manner is frequently compromised by more than one barrier (WHO, 2003).

The major factors known to affect medication compliance are as follows:

3.1 Demographics and socio-economic factors

Demographic, such as age, gender, ethnicity, and socio-economic status have been included in almost every analysis of adherence, although they do not seem to be consistent correlates of whether or not a patient keeps appointments or follows a medication regimen (Platt, 1994).

A study by Albaz in Saudi Arabia in 1997 concluded that organizational variables (time spent with the doctor, continuity of care by the doctor, communication style of the doctor and interpersonal style of the doctor) are far more important than sociodemographic

variables (gender, marital status, age, educational level and health status) in affecting patients' adherence (Albaz, 1997).

Kem, found in 2003 that demographic variables such as age and socioeconomic status have an impact on adherence. Increasing age is generally associated with increasing adherence until patients enter their 70s, when adherence declines. This decrease may be due in part to failing memory or the need for complex medication regimens as people age (Kem, 2003).

Patients who are dependent on significant others, have limited access to transportation, live far away from their clinic, or have a fear of being victimized en route to see a physician may also be unlikely to adhere to treatment regimens (Anderson and Kerk, 1982).

Joel, et al. in 2002 studied adherence in an indigent population, they found that adherence to chronic drug regimens is often suboptimal, lower socioeconomic and minority populations have greater barriers to adherence, which may thwart efforts at improving care and outcomes (Joel et al., 2002).

The out-of-pocket costs of medications have a profound impact on compliance, especially for the elderly and the poor. Patients typically cope with economic hardship by not having prescriptions filled, taking a smaller dose, or buying a cheaper over-the-counter product that is presumed to have a similar effect. Sadly, recent data suggest that patients only rarely discuss this issue with their health care providers, feeling that the cost issue is not their doctors' problem (Kem, 2003).

A retrospective cohort study of newly treated patients (aged 18-64 years) was conducted Adherence with antihyperglycemic pharmacotherapy was conductd by Hertz in 2005, and found that adherence was poor among working-aged patients newly treated for type 2 diabetes (Hertz, 2005).

3.2 Patient-based factors

Patient-related factors represent knowledge, attitudes, beliefs, perceptions and expectations of the patient. Patients' knowledge and beliefs about their illness, motivation to manage it, confidence (self-efficacy) in their ability to engage in illness-management behaviours, and expectations regarding the outcome of treatment and the consequences of poor adherence, interact in ways not yet fully understood to influence adherence behaviour (WHO, 2003).

A study was done by Cramer in 1991, he found in responses to a questionnaire, typical reasons cited by patients for not taking their medications included forgetfulness (30 percent), other priorities (16 percent), decision to omit doses (11 percent), lack of information (9 percent), and emotional factors (7 percent), 27 percent of the respondents did not provide a reason for poor adherence to a regimen (Cramer, 1991).

3.2.1 Knowledge:

It has been assumed by many that patients who are knowledgeable about their illness and therapeutic regimen usually are more likely to be compliant, studies suggest that increase patient knowledge does not necessary affected patient's behavior and compliance (Jaser,1999).

In a study conducted in Egypt by Kamel, et al. in 1999 to determined diabetics' knowledge of the disease and their management behavior. The study aimed to describe the level of knowledge of diabetic patients about the disease, showed the relationship between demographic variables (age, sex and education) and level of knowledge and revealed the relationship between knowledge and management-related behavior of diabetics. The researcher studied 300 randomly chosen diabetic patients to assess their behaviors in relation to management of their disease, they found that the majority of diabetic patients

(90.0%) had poor knowledge about the disease, 83.7% had poor knowledge about the complications associated with diabetes and 96.3% had poor awareness of how to control the disease. The poor level of knowledge that diabetics had about their disease suggested that health care providers need to be trained in the areas of information, education and communication (Kamel, et al., 1999). Numerous studies have shown a relationship between psychosocial factors and treatment adherence in diabetes. Wilson and colleagues reported that mood, knowledge of diabetes care, social support and health beliefs were collectively predictive of better compliance (Wilson et al., 1986).

Adherence is more likely if the patient has experienced the illness previously or has known someone impaired by the illness in question. Such experience may make patients aware of their vulnerability and of the need to act to minimize the risks of disease (Anderson & Kirk, 1982).

Health information tailored specifically to the individual appears more effective than generic information in promoting risk-reducing behaviour changes in overweight subjects (Clark, et al., 1999).

Petty and Cacioppo in 1981 proposes that people are more likely to process information thoughtfully if they perceive it as personally relevant.

3.2.2 Attitudes and beliefs about non-pharmacological treatment

A study examined attitudes and beliefs about exercise among 83 persons with non-insulin-dependent diabetes who had completed outpatient diabetes counseling conducted by Swift, et al. in 1995 adapt the health belief model which labeled the exercise behavior model, guided perceptual measures which indicated that fifty-two percent of the subjects were exercising 3 or more days per week. Those with a greater length of time since

diabetes counseling were more likely to be currently exercising. Positive and negative attitudes toward exercise characterized the group however, only negative attitudes were related to exercise. Both exercisers and non-exercisers perceived barriers to exercise. Other people, chance happenings, physical discomfort, and perceptions of fitness, weight, and appearance played a role in whether the subjects exercised. The results indicate that providing assistance in identifying support for exercise and overcoming perceived barriers to exercise may increase compliance to this important aspect of the diabetes regimen (Swift, et al., 1995).

Physical activity is integral to the management of type 2 diabetes. Unfortunately, the majority of adults with type 2 diabetes do not regularly engage in physical activity, in a study conducted by Hays and Clark in 1999, they found that the majority of the respondents (54.6%) reported zero min of weekly physical activity. This was especially true of older female respondents, they also found that physical activity knowledge varied by age-group, and barriers to physical activity were prevalent in all groups, so they concluded that the low prevalence of physical activity should raise concerns among clinicians (Hays and Clark, 1999).

A survey was conducted by Searle and Ready in 1991 to assess the potential for an exercise and weight control program for persons with type II diabetes. Questionnaire forms were sent to 1,000 individuals with diabetes, who were randomly selected from the provincial health records office. Physicians and dietitians were the primary sources of information about both exercise and diet. Although few respondents participated in organized (7.7%) or informal (36.8%) exercise programs, or expressed an interest in participating (36.8%), the majority (84.0%) believed that they should get more exercise. This points to a gap between

attitude and behaviour. It was concluded that barriers must be assessed, and behaviour modification included, if diet and exercise programs are to be successful (Searle and Ready, 1991).

3.2.3 Attitudes and beliefes toward disease

Non-adherence in many chronic illnesses has been linked to attitude of a patient toward him/herself and the illness (Wichowski and Kubach, 1997).

In a study was done to investigate attitudes of people with diabetes toward their disease and its treatment from their point of view, it was found that the reaction and attitude physicians displayed toward patients at the point of diagnosis were crucial in influencing attitudes toward perceived seriousness of the disease and consequently compliance.

Difficulties in adhering to a treatment plan and inadequate perceived seriousness of the disease were factors contributing to a lack of compliance. Participants reported that when diabetes complications started their compliance improved (Dietrich, 1996).

Patients are most likely to comply with medication recommendations if they recognize that: diabetes is a serious disease with potentially serious consequences, and the risk of those consequences can be reduced through active self-care. Unfortunately, many people with diabetes minimize the dangers of not controlling their disease while many others recognize these dangers but feel helpless in preventing them. Studies show that health beliefs and diabetes self-efficacy predict adherence to diabetes self-care recommendations (Aljasem, et al., 2001).

Physicians seem to agree that non-compliance by diabetic patients is a problem. Despite this, there have been few qualitative studies on the actual behaviors, beliefs, and attitudes of diabetic patients, a study conducted by McCord and Brandenburg in 1995, they concluded

that a better understanding of patients' beliefs and attitudes may help physicians increase motivation, understanding, and compliance of diabetic patients (McCord and Brandenburg, 1995).

3.2.4 Patient beliefs about their medications

Patients are most likely to comply with medication recommendations when they can recognize that the medication is helping them. Unfortunately, few patients can feel the benefits of important diabetes medications, especially those that lower blood pressure and cholesterol levels. Patients may sometimes notice immediate positive benefits when blood glucose levels are lowered (eg, reduced fatigue or improved sleep quality), but many patients do not feel these changes, and some may become aware of only negative consequences (eg, hypoglycemia). The absence of any perceived evidence that a medication is working makes it essential that patients understand and appreciate the drug's "invisible" benefits. Compliance is also impaired when significant side effects occur. In addition to hypoglycemia, OHAs may cause gastrointestinal distress, significant weight gain, and other troublesome side effects. In some cases, as in the resistance many people with type 2 diabetes feel about beginning insulin therapy, the problem may be personal beliefs (often based on invalid assumptions) about the potential side effects of the medication (Polonsky, et al., 2003).

Anderson & Kirk in 1982, suggest that if an illness has easily recognizable and unpleasant symptoms that are improved by following treatment recommendations, adherence is more likely. In diabetes, many of the symptoms are not evident until later in life. Therefore, many individuals will not feel the urgency of undergoing a treatment regimen or making lifestyle changes immediately.

3.2.5 Social and Health Beliefs:

Patients hold many beliefs about their health and about the potential efficacy of any proposed treatment action. Patients' beliefs can be based on: misconceptions, faulty information, and/or cultural conditioning. For example, some elderly people may believe:"You need to give your body some rest from medicine once in awhile or else your body becomes dependent on it or immune to it," or 'You only take medicine when you are ill and not when you feel better," or "If one dose is good, two must be better. These beliefs and feelings may be shared and supported by significant others in the patient's life (Kusserow, et al., 1999).

Lack of family and social support has been linked to poor compliance with prescribed medication use (and other self-care behaviors) across a number of different disease states When patients have friends or family members who are providing emotional and/or material support (eg, reminders to take medications), it is more likely that higher levels of medication compliance will be maintained. Several studies have shown that persons with diabetes who have greater social support are more likely to follow insulin regimen recommendations (Ruggiero, et al., 1990).

3.2.6 Belief and use of traditional remedies by diabetic patients

Al-Saeedi et al, in 2003, interviewed 1039 diabetic patients in Saudi Arabia using a structured questionnaire about belief in traditional herbal remedies. The study showed that 15.6% of the sample believed that traditional medicines were safe and effective and 25.8% that they might be beneficial. One-third of patients were using traditional remedies. A statistically significant relationship was shown between belief in traditional medicines and variables such as female sex, positive family history of diabetes, duration of diabetes and compliance with diet. However, there was no relationship with other compliance variables

or with glucose and weight control. They concluded that efforts should be made to enhance diabetic education among patients on the basis of evidence-based practice (Al-Saeedi, et al., 2003).

3.3 Regimen factors

3.3.1 Polypharmacy

Non-adherence to polypharmacy regimens may be defined as overutilisation, underutilisation, discontinuation or abuse of medication, and is most often associated with preventable increases in morbidity and mortality.

Polypharmacy is problematic for older persons because it is the greatest risk factor for ADRs (adverse drug reactions), drug interactions, reduced compliance and increased emergency room visits, hospitalizations, and nursing home admissions (Michael, 2004).

Dosing frequency is inversely related to compliance. The highest levels of compliance are seen with oral medications taken once daily. Paes et al for example, found that OHA compliance dropped from 79% for once-daily medications to 38% for medications taken 3 times a day. In addition, when patients are taking multiple OHAs, compliance levels fall. Even when OHAs are taken only once daily, problems may arise. Overconsumption of once-daily OHAs has been shown to occur in as many as one-third of patients. Treatment complexity issues are especially important for elderly patients, who may have difficulty with memory or concentration (Paes, et al., 1997).

In another study was conducted by Winkler et al. in 2002 to collect information about the dynamics and patterns of compliance of elderly patients with type 2 diabetes mellitus on oral treatment. They found that once daily dosage led to significantly better adherence rates than two or three times daily regimens. However, over-compliance was surprisingly high and occurred more frequently on a once daily regimen (Winkler, et al., 2002).

Similarly a study done by Jaser, in 1999 in Palestine, he found that the compliance rate was significantly higher among patients taking one type of hypoglycemic drugs and among patients on single daily dose (Jaser, 1999).

Grant, et al. in 2003, randomly selected patients with type 2 diabetes from a single community health center responded to a pharmacist-administered questionnaire regarding medication use to determine medication adherence and predictors of suboptimal adherence in a community cohort of patients with diabetes and to test the hypothesis that adherence decreases with increased number of medicines prescribed. They found that patients reported very high medication adherence rates regardless of number of medicines prescribed. Among patients on multiple medicines, most patients with suboptimal adherence were perfectly adherent to all but one medicine. Unreported side effects and a lack of confidence in immediate or future benefits were significant predictors of suboptimal adherence. Physicians should not feel deterred from prescribing multiple agents in order to achieve adequate control of hyperglycemia, hypertension, and hyperlipidemia (Grant, et al., 2003).

3.3.2 Type of medicine

A literature search (1966–2003) was performed to identify reports with quantitative data on adherence with oral hypoglycemic agents (OHAs) and insulin and correlations between adherence rates and glycemic control. Adequate documentation of adherence was found in 15 retrospective studies of OHA prescription refill rates, 5 prospective electronic monitoring OHA studies, and 3 retrospective insulin studies. Retrospective analyses showed that adherence to OHA therapy ranged from 36 to 93% in patients remaining on treatment for 6–24 months. Prospective electronic monitoring studies documented that

patients took 67–85% of OHA doses as prescribed. Electronic monitoring identified poor compliers for interventions that improved adherence (61–79%; $P < 0.05$). Young patients filled prescriptions for one-third of prescribed insulin doses. Insulin adherence among patients with type 2 diabetes was 62–64%. This review confirms that many patients for whom diabetes medication was prescribed were poor compliers with treatment, including both OHAs and insulin. However, electronic monitoring systems were useful in improving adherence for individual patients. Similar electronic monitoring systems for insulin administration could help healthcare providers determine patients needing additional support (Joyce, 2004).

3.3.3 Complexity of medication instructions

Medication compliance is likely to be impaired when patients are not certain how medications are to be used (ie, “I'm supposed to take my pills at dinner on an empty stomach, but what if my stomach isn't that empty right before dinner?”). This may be due to problems with “health literacy,” where the patient is unable to understand, and thus follow, the provider's specific recommendations. Such confusion may also result when providers do not explain their recommendations clearly, if at all. This may be why OHA compliance is better in patients who rated their communication with their health care provider as "good" (Ciechanowski, et al., 2005). A meta-analysis of adherence studies suggesting that an individual with a history of adherence to a specific treatment regimen would react in a similar fashion to subsequent applications of that same regimen (Dunbar, et al., 1990).

3.4 Provider-based factors:

Role of the Physician: Although most research focuses on the issue of compliance as a patient problem, compliance is the physician's responsibility as well as the patient's. Physicians generally underestimate the levels of noncompliance among their own patients? They have also been shown to be unreliable predictors of whether or not individual patients will comply. Physicians' beliefs about and attitudes toward diabetic patients can affect their interaction and communication with them (Kusserow, et al., 1999).

Provider characteristics and the medical system also affect patients' adherence. Overall patient satisfaction with medical care has been found to correlate with increased adherence. The perception of providers as being warm and caring has been related to greater adherence. Long waiting time and other procedural barriers have been found to decrease adherence to both keeping appointments and taking medications. Because treatment adherence is a challenge not only for the patient but also for the provider, the locus of responsibility and commitment to treatment adherence shifts from being solely a function of the individual to also becoming a function of the provider and the health care team. The relationship between the patient and the provider becomes a therapeutic alliance where both parties work toward a common goal: improving the health of the patient. Defining this goal and the patient's commitment to it largely depends on the therapeutic alliance and the ability of the provider to assess the patient's readiness (Asim, 2004).

The physician-patient encounter is a situation in which patients must learn a very and set of expectations about: the purpose of the medication; which medication should be taken; how long each medication should be taken; and the dosage schedule that should be followed. (Kusserow, et al., 1999).

Anderson and Kirk in 1982 stated that physicians must be aware of the likelihood of noncompliance in individual patients and make efforts to persuade patients of the importance of adherence to a program designed to reach and maintain therapeutic goals. They assert that it is the physician's responsibility to teach, motivate, and strengthen the patient to maximize adherence as part of a "therapeutic partnership" (Anderson and Kirk, 1982).

In Svarstaad's study on physician-patient interaction it was evident that physicians frequently did not discuss their expectations in an explicit manner. Of the 347 medications prescribed during the course of that study: Seventeen percent were never discussed at all. In only ten percent of the cases were patients told how long to take the medication. Dosage schedules were discussed ambiguously 'Take two capsules every four hours" without specifying how many should be taken in a twenty- four hour period. Patients were not always given printed or written instructions for proper use of medications (Kusserow, et al., 1999).

3.5 Health care system

Relatively little research has been conducted on the effects of health care team and system-related factors on adherence. As stated by WHO in 2003, a good patient-provider relationship may improve adherence whereas more broadly, health care systems create barriers to adherence by limiting access to health care, using a restricted formulary and having prohibitively high costs for drugs, co-payments, or both.

System variables include the availability and accessibility of services, support for education of patients, data collection and information management, provision of feedback to patients and health care providers, community supports available to patients, and the training

provided to health service providers. Systems direct providers' schedules, dictate appointment lengths, allocate resources, set fee structures and establish organizational priorities (WHO, 2003).

The failure to care adequately for patients with type 2 DM may be assigned to a lack of patient adherence, a failure of physicians' knowledge and skill level, or insufficient funding and organization of necessary programmes in the current health care system (Brown, et al., 2002).

3.6 Condition-related factors

Condition-related factors represent particular illness-related demands and co-morbidities faced by the patient. Some strong determinants of adherence are those related to the severity of symptoms, level of disability (physical, psychological, social and vocational), rate of progression and severity of the disease, and the availability of effective treatments. Their impact depends on how they influence patients' risk perception, the importance of following treatment, and the priority placed on adherence (WHO, 2003).

Presence of other disease/chronic diseases decreases the compliance, (Jaser, 1999).

It would seem important to take such a psychological profile into consideration when attempting to understand and even alter the health beliefs (Harris, et al., 1984).

For many people, effective, regular diabetes self-care is very difficult. People often make poor personal decisions about health (not just people with diabetes) and do not adequately confront the underlying emotional and psychological issues associated with a diagnosis of diabetes. People with diabetes may feel angry, guilty, resentful or afraid when confronted by the fact of diabetes, and these reactions may interfere with their ability or desire to manage their illness effectively (Wilson, et al., 1986).

Depression is at least twice as common in patients with diabetes as compared with the non-diabetic population. Recent evidence suggests that as many as one-quarter of patients with diabetes may be suffering with a moderate to major depressive disorder, and depression may often go undiagnosed and/or untreated. Needless to say, depression may contribute to problematic medication use, due to increases in forgetfulness and/or a loss of interest in protecting one's health (Mojtabai and Olfson, 2003).

Chapter 4

Methodology

4.1 Study design

It is a cross-sectional study. Cross-sectional study is generally carried out in a population at a part of time or over a short period of time. This type of study is quick and gives some insight into the association between cause and effect, "compliance and other variables", and it provides important pointers to the possible causes.

4.2 Study population

The population of the study consists of a sample of patients from both genders with proved type-2 diabetes patients who registered at Diabetic Clinic in Al-Rimal Central Clinic, According to diabetic care medical records in 2006 the target population is 6400 patients.

4.3 Sample size

A presentative sample of 197 sample size were determined using EPI-6 – program.
19 patients (10%) were added. The total sample size was consisted of 216 patients.

4.4 Sampling method

Cases are chosen by convenient sampling method.

The diabetic clinic works three days per week. Diabetic patients come to Al- Rimal diabetic clinic from different districs of Gaza Strip according to their appointment.

Approximately 30 patients are seen per day, 5-10 patients were selected per each visit.

4.5 Eligibility criteria

4.5.1 Inclusion criteria

Type2 diabetic patients who are registered, treated and followed in central diabetic clinic at Al-Rimal clinic, both genders male and female.

4.5.2 Exclusion criteria

Type1 diabetic patients both genders male and female.

4.6 Setting of the study

The study is carried out at Al- Rimal governmental central diabetic clinic- Gaza City .

It is one of the specialized clinics of primary health care central clinics of Ministry of Health in Gaza Strip.

4.7 Data collection

Data collection was carried out using retrospective review of medical records, structured face to face questionnaire and biophysiological measures.

The questionnaire was designed and prepared to compile information relating to the objectives of the study.

The questionnaire consisting of two parts: information from the patients (personal, sociodemographic, family history of diabetes, lifestyle, medical history of other chronic diseases, medication, knowledge, attitude and practice of patients), and information from the patient's medical file includes (Date of diagnosis, management plan, and biophysiological measures that considered as an indicators for the glycemic control includes the last two reading one year before the date of interview for FBS and HbA1c, the other biophysiological measures include: Total cholesterol, Triglyceride, last four reading of blood pressure, weight and hight for calculation of BMI). The instrument used was in Arabic language because it is the mother language for the participants, annex (7). The average time for filling a questionnaire was 15-20 minutes. Total period of data collection was three months.

Accordind to ADA, 2006 the normal values of the biophysiological measures was as follow: HbA1c=7%, FBS=126mg/dl, total cholesterol=200mg/dl, triglyceride =150mg/dl, Blood pressure=130/80mmHg, Body Mass Index(the weight in kilograms divided by the square of the height in meters),normal weight= BMI range between18.5-24.9, overweight=BMI range between 25-29.9, Obese= BMI range between 30-39.9, morbid obese= BMI range between 40 and over 40. The researcher used these normal values to measure the objectives of the study.

4.8 Compliance definition:

The extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" (WHO, 2003).

In this study compliance was discussed and measured according to the medication regimens plan using indirect method, so that compliance was measured by questioning the patient (or using a questionnaire), then every participant was asked about the medication regimen and comparing the mentioned plan with the exact regimen which had been written by the doctors in his file, if the mentioned plan was compatible with the written one, that participant was considered as compliant and if not, considered as non-compliant.

The non-compliance then was studied in relation to different variables of the study and to biophysiological measures including (HbA1c which is considered as a good indicator of therapeutic outcomes and the glycemic control for the last three months, FBS which reflect the daily glycemic control,blood pressure, total cholesterol and triglyceride). Non-compliance was also dicussed according to the life style (diet and physical activity).

4.9 Content validity

The instrument used for data collection in this study is professtionally prepared with high face validity. The instrument designed after reviewing related literature to enhance content related validity. The researcher depends also on content validity, where the questionnaire was distributed to 10 experts on Public Health and specialists in the field where discussed the questionnaire content validity. Their comments concerning some items were added and/or modified.

4.10 Data entry and analysis

Data was entered and analyzed using statistical package of social science version 10 (SPSS). Data cleaning was performed to check entry errors. Data analysis was as follow: Defining and coding of data, Descriptive analysis was performed to examine the distribution of different factors among the study population Using frequency tables for the study variables.

The dependent variable in the study was the non compliant participants toward their medication regimen, the independent variables were socio-demographic and economic factors, Patient Factors (knowledge, attitude, feelings, beliefs and practice), conditions related problems, regimen factors, provider-based factors and health care system factors.

The relationship between the dependent variables and the independent variables were tested by using Chi Square, the level of significance by using P-value and odds ratio for different variables.

4.11 Ethical matter

1-Helsinki committee (Ethical committee in the Gaza Strip) approval to conduct the study (annex 4).

2-Ministry Of Health approval to collect data from Al- Rimal central diabetic clinic (annex 5).

3-Explanation of purpose of the study, instrument, period of interview, voluntary and optional participation and confidentiality pledge (annex 6).

4-All the ethical concepts were taken into consideration: respect of people, dignity and privacy.

5-Confidentiality was given and maintained all the time.

4.12 Pilot study

A pilot study was carried out on 15 subjects selected by convenient sampling methods to examine predictability, reliability, and validity of study, and to identify any defects in the study design and also areas of difficulties and ambiguity so that changes and adjustments on the design will be made. After piloting process some changes and modifications in the questions were done. These subjects were omitted from the study.

4.13 Limitation of the study

The study included only the registered patients at Al- Rimal central diabetic clinic as it is the only central clinic that have updating files (hard and electronic) which provide rapid and available full data about the patient where information of the study was taken especially HbA1c and this test again is performed only in Al-Rimal clinic.

Convenient sampling is one of the weakest way of sampling.

Chapter 5

Results

Introduction

This chapter represents the core results of the study including socio-demographic characteristic of the study population, health status, risk factors of diabetes, prevalence of non-compliance and associated factors that affecting compliance in the study population.

5.1 Socio-demographic and economic characteristic of the study population

The study population was 216 diabetic patients, type-2 who are attending Al-Rimal clinic, the study showed obvious variations in socio-demographic characteristic.

The distribution of study population according to socio-demographic characteristic including gender, age, marital status, locality, educational level, consanguineous marriage**,** occupation, family size and income presented in table (5.1)

Table 5.1: Distribution of the study sample by sociodemographic and economic characteristics

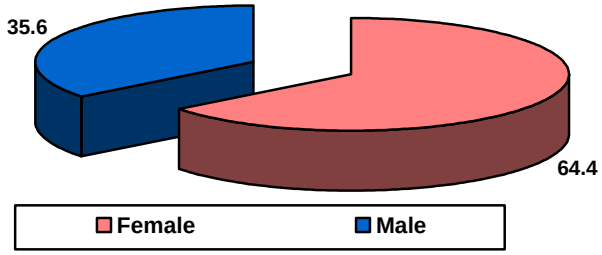
Characteristics		Frequency (N 216)	Percent %
Sex	Male	77	35.6
	Female	139	64.4
Age Group	30-49 years	70	32.4
	50-64 years	112	51.9
	65 years & more	34	15.7
Marital status	Single	14	6.5
	Married	202	93.5
Locality	North Gaza	45	20.8
	Gaza	140	64.8
	Mid-zone	31	14.4
Educational level	Low (0-6years)	110	50.9
	Medium (7-12years)	89	41.2
	High (>12years)	17	7.9

Consanguineous marriage	First degree	73	33.8
	Second degree	33	15.3
	No consanguinity	110	50.9
Occupation	Working	22	10.2
	Not working	194	89.8
Family size	1-5	69	31.9
	6-10	103	47.7
	>10	44	20.4
Income	<1000 NIS	52	24.1
	1000-2000 NIS	48	22.2
	>2000 NIS	40	18.5
	Refuse to answer	76	35.2

5.1.1 Gender

Considering the gender, diabetic females were twice more than males (64.4% and 35.6% respectively) as shown in Figure (5.1).

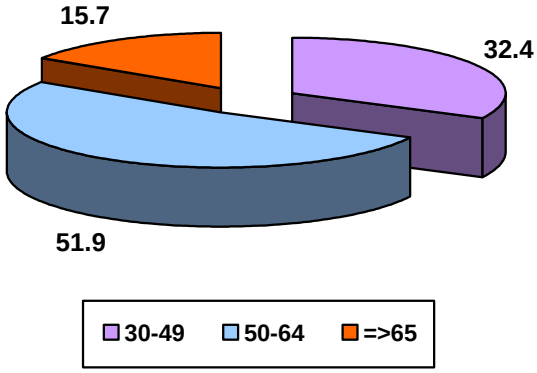
Figure 5.1: Distribution of study population by gender



5.1.2Age

The mean age of patients participated in the study was 54.4 years with standard deviation (SD) 10.3, median 55 years and range from 31 to 85 years old. The highest age category was among middle age group (50-64years), it was represented by 51.9%, then followed by the young age group (30-49), represented by 32.4% then the least percentage 15.7% was among age 65 years and over as shown in Figure(5.2).

Figure 5.2: Distribution of the study population by age group


15.7
32.4
51.9
30-49
50-64
=>65

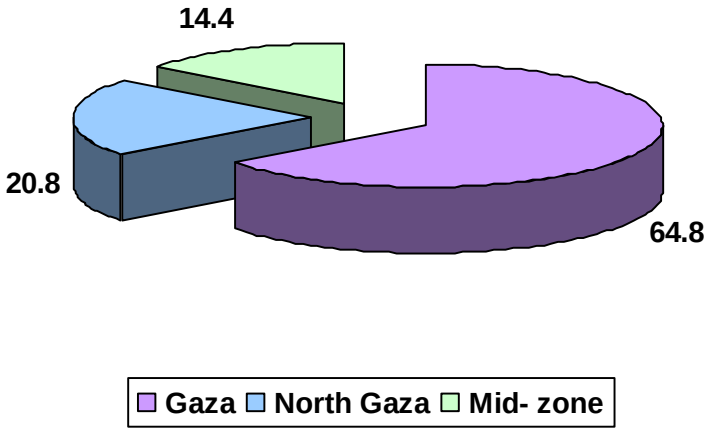
5.1.3 Marital status

The samples showed that the majority were married (93.5%) and 6.5% were single.

5.1.4 Locality

Concerning the locality, most of sample was from Gaza 64.8%, followed by North Gaza 20.8%, and the lowest were from Mid-zone 14.4% as demonstrated in figure (5.3).

Figure 5.3: Distribution of the study population by place of residence



5.1.5 Educational level

Regarding the educational level, the researcher categorized and re-coded the years of education into three categories. The first was low level of 6 years of education and less which represented the majority of the study population (50.9%), the second group was the median level from 7 to 12 years, it was represented by 41.2%, and the third group, high level with more than 12 years of education was represented by 7.9%.

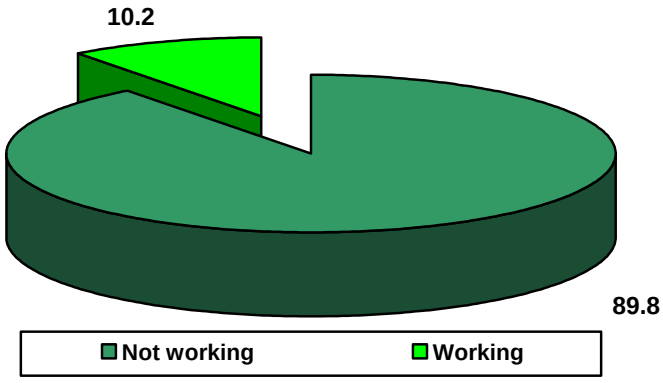
5.1.6 Consanguineous marriage:

There were 73 (33.8%) had first degree consanguinity (cousin), 33 (15.3) were second degree consanguinity (from the family) and the majority were not consanguineous marriage (50.9%).

5.1.7 Occupation

Concerning the occupation, the majority of the sample didn't work (89.9%), only 10.2% were working as shown in figure (5.4).

Figure 5.4: Distribution of study population by occupation



5.1.8 Family size

As showed in table (5.1), the highest percentage 47.7% had a family size ranged between (6-10 persons), followed by family size ranged between (1-5 persons) represented by 31.9%, while the family size of more than 10 persons represented by 20.4%.

5.1.9 Income

Income was divided into three categories; first group was below 1000 NIS, the second category range between 1000-2000 NIS, and the third category above 2000 NIS as shown in table (5.1). Only 18.5% their income was above 2000 NIS, 22.2% of the sample, their income was between 1000-2000 NIS and 24.1% income was below or equal to 2000 NIS, while 35.2% of the study population refused to answer to that question and could be explained as they considered as a confidential matter or didn't know the monthly income of the family.

5.2 Health profile

Health profile for each diabetic patient includes duration of diabetes, family history, associated chronic disease, initial treatment and current treatment as shown in table (5.2) and (5.3) respectively.

Duration of disease was divided into two groups, first group was ten years and over, represented the majority of study population by 64.8%, and the second group included those with duration of diabetes less than ten years represented by 35.2% of study population as shown in table (5.2). A recent study revealed that high post-meal blood sugars cause nerves damage. Ten years of very high post-meal values will eventually destroy the beta cells. By the time; ten years of exposure to high blood sugars have had time to ruin the nerves, blood vessels, retina, kidneys and other useful bits of equipment that we need to stay alive (Tracy, 2006).

Regarding the family history, the majority of the sample had positive family history, it was represented by 78.2%, family history of diabetes related to mother representing with 29.7%,

who related to brother or sister was representing also by (29.7%), 18% related to the father, and others related to uncle, grandfather and son or daughter.

Considering the association of chronic diseases 59.7% of the study population had associated chronic diseases while 40.3% did not. The highest percent (44.9%) of sample population had hypertension, while about 8.8% with ischemic heart disease (IHD) and 5.1% with renal diseases.

Table 5.2: Distribution of study population by duration of diabetes, family history and associated chronic diseases

Variables		Frequency	Percent %
Duration of diabetes	10 years &over	140	64.8
	<10 years	76	35.2
Family History	Positive	169	78.2
	Negative	47	21.8
1-Father		54	18
2-Mother		89	29.7
3-Brother\sister		89	29.7
4-son\daughter		10	3.3
5- uncle		37	12.3
6-Grandfather		21	7
Associated chronic diseases	Yes	129	59.7
	No	87	40.3
1-hypertension		97	44.9
2-IHD		19	8.8
3-Renal		11	5.1

As shown in table (5.3), all patients were asked about their treatment (Initial and current). Concerning initiation of treatment, there were 33.3 % of the study population who started their treatment with diet as non-pharmacological treatment. The highest percent were started with hypoglycemic agent only (60.2%), and 6.5%were started with insulin only. As

a comparison, all patients who were on diet only had been changed to hypoglycemic agents, insulin or mixed treatment (hypoglycemic agents and insulin), they were represented with 64.4%, 17.6% and 18.1% respectively.

Table 5.3: Comparison between initial treatment and current treatment regimen

Treatment regimen	Initial treatment		Current treatment	
	No	%	No	%
Diet	72	33.3	00	0.0
Hypoglycemic agent	130	60.2	139	64.4
Insulin	14	6.5	38	17.6
Mixed	00	0.0	39	18.1

This could be explained by that diabetic disease needs a good control. Once the non-pharmacological treatment is insufficient to control diabetes, other forms of pharmacological treatment should be added.

5.3 Prevalence of non-compliance among study population

The researcher asked the patients about their treatment and frequency of doses, and compared what patients mentioned with the exact regimen that had been written in their files, any missing to their current treatment or doses frequency was considered as non-compliance. The results revealed that the prevalence of non- compliance among the study population was 109 (50.5%), as shown in table (5.4). According to World Health Organization a number of rigorous reviews have found that, in developed countries, adherence among patients suffering chronic diseases average only 50% (WHO, 2003). In this study adherence among diabetic patients was 49.5%.

Table 5.4: Distribution of study population according to compliance to management plan and possible reasons for non-compliance:

Variable	Frequency	Percent %
Compliance to management plan		
Compliant	107	49.5
Non –compliant	109	50.5
Total	216	100.0
		Reasons of non-compliance
Forgetfulness	71	66.4
Frustration	26	24.3
Feeling better without treatment	21	19.6
Polypharmacy	15	14.0
Fear of drug side-effect	13	12.1
Unavailability of drugs	9	8.4

Figure 5.5: Distribution of the study population by reasons of non compliance

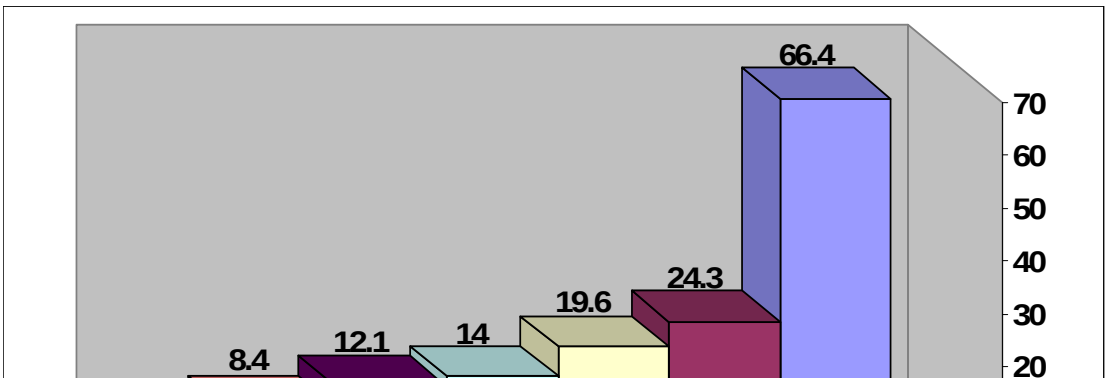


Figure (5.5) clarified the percentage of possible causes of non-compliance as mentioned by the patients. Typical reasons cited by patients for not taking their medications included forgetfullness, it is about 66.4%, frustration 24.3%, feeling better without treatment 19.6%, polypharmacy 14%, and other causes such as fear from drug side-effect and unavailability of drugs which representing by 12.1%, 8.4% respectively. The results of the present study was congruent with other study; research on adherence has typically focused on the barriers patients face in taking their medications conducted by Osterber and Blaschke in 2005, , they claimed that common barriers to adherence were forgetfulness 30%, which was found in this study as the highest percentage 66.4%, other barriers as found by Osterber and Blaschke were related to the other priorities represented by 16%, decision to omit doses 11%, lack of information 9%, and emotional factors 7%, and 27% of the respondents did not provide a reason for poor adherence to a regimen .

5.4 Control of diabetes

Control of diabetes was measured according to the biophysiological markers including glycated haemoglobin (HbA1c) and fasting blood sugar (FBS).

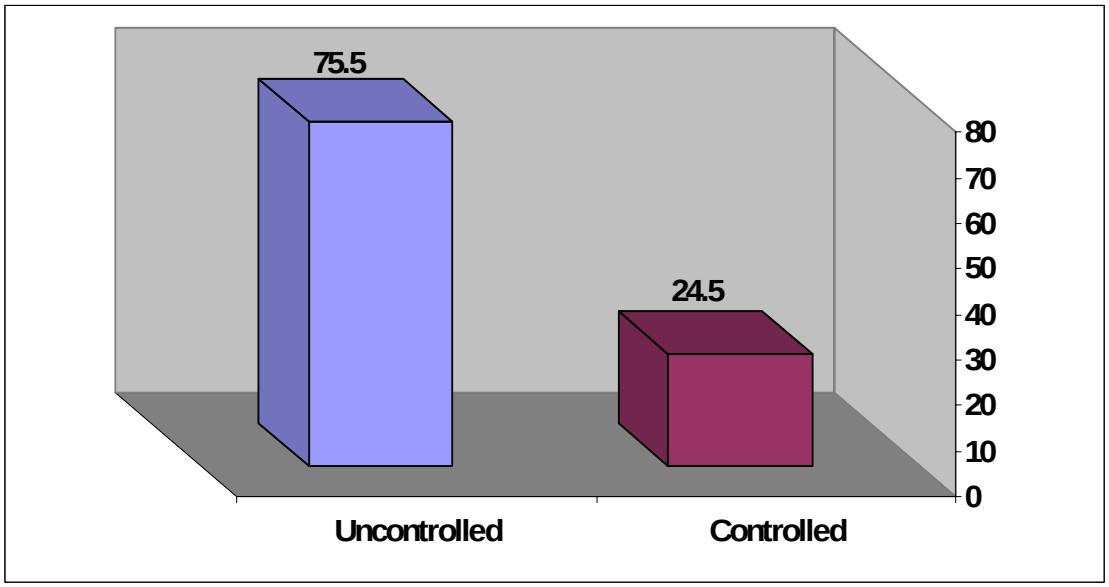
Table 5.5: Distribution of study population according to the biophysiological marker

Biophysiological Measures	**Frequency (N 216)**	**Percent %**
		HbA1c
less than 7%	53	24.5
more than 7%	163	75.5
FBS		
less than 126 mg/dl	23	10.5
more than 126 mg/dl	193	89.4

As shown in table (5.5), according to HbA1c (less than 7 %), the prevalence of control was 24.5%. According to FBS (less than 126mg/dl), the prevalence of control was 10.5%.

The hemoglobin A1c goal for people with diabetes is less than 7 percent. The Diabetes Control and Complications Trial, DCCT findings showed that people with diabetes who keep their hemoglobin A1c levels close to 7 percent have a much better chance of delaying or preventing diabetes problems that affect the eyes, kidneys, and nerves than people with hemoglobin A1c levels 8 percent or higher. A change in treatment is almost always needed if a person's hemoglobin A1c is over 8 percent.

Figure 5.6: Distribution of controlled and uncontrolled of study population



5.5 Knowledge about the disease

Knowledge of patients was assessed by asking the patients about diabetes and drugs. They were asked if diabetes is a curable disease or not, and they were asked about drug side-effects. Table (5.6) clarify that about one third of the sample population 30.1% answered that diabetes is a curable disease, 11.1% of them said that they didn't know weather diabetes is a curable disease or not, and 58.8% of the study sample stated that diabetes is not a curable disease.

61.1% of patients mentioned that they had knowledge about drugs side-effects, and the remaining 38.9% were not having this knowledge. The patients who claimed that they had knowledge were asked about the source of information, the main source of information was from doctors and nurses, represented by 70.9%, 20.9% respectively and 8.4% from other sources of information which was related to relatives and neighbors, drug leaflets or from media.

Table 5.6: Distribution of study population by knowledge of the disease, drug side effects and source of information

Variable	Frequency	Percent %
1-Knowledge of disease		
Could be cured	65	30.1
Couldn't be cured	127	58.8
Don't know	24	11.1

2-Knowledge about drug side effects		
Yes	132	61.1
No	84	38.9
3-Source of information		
Doctor	105	70.9
Nurse	31	20.9
Others	12	8.4

Generally, a moderate proportion of diabetic patients had knowledge about diabetes and drug side-effects 58.8%, and 61.1% respectively, and the main source of information was from the medical staff (doctors and nurses). This could be explained as health providers have a role in patient's knowledge about their disease.

A study conducted in Egypt by Kamel et al, 1999 to determined diabetics' knowledge of the disease, they found that the majority of diabetic patients (90.0%) had poor knowledge about the disease.

5.6 Attitudes and practices

The researcher clarified the attitude of respondents and their practices as shown in table (5.7), all participants were asked whether they had ever used drugs prescribed to others or about usage of traditional remedies. It was found 89.8% of study population had never

used drugs prescribed to others, 7.9% of patients used drugs had been prescribed to others, and 2.3% used sometimes.

Concerning usage of traditional remedies, 19.9% used in the past, and 10.2% used in the past and still using, among them 1.9% were used to stop their treatment when taking the traditional remedies. 70% of respondents claimed that they had never used the traditional remedies. It was clear that there is an attitude of some patients towards either using traditional remedies or using drugs prescribed to others.

The respondents were also asked about their medications; regularity of taking their medications, reliance of doses, and their reaction and practice in case of missing a dose in its proper time, or relieve from diabetic symptoms.

The vast majority (88%) of the study population claimed that they took their drugs regularly as prescribed by doctors, 10.6% claimed they sometimes be regular in taking their drugs and the remaining 1.4% a certain that they didn't take their drugs regularly.

Table 5.7: Distribution of study population by their attitudes and practices regarding antidiabetic drugs

Variable	No (n 216)	Percent %
1- Use drugs prescribed to others		
Yes	17	7.9
Sometimes	5	2.3
No	194	89.8

2-Using traditional remedies		
Yes, still use	22	10.2
Yes, in the past	43	19.9
Never used	151	69.9
3-Take his drug regularly		
Yes	190	88.0
Sometimes	23	10.6
No	3	1.4
4-Reliance		
Self reliance	200	92.6
Relied on other	16	7.4
5-Missing to take the drug		
Take it soon	170	78.7
Don’t take it at all	46	21.3
6-Relieve diabetic symptoms		
Continue taking the drug	182	84.3

Decrease the dose	12	5.6
Stop the drug	10	4.5
Consult the doctor	12	5.6

Moreover, as shown in table (5.7), 92.6% of the study population depends on themselves reliance for their dose time and this is could be susceptible for forgetfulness. However, 7.4% relied on others.

The patients were asked in case of missing their drugs on time, about three quarter (78.7%) claimed that they took their drugs soon once they remember the dose, the remaining 21.3% certain that they didn't take them in case of missing.

The majority of the study population (84.3%) mentioned that they continue to take their medications even if they relieved from diabetic symptoms. Meanwhile, 5.6% claimed that they consult their doctors, 5.6% decrease the dose and 4.5% stop the drug.

When patients have friends or family members who are providing emotional and/or support (eg, reminders to take medications), it is more likely that higher levels of medication compliance will be maintained. Several studies have shown that persons with diabetes who have greater social support are more likely to follow regimen recommendations (Paes, et al., 1997).

In this study the majority of study population (92.6%) depending on themselves in remembering there doses which is susceptible for forgetfulness. It was shown in table (5.7), the majority of study population who were non-compliant 66.4% of them related their causes to forgetfulness.

Concerning the traditional remedies, a study was done in Saudi Arabia showed one-third of patients were using traditional remedies (Al-Saeedi, et al, 2003), and this result congruent with the present study were about 30% of the study population found to use traditional remedies either at present or in the past.

5.7 Attitudes, feeling and beliefs

An attitude of participants toward their disease and treatment regimen is shown in table (5.8). About 17.6% feeling not to take the drugs, 14.4% feeling sometimes not to take the drugs, the reasons for their desire not to take their drugs; fear from drug side effects at present (26.1%), fear from drug side effect in the future (20.3%), fear from drug dependence (17.4%), on the other hand 5.8% feel there is no confidence with drugs and 30.4% related to other causes that mentioned by patients who were on insulin treatment, they specify their reasons as fear from hypoglycemia.

Table 5.8: Distribution of study population by their feeling and beliefs towards the antidiabetic drugs.

Variable	No (n 216)	Percent %
1-Feeling not to take the drug		
Yes	38	17.6
Sometimes	31	14.4
No	147	68.1
Reasons		

Fear of side effects	18	26.1
Fear of side effects in future	14	20.3
Fear of dependence	12	17.4
No confidence with drugs	4	5.8
Others	21	30.4
Feeling to have a rest from drugs		
Yes	34	15.7
No	182	84.3
Believing that the drug is not needed		
Yes	35	16.2
Sometimes	48	22.2
No	133	61.6

As the participants were asked if they feel at any time a need to have a rest period from drug taking, 15.7% prefer to have a rest and the remaining 84.3% did not.

Regarding participants believe in their need to medication to control the disease, there was 16.2% believing in their need to medication, while 22.2% stated that they sometimes

believing in their need to medication, and 61.6% were certain that they believe in medication and to take a rest is not logic.

As stated by Kusserow et al, in 1999, patients are most likely to comply with medication recommendations when they can recognize that the medication is helping them.

Patients' beliefs can be based on: misconceptions, faulty information, and/or cultural conditioning. For example, some people may believe:" You need to give your body some rest from medicine once in awhile or else your body becomes dependent on it or immune to it," Or 'You only take medicine when you are ill and not when you feel better, some may become aware of only negative consequences eg: hypoglycemia, and these beliefs congruent with the finding in this study that were related to diabetic feeling and beliefs (Kusserow, et al., 1999).

5.8 Attitude, practice and knowledge regarding life-style

Regarding life-style, all the respondents were asked about diet and physical activity as shown in table (5.9). More than one third of the study population (38.9%) did not follow any diet regimen as they had mentioned, on the other hand 61.1% claimed that they follow a diet regimen but the sources of getting or following a good diet regimen varies as follow; nearly half of them had the diet regimen advice from their doctors (51.1%) and 23.7% from nurses while the other sources of diet regimen were from protocols, relatives and neighbors presenting by 16.8% and 8.4% respectively.

Table 5.9: Distribution of study population by their attitudes and practices regarding life-style

Variables	No (n 216)	Percent %
Following Diet regimen		

Yes	132	61.1
No	84	38.9
Source of getting the diet regimen		
Doctor	67	51.1
Nurses	31	23.7
Protocols	22	16.8
Relatives and others	11	8.4
Benefit of exercise		
Yes, beneficial	213	98.6
No	3	1.4
Practice exercise		
Yes	83	38.4
No	133	61.6
Frequency of practice		
Three days or more per week	39	18.1
Less than three days week	44	20.3
For those who treated by Insulin (n 77, 35.6%)		
Who give you the injection		
Myself	57	74.0
Family member	18	23.4
Others	2	2.6
Received training on injection		
Yes	53	93.0
No	4	7.0
Who trained you		
Health providers	38	71.7
Family members	11	20.8
Others	4	7.5
Necessity of eating after insulin injection		
Yes	72	93.5
No	5	6.5

It was found that 98.6% of study population believed in the benefit of exercise for their health, in spite that only 38.4% of the subjects was actually practicing exercise (brisk walking), and among them 18.1% of them were exercising 3 or more days per week, 20.3% were exercising less than 3 days per week.

These results was congruent with the results of a survey conducted by Searle and Ready 1991, they found that physicians and dietitians were the primary sources of information about both exercise and diet, and they found that although few respondents participated in organized (7.7%) or informal (36.8%) exercise programs, or expressed an interest in participating (36.8%), the majority (84.0%) believed that they should get more exercise (Searle and Ready, 1991). This points to a gap between attitude and behaviour.

In a study conducted by Hays and Clark in 1999, they found that the majority of the respondents (54.6%) reported zero min of weekly physical activity. This result agreed with the results in the presented study, as 61.6% of respondents were not exercising at all.

Being overweight can be prevented by regular physical activity. A second, independent benefit of regular physical activity is improved blood sugar control in persons who already have type 2 diabetes (PHAC, 2001).

In conclusion as found in the result; the majority of study population didn't follow the non-pharmacological treatment (Diet and exercise) in spite of their believing in them.

For those who treated with insulin (n=77, 35.6%), they were asked about the injection, training and knowledge. The majority (74%) of patients who were treated with insulin took the injection by themselves, and 23.4% by other members of the family and 2.6% by others like neighbors, relatives or medical providers.

Concerning the training, 93% of respondents received training, among them 71.7% were trained by health providers, 20.8% were trained by family members and 7.5% were trained by others. As a neglection of eating after half an hour of injection could expose diabetic patients to hypoglycemia, the respondents were asked about their knowledge, 93.5% of patients mentioned that eating after insulin is necessary, among them only 51.4% who knew that eating should be after half an hour, while 44.4% of them thought that eating could be directly after injection, and 4.2% thought that eating could be after more than one hour. Although most of participants who were on insulin injection had a training 93%, or had an information about treatment. But it is necessary to enhance the awareness and the education about the proper way of taking insulin and precocious from drug side effects.

5.9 Medications, sources, availability and polypharmacy:

The study results showed that the majority of patients 88.9% got their drugs from governmental health center, 6.9% got their drugs from UNRWA, while 4.2% of participants got their drugs from others such as neighbors, relatives, private pharmacy, The majority 62% of the study population were certain that drugs is always available, 35.2% claimed that drugs are sometimes available and who mentioned that drugs are not available at all was represented by 2.8% as shown in table (5.10).

Table 5.10: Distribution of study population by sources of drug prescription, availability of drugs and number of daily medication

Variable	No (n 216)	Percent %
Sources of drug prescription		
Governmental health center	192	88.9
UNRWA	15	6.9
Other sites	9	4.2
Availability of drugs		
Always available	134	62
Sometimes available	76	35.2
Not available	6	2.8
Other sources to get drugs		
UNRWA clinic	23	10.6
another governmental clinic	2	0.9
private pharmacy	133	61.6
Use drugs from relatives	13	6
Remain without treatment	45	20.9

Taking drugs other than antidiabetic drugs		
Yes	129	59.7
No	87	40.3
No of daily drugs taken by patients		
One drug	33	15.3
Two-Three drugs	109	50.5
> three drugs	74	34.3

All the participants were asked about other sources of drug prescription in case of unavailability of drugs in the governmental health center. The results showed that the majority mentioned that they bought their drugs from a private pharmacy represented by 61.6%, others 20.9% remained without treatments, other options of getting the drugs varies between UNRWA, relatives and another governmental clinic 10.6%, 6%, and 0.9 respectively.

Among the study population 59.7% were taking drugs other than diabetic drugs. Regarding the number of daily drugs taken by diabetic patients including the diabetic drugs, more than half of study sample were taking two or three drugs per day which was represented by 50.5%, and 34.3% of patients were taking more than three drugs per day, and the remaining 15.3% of the participants were taking only one drug as clarified in table (5.10).

5.10 Diabetic risk factors

Concerning the risk factors as shown in table (5.11), the majority of study population had uncontrolled blood pressure, more than 130/80mmHg and represented by 68.5%, Patients with diabetes have a much higher rate of hypertension than would be expected in the general population (Sheeri, et al., 2002), According to International Diabetes Federation, (2005). Blood pressure control can reduce cardiovascular disease (heart disease and stroke) by approximately 33% to 50% and can reduce microvascular disease (eye, kidney, and nerve disease) by approximately 33%. In general, for every 10 millimeters of mercury (mm Hg) reduction in systolic blood pressure, the risk for any complication related to diabetes is reduced by 12%. (CDC, 2005).

Additionally, about two thirds (64.8%) of the study population had hypercholesterolemia, 68.5% had hyper triglyceridemia, and more than half of the respondents were obese (52.8%), 10.2% were reported as morbid obese, 30.6% were overweight and only 6.5% who were within normal body mass index. Regarding smoking only 4.6% were smokers, 1.9% were ex-smokers (stopped smoking for more than six months), and the majority were non-smokers 93.5%, this could be related to that most of the study population were females.

Astrup in 2001 found that 80-95% of the increase in diabetes can be attributed to obesity and overweight with abdominal fat distribution (Astrup, 2001).

Table 5.11: Distribution of study population by the risk factors

Variable(Risk factors)	No (n 216)	Percent %

1-Blood Pressure		
Controlled	68	31.5
Uncontrolled	148	68.5
2-BMI		
18.5-24.9(Normal**)**	14	6.5
25-29.9(overweight**)**	66	30.6
30-39.9(obese)	114	52.8
40->40(morbid obese)	22	10.2
3-Hypercholesterolemia		
0-200 mg/dl	76	35.2
>200 mg/dl	140	64.8
4-Hypertriglyceremia		
0-150 mg/dl	68	31.5
>150 mg/dl	148	68.5
5-Smoking		
Yes	10	4.6

No	202	93.5
Ex-smoker (more than 6months)	4	1.9

According to the MOH, annual report in 2005 the incidence of diabetic patients in 2002 with obesity is 60.8% (42.3% in males and 72.4% in females), (MOH, 2005), in this study it was about 52.8% as obese and 10.2% as morbid obese which is congruent with the MOH annual report in 2005.

5.11 Complications of diabetes

Table (5.12) clarifies the complication of diabetes that affect the study population. It was found that 57.9% of them had complication, 37% didn't have and 5.1% mentioned that they did not know whether they have complication or not.

The highest complications were ophthalmic, neuropathy and diabetic foot represented as 56.8%, 44.8% and 34.4% respectively, followed by ischemic heart disease (IHD), renal and cerebrovascular complications 15.2%, 8.8%, and 0.8% respectively.

Table 5.12: Distribution of study population by complication of diabetes

Variable	No (n 216)	Percent %
Having complications		

Yes	125	57.9
No	80	37
Didn't Know	11	5.1
Type of complication (n 125)		
Ophthalmic	71	56.8
Renal	11	8.8
Diabetic foot	43	34.4
Neuropathy	56	44.8
IHD	19	15.2
CVA	1	0.8

5.12 Diabetic clinic visit

It was found that 88% of study population respect their appointments to the diabetic clinic, while 12% were not. The proportion who did not respect their appointments related the causes to the increasing waiting time, it was represented by 77.8 of causes, the other causes related to either doctors did not give the patients' their care or attention (14.8%) or unavailability of drugs (7.2%).

Table 5.13: Distribution of study population according to the clinic visit

Clinic Visit Appointment	Frequency	Percent %
Respect appointments to the diabetic clinic		
Yes	190	88
No	26	12
Reasons for not keeping the appointment		
Waiting time	21	77.8
Doctors did not give attention	2	14.8
Unavailability of drugs	4	7.2

5.13 Monitoring of glycemic control

It was shown that only 11.1% of study population checking the glucose level by themselves, Self-monitoring of blood glucose (SMBG), the frequency of using SMBG was distributed as follow; daily use (8.3%), weekly use (16.7%), monthly use (20.8%) and more than monthly use (54.2%). It was clear that self-monitoring of blood glucose represented a small percentage 11.1%. According to American Diabetes Association in 2006, self-monitoring of blood glucose considered as an integral part of the management strategy and for patients using less frequent insulin injections or oral agents or medical nutrition therapy (MNT) alone, SMBG is useful in achieving glycemic goals.

Table 5.14: Distribution of study population according to the self-management

Variable	Frequency	Percent %
Self-monitoring of blood glucose (SMBG)		
Yes	24	11.1
No	192	88.9
		Frequency of measurement
Daily	2	8.3
Weekly	4	16.7
monthly	5	20.8
More than monthly	13	54.2

5.13 Compliance and socio-demographic factors

Table (5.15) clarifies the relationship between selected socio-demographic factors and non compliance, which are gender, age, marital status, locality, educational level, occupation and income.

Comparing between males and females regarding the non compliance rate, it was the highest among female as 52.9% of female were not complied, while 46.1% of males were not complied. Although the non- compliance rate was higher among females the difference didn't reach a statistical significant (P=0.393).

Non-compliance rate varies from one age group to another. Non-compliance with percentage 60% was higher among age group (30-49) than those who were complaints (40%) and similarly the non compliance rate was higher among age 65 years and over. On the other hand among age group (50-64), the compliance rate increased, 56.2% were compliers and higher than the non compliant.

Table 5.15: The relationship between compliance and sociodemographic and economic variables

Sociodemographic characteristics	Compliant		Non -compliant		X^2	P -value
	No	%	No	%		
Sex						
Male	41	53.9	35	46.1	0.912	0.393
Female	66	47.1	74	52.9		
Age Group						
30-49	28	40	42	60	4.650	0.098
50-64	63	56.2	49	43.8		
65&over	16	47.1	18	52.9		
Marital status						
Single	9	64.3	5	35.7	1.303	0.282
Married	98	48.5	104	51.5		
Locality						
North Gaza	25	55.6	20	44.4	1.372	0.504
Gaza	69	49.3	71	50.7		
Mid-Zone	13	41.9	18	58.1		

Educational level						
Low	61	55.5	49	45.5	3.180	0.204
Medium	39	43.8	50	56.2		
High	7	41.2	10	58.8		
Consanguinity						
First degree	30	41.1	43	58.9	4.788	0.091
Second degree	21	63.6	12	36.4		
No consanguinity	56	50.9	54	49.1		
Occupation						
Working	12	54.5	10	45.5	0.246	0.659
Not working	95	49	99	51		
Family number						
1-5	33	47.8	36	52.2	0.718	0.698
6-10	54	52.4	49	47.6		
>10	20	45.5	24	54.5		
Income						
<1000 NIS	28	53.8	24	46.2	2.005	0.571
1000-2000 NIS	24	50	24	50		
>2000 NIS	22	55	18	45		
Refuse the answer	33	43.4	43	56.6		

In conclusion, the compliance rate is the highest among the middle age group (50-64) but the result did not reach the statistical significance (P= 0.098). This result agree with Platt, (1994), Platt stated that demographic factors, such as age, gender, ethnicity, and socio-economic status have been included in almost every analysis of adherence although they do not seem to be consistent correlates of whether or not a patient keeps appointments or follows a medication regimen (Platt,1994). And the results agreed with Albaz in Saudi Arabia in 1997, who concluded that organizational variables (time spent with the doctor, continuity of care by the doctor, communication style of the doctor and interpersonal style of the doctor) are far more important than sociodemographic variables (gender, marital status, age, educational level and health status) in affecting patients.

As shown in the results, increasing age is generally associated with increasing adherence until patients enter their 65s, when adherence declines, this result agree with Kem in 2003 as he found that compliance is generally associated with increasing age until patients enter 70s and this decrease might be due in part to failing memory or the need for complex medication regimens as people age (Kem, 2003).

Regarding the marital status, it was found that the majority were married represented 93.5%, and the compliants were 51.5% among them. It did not reach the statistical significance(P=0.282).

Concerning the locality of the study population, the proportion who were not compliants were more than who were compliant in Gaza and Mid-Zone represented by 50.7%, and 58.1% respectively. In North-Gaza the compliants 55.6% were higher. The result did not reach the statistical significance (P=0.504).

As mentioned before, the researcher categorized the education level into three categories. The first was low level of 6 years of education and less, the second group was the median level from 7 to 12 years, and the third group, high level with more than 12 years of education. It was found that as the degree of education increased, the non compliance increased too; among the median level of education, 56.2% were not compliant and 58.8% were not compliant among the high level, but did not reach the statistical significance (P=0.204).

Concerning the consanguinity, the non compliance rate was the highest among those who had first degree consanguinity, the result did not reach the statistical significance(P=0.091).

Regarding the occupation, it was found that 89.9% of the study population was not working; about half of non-workers (51%) were not complaints while the majority of

workers 54.5% were compliant. Hertz, et al in 2005 found that adherence was poor among working-aged patients but in this study adherence was good among workers but the result did not reach the statistical significance (P=0.659).

Number of Participants family size were divided into three categories as shown in table (5.15), the non compliance rate was higher among the group who had family size above 10 persons but the result didn't reach the statistical significance (P=0.698).

Concerning the income, it was found that the compliance rate little bit increased among both groups who their income below 1000 NIS and above 2000 NIS and there were no difference in compliance rate with those their monthly income is between 1000-2000 NIS. The result did not reach the statistical significance (P=0.571).

This is congruent with Platt, in 1994 who stated that socio-economic status not seemed to be consistent correlates with compliance. On the other hand Joel, et al. in 2002 found that adherence for chronic drug regimen is often suboptimal, lower socioeconomic and minority population have greater barriers to adherence (Joel, et al., 2002).

5.14 Compliance and health profile

The researcher studied the relationship between compliance and health profile, including duration of diabetes, family history and associated chronic disease. It was found that the non compliance rate was higher among participants who had diabetes for more than ten years and were represented by 52.6%, while it decreased among participants who had diabetes for less than ten years (49.3%). This indicates that the compliance rate decreased as the duration of diabetes increased, but it didn't reach the statistical significance (P=0.671).

Among patients who had positive family history, 50.9% found to be not-compliant, which is higher than the complaints. On the other hand the compliance rate was higher among patients who didn't have positive family history (51%). It was shown that compliance rate decreased when patients had positive family history of diabetes. Regarding patients who had positive family history especially their mothers, 58.4% were not compliant and higher than those compliant (41.6%) and this result was statistically significant (P=0.046, OR=0.526 and C.I= (0.285-0.970). this result could indicate that there is a negative relationship between compliance and family history, especially when the mother is diabetic.

Table 5.16: The relationship between compliance and health profile

Health profile	Compliant		Non compliant		X^2	P- value
	No	%	No	%		
Duration of diabetes						
<10 years	71	50.7	69	49.3	0.221	0.671
>10 years	36	47.4	40	52.6		
Family history						
Yes	83	49.1	86	50.9	0.056	0.870
No	24	51.1	23	48.9		
Mother						
Yes	37	41.6	52	58.4	4.276	0.046
No	46	57.5	34	42.5		
O.R=0.526	**C.I=(0.285-0.970)**					
Associated chronic diseases						
Yes	59	45.7	70	54.3	1.851	0.212
No	48	55.2	39	44.8		
Hypertension						
Yes	46	47.4	51	52.6	0.315	0.587
No	61	51.3	58	48.7		
Ischemic heart disease						
Yes	5	26.3	14	73.7	4.494	0.052
No	102	51.8	95	48.2		
Kidney disease						
Yes	6	54.5	5	45.5	0.116	0.767
No	101	49.3	104	50.7		

The non-compliance rate generally increased as there were associated chronic diseases. While 54.3% of patients were not compliant, 45.7% were complied, but it didn't reach the statistical significance. Considering hypertension and ischemic heart disease, the non compliant patients were higher than the complaints as shown in table (5.16), the result reach the statistical significant with those associated ischemic heart disease (P=0.052).

5.15 Compliance and current treatment

Concerning the current treatment, the participants who were on oral hypoglycemic agents (OHAs) alone, the compliance rate was higher than the non compliance rate represented by 51.8%, among participants who were on insulin alone, the non compliance rate was more higher, represented by 57.9%, similarly among those who on mixed treatment (OHAs and insulin) again the non compliance was more than the compliance rate represented by 51.3% as shown in table (5.17). The results didn't reach the statistical significance.

Table 5.17: The relationship between compliance and current treatment

Current treatment	Compliant		Non compliant		X^2	P –value
	No	%	No	%		
Oral hypoglycemic agent(OHA)						
Yes	72	51.8	67	48.2	0.798	0.396
No	35	45.5	42	54.5		
Insulin						
Yes	16	42.1	22	57.9	1.019	0.373
No	91	51.1	87	48.9		
Mixed						
Yes	19	48.7	20	51.3	0.013	1.000
No	88	49.7	89	50.3		

As mentioned by Polonsky, et al. in 2003, many people with type 2 diabetes feel about beginning insulin therapy, and this result is congruent with the results of the presenting study. Similarly, a review of literature search (1966–2003) was performed and confirmed that many patients for whom diabetes medication was prescribed were poor compliers with treatment, including both OHAs and insulin (Joyce, 2004).

5.16 Compliance and control measures of diabetes

As mentioned before the control of diabetes was measured according to the biophysiological markers including glycated haemoglobin (HbA1c) and fasting blood sugar (FBS) as an indicators of therapeutic outcomes. The compliers were much higher among controlled group whose HbA1c was less than 7%. The relationship between compliance and the control of disease was highly significant (P=0.000), as the compliance increased control of disease increased by five times, (OR=5.021, C.I(2.456-10.268). Regarding FBS, the compliers were higher among controlled group whose FBS below 126mg/dl and the result was statistical significant (P=0.004, OR=4.207, C.I= (1.501-11.789).

Table 5.18: The relationship between compliance and the biophysiological markers

Biophysiological Markers	Compliant		Non compliant		X^2	P –value
	No	%	No	%		
HbA1c						
less than 7percent	41	77.4	12	22.6	21.747	0.000
more than 7percent	66	40.5	97	59.5		
OR= 5.021	**C.I(2.456-10.268)**					
FBS						
less than 126	18	78.3	5	21.7	8.496	0.004
more than 126	89	46.1	104	53.9		
OR=4.207	**C.I(1.501-11.789)**					

A single HbA1c value taken every 2 to 3 months serves as an integrated index of blood glucose control over those months and thus provides an objective view of the patients' glycemic control between checkups, as showed in the landmark nine-year Diabetes Control and Complications Trial (DCCT), which completed in 1993, the risk for development and progression of the chronic complications of diabetes is closely related to the degree of glycemic control, as measured by HbA1c determinations (Gonen, et al.,1997). Similarly the

results of the United Kingdom Prospective Diabetes Study show that lowering blood glucose levels, as measured by HbA1c determinations, reduces the incidence of microvascular complications in Type 2 diabetes.(Gonen, et al.,1997).

5.17 Compliance and knowledge

In this field, different variables concerning the relationship between the patients and compliance rate were included. These were related to the information of the patient about the cure from diabetes, knowledge of drugs and their side-effect and the source of information. Patients who believed in that diabetes is a curable disease have higher compliance rates 52.3%, whereas the non compliance rate was higher among patients who didn't have a knowledge about the disease weather it is a curable disease or not. The results did not reach a statistical significant level (P=0.443). so that patients beliefs or knowledge reflect a positive action but not significant on their compliance. The presenting results disagree with the results of Jaser in 1999, where he found that patients' beliefs didn't reflect positive action on their compliance (Jaser,1999).

The participants where asked about drug side-effects knowledge, the majority of those who didn't know about drug side-effects were not complaints and presented by 75%, on the other hand the complaints were higher among those who had a knowledge of drugs, represented by 65.2%, the difference was strongly statistical significant with P=0.000, so there is a positive association between knowledge and compliance and the risk of poor knowledge to increase the non compliant rate was about six times higher (OR=5.609, C.I=(3.048-10.322)).

Table 5.19: The relationship between compliance and knowledge about the disease, drugs side effects and source of information

Variables	Compliant		Non compliant		X^2	P -value
	No	%	No	%		
Knowledge of diabetes						
Curable	34	52.3	31	47.7	1.628	0.443
Not curable	64	50.4	63	49.6		
Did not know	9	37.5	15	62.5		
Knowledge of drug side- effects						
Yes	86	65.2	46	34.8	33.106	0.000
No	21	25.0	63	75.0		
OR=5.609			**C.I=(3.048-10.322)**			
Source of information						
1-From the doctor						
Yes	71	67.6	34	32.4	1.909	0.187
No	15	53.6	13	46.4		
2-From the nurse						
Yes	19	61.3	12	38.7	0.170	0.675
No	66	63.3	35	34.7		

Generally, knowledge and awareness are an important factors to enhance compliance, this result is congruent with Wilson and colleagues in 1986, they reported that mood, knowledge of diabetes care, social support and health beliefs were collectively predictive of better compliance. Similarly Petty and Cacioppo (1981) proposed that people are more likely to process information thoughtfully if they perceive it as personally relevant (Petty and Cacioppo, 1981).

The results also showed that the mean source of information about disease, drugs and side-effects of medicine was the doctors and the nurses and the compliance rates among them was higher than the non compliance but the difference didn't reach the statistical significance.

5.18 Compliance and attitude regarding medicine

Considering feeling and believes of diabetic patients and their compliance toward regimen plan, table (5.20) clarifies that patients who believed in that medicine is not needed, 62.9% of them were not compliant and higher than who were compliant represented by 37.1%. Among those who believed in that medicine is sometimes not needed, 56.2% were not compliant and higher than who were compliant (43.8%). While those who believe in that medicine is needed, the compliant participants about 54.9% were higher than who were not complaints.

As shown in the results, as believing in the need of medicine increased, compliance increased too but the result didn't reach the statistical significance (P=0.116).

Table 5.20: The relationship between compliance and attitude regarding medicine

Feeling & beliefs	Compliant		Non compliant		X^2	P-Value
	No	%	No	%		
Believing in that medicine is not needed						
Yes	13	37.1	22	62.9	4.317	0.116
Sometimes	21	43.8	27	56.2		
No	73	54.9	60	45.1		
Feeling didn't like to take medicine						
Yes	10	26.3	28	73.3	12.315	0.002
Sometimes	13	41.9	18	58.1		
No	84	57.1	63	42.9		
Feeling in need for rest period						
Yes	9	26.5	25	73.5	8.589	0.005
No	98	53.8	84	46.2		
OR=0.309			**C.I=(0.136-0.698)**			

It was found that feeling toward taking the medicine, the non-compliance rate increased among participants who feel or sometimes feel that they didn't like to take the medicine 73.3%, and 58.1% respectively, while the complaints 57.1% were higher than the non compliant among those feeling was positive toward taking the medicine. This indicate that patients' feeling affect significantly the compliance (P=0.002).

It was found that the compliance rate 26.5% decreased compared with the non- compliant rate 73.5% regarding participants feeling in need to have a rest period from medicine and the results reach the statistical significant, P=0.005, OR=0.309 and C.I=(0.136-0.698).

In conclusion, the compliance rate significantly decreased and associated with patients' feeling; (didn't like to take medicine or feeling in need for rest period). The present study was congruent with results of Jaser, 1999 regarding patients feeling and beliefs.

Non-adherence in many chronic illnesses has been linked to attitude of a patient toward him/herself and the illness (Wichowski and Kubach, 1997).

A study conducted by McCord and Brandenburg, in 1995, they concluded that a better understanding of patients' beliefs and attitudes may help physicians increase motivation, understanding, and compliance of diabetic patients.

5.19 Compliance and attitude and practice regarding medicine

Concerning the attitudes, the non compliance rate was higher among participants who could sometimes use others drugs and among those who didn't use others drugs, they represented 60% and 51.5% respectively, on the other hand the compliers among those who used to take drugs prescribed to others were higher 64.7%, although the result didn't reach the statistical significance (P=0.399), but this result indicate that the compliants tried to get their drug even from other.

As mentioned before, small percent of participants who used traditional remedies around 20% used in the past, and 10% still use, among them the non-compliance rates 46.5% and 40.9% respectively were lesser than the compliance rates as presented in the table (5.21), this means that using of traditional remedies or not didn't affect the compliance but the result didn't reach the statistical significance. Similarly Al-Saeedi, et al. in 2003, found a statistically significant relationship between belief in traditional medicines and variables such as female sex, positive family history of diabetes, duration of diabetes and compliance with diet, but they didn't found relationship with other compliance variables or with glucose and weight control and they concluded that efforts should be made to enhance diabetic education among patients on the basis of evidence-based practice.

Regarding the regularity of drug taking as mentioned by the participants, those who claimed that they sometimes be regular, all of them were not complaints (100%), and participants who claimed that they were not be regular in taking their drugs, the non compliance rate was 66.7% higher than the compliance rate 33.3%. The compliance rate 55.8% among participants who mentioned that they were regularly taking their drugs was

higher than the non compliance rate. The result had shown a highly statistical significance with (P=0.000).

Table 5.21: The relationship between compliance and their attitude and practice regarding medicine

Feeling & beliefs	Compliant		Non compliant		X^2	P –value
	No	%	No	%		
Using of drugs had been prescribed to others						
Yes	11	64.7	6	35.3	1.838	0.399
Sometimes	2	40.0	3	60.0		
No	94	48.5	100	51.5		
Using of traditional remedies						
Yes	13	59.1	9	40.9	1.455	0.483
Yes, in the past	23	53.5	20	46.5		
Never used	71	47.0	80	53.0		
Taking of drug regularly						
Yes	106	55.8	84	44.2	25.864	0.000
Sometimes	0.0	0.0	23	100		
No	1	33.3	2	66.7		
Reliance						
Self reliance	100	50.0	100	50.0	0.232	0.796
Relied on others	7	43.8	9	56.3		
Missing to take drug						
Take it soon	98	57.6	72	42.4	21.003	0.000
Not take it	9	19.6	37	80.4		
OR=5.596		**C.I=(2.541-12.323)**				
Relieve from diabetic symptoms(feeling improvement)						
Continue taking drugs	91	50	91	50	4.915	0.178
Decrease the dose	6	50.0	6	50.0		
Stop the drugs	2	20.0	8	80.0		
Consult the doctor	8	66.7	4	33.3		

It was found that among participants who depends on themselves in reliance, half of them were non complaints, and it was found 56.3% among patients who relied on others were non complaints and higher than compliant, but the results didn't reach the statistical significance.

In case of missing a dose most of participants who claimed that didn't take the dose later were also non compliant to their regimen (80.4%), and they were about six times higher than the complaints (OR=5.596, C.I=(2.541-12.323)) and the result was strongly associated with compliance and reach the statistical significance where (P=0.000). This was congruent with as mentioned before about the causes of non compliance where it was found that forgetfulness is the common cause of non compliance (66.4%).

The participants were asked about their practice once the diabetic symptoms relieved and by comparison most of patients who claimed that they stop treatment were not compliant (80%), while among those who decide to decrease the dose 50% were not compliant. The others who mentioned either continue the treatment or consult their doctors(The good options), the non compliance rate was lesser among them (50%, and 33.3% respectively), although the result didn't reach the statistical significance, but the result indicate that compliance is negatively affected by feeling of symptoms that means when the symptoms disappear compliance decrease too, so it is important to give attention to this point by health providers and to educate the patients not to discontinue the treatment and to clarify that their goal of treatment is to decrease the symptoms and to improve their health and the quality of life.

The result disagrees with Anderson and Kirk in 1982, who suggest that if an illness has easily recognizable and unpleasant symptoms that are improved by following treatment recommendations, adherence is more likely.

5.20 Compliance and life style

It was important to study the relationship between compliance and the non-pharmacological factors (diet and exercise). Diet and exercise are the cornerstones of treatment for persons with type 2 diabetes mellitus (Shultz, et al., 2001).

It was found that 73.8% were non compliant to regimen treatment and not following any diet regimen while only 26.2% were compliants and not following a special diet, as shown the result revealed that the compliance rate had a strong statistical significance with the diet regimen, (P=0.000). The non compliants were five times higher among those who didn't follow diet regimen (OR=5.097 and C.I=(2.789-9.314)).

Table 5.22: The relationship between compliance and physical activity, benefits and diet

Variables	Compliant		Non compliant		X^2	P - value
	No	%	No	%		
Following diet regimen						
Yes	85	64.4	47	35.6	29.971	0.000
No	22	26.2	62	73.8		
OR=5.097	**C.I=(2.789-9.314)**					
Benefits of physical activity						
Yes beneficial	105	49.3	108	50.7	0.357	0.620
No	2	66.7	1	33.3		
Practice of physical activity						
Yes	48	57.8	35	42.2	3.710	0.069
No	59	44.4	74	55.6		
OR=1.720	**C.I=(0.989-2.993)**					

About half of patients who believed in that exercise is beneficial were not compliants 50.7% but the result didn't reach the statistical significance. Among patients who did not practice physical activity 55.6% were not compliants where 44.4% were compliants and

didn't reach statistical significance. As it was shown non-compliance rate was higher among patients who didn't follow a special diet regimen and who didn't practice any physical activity.

There is now substantial evidence that type 2 diabetes can be prevented or delayed by lifestyle interventions, i.e. diet and exercise should be the first choice in order to avoid weight gain when preventing diabetes. The incidence of newly diagnosed type 2 diabetes decreased parallel with weight loss (Germendy, 2003). Generally regular physical activity is improved blood sugar control in persons who already have type 2 diabetes (PHAC, 2001). So it is important to focus on lifestyle intervention and to increase the education in this field.

5.21 Compliance and insulin

The proportion of participants who treated with insulin (35.6%), the non compliance rate was the highest among them, represented by 54.5%, it didn't reach the statistical significance (P=0.396).

the result was congruent with a review of literature search (1966–2003), which confirmed that many patients for whom diabetes medication was prescribed were poor compliants with treatment, including both OHAs and insulin (Joyce, 2004).

Table 5.23: The relationship between compliance and insulin

Variable	Compliant		Non compliant		X^2	P – value
	No	%	No	%		
On Insulin						
Yes	35	45.5	42	54.5	0.798	0.396
No	72	51.8	67	48.2		
Who give the injection						
Myself	30	52.6	27	47.4	5.119	0.077
Person from the family	4	22.2	14	77.8		
Others	1	50	1	50		
Training						
Yes	29	54.7	24	45.3	1.317	0.336
No	1	25	3	75		
OR=3.625		**C.I=(0.354-37.142)**				
Eat after injection						
Yes	32	45.1	39	54.9	0.049	1.000
No	2	40	3	60		
Time of eating after the injection						
Directly after the injection	13	40.6	19	59.4	0.992	0.609
After half an hour	18	48.6	19	51.4		
After an hour	2	66.7	1	33.3		

As mentioned before, the majority of participants were taking the injection by themselves (74%), and most of them were compliants 52.6%, and among those who received training on injection were compliants represented by 54.7%. The result didn't reach the statistical significance (P= 0.336) but the risk of non compliance to increase was three times higher if they were not trained, so that training on injection improve the compliance.

As shown in the same table eating after the injection had no statistical significant with compliance.

5.22 Compliance and risk factors

The researcher studied the relationship between selected risk factors and compliance; they include smoking, blood pressure, hypercholesterolemia, hypertriglyceridemia, and obesity.

As mentioned before only 4.6% were smokers and had no effect on the compliance rate in this study. Regarding other risk factors the non compliant patients in general were higher than the complaints. It was found that 54.1% of patients who had high blood pressure were not compliant while 45.9% were complaints but it didn't reach the statistical significant. Among patients who had hypercholesterolemia, 51.4% were not complaints and also didn't reach the statistical significant. Concerning hypertriglyceridemia 55.4% were not compliant and higher than compliant, the relation was statistically significant as P-value=0.040, the risk of non compliant patients to have hypertriglyceridemia was twice more than that who were complaints where OR=1.88 and C.I=(1.052-3.383).

It was clear in the same table that the non- compliant among obese patients (54.4%) and among the morbid obese patients (72.7%) were higher than the compliant patients (45.6%, and 27.3% respectively), and this result reach the statistical significance, P=0.016.

Most hyperlipidemia is caused by lifestyle habits or treatable medical conditions (SVS, 2006).

Table 5.24: The relationship between selected risk factors and compliance:

Risk factors	Compliant		Non compliant		X^2	P –value
	No	%	No	%		
1-Smoking						
Yes	5	50.0	5	50.0	1.061	0.588
No	99	49.0	103	51.0		
2-Blood pressure						
Yes	68	45.9	80	54.1	2.425	0.143
No	39	57.4	29	42.6		
3-Hypercholesterolemia						
Yes	68	48.6	72	51.4	0.148	0.776
No	39	51.3	37	48.7		
4-Hypertriglyceridemia						
Yes	66	44.6	82	55.4	4.594	0.040
No	41	60.3	27	39.7		
OR=1.887		**C.I=(1.052-3.383)**				
5-Obesity (BMI)						
• 18.5-24.9	7	50.0	7	50.0	10.314	0.016
• 25-29.9	42	63.6	24	36.4		
• 30-39.9	52	45.6	62	54.4		
• >40	6	27.3	16	72.7		

There is strong evidence that weight loss in overweight and obese individuals reduces risk factors for diabetes and cardiovascular disease and a strong evidence exists that weight loss reduces blood pressure in both overweight hypertensive and nonhypertensive individuals; reduces serum triglycerides (Adrienne, 1998).

5.23 Compliance and diabetic complications

In general, as shown in table(5.25), non compliance rate was higher among patients who had any of diabetic complication, representing by 57.6%, and was lesser among who didn't have diabetic complication represented by 41.3%, the result indicated that compliance rate significantly associated with diabetic complication and it reached the statistical significance as (P=0.046).

Table 5.25: The relationship between compliance and diabetic complications:

Diabetic Complication	Compliant		Non compliant		X^2	P –value
	No	%	No	%		
					Having diabetic complication	
Yes	53	42.4	72	57.6	6.138	0.046
No	47	58.8	33	41.3		
Didn't know	7	63.6	4	36.4		
1-Ophthalmic (retinopathy)						
Yes	24	33.8	47	66.2	4.974	0.030
No	29	53.7	25	46.3		
OR=0.44		**C.I=(0.213-0.910)**				
2-Renal						
Yes	6	54.5	5	45.5	0.832	0.524
No	46	40.4	68	59.6		
3-Diabetic foot						
Yes	12	27.9	31	72.1	5.059	0.035
No	40	48.8	42	51.2		
OR=0.406		**C.I=(0.184-0.900)**				
4-Neurological						
Yes	24	42.9	32	57.1	0.066	0.856
No	28	40.6	41	59.4		
5-Ischemic heart disease						
Yes	5	26.3	14	73.7	2.154	0.206
No	47	44.3	59	55.7		
6-Cerebrovascular accident						
Yes	1	100.0	0	0.0	1.415	0.416
No	51	41.1	73	58.9		

As stated before retinopathy was the most frequent complication among the study population (57%), the non compliance rate was higher among patients who had retinopathy represented by 66.2% and was lesser in those without retinopathy with percent of 46.3%, the result reach the statistical significance (P=0.030). The results revealed that there was a negative association between retinopathy and compliance (OR=0.44, C.I=(0.213-0.910)).

Similarly there was a negative association between compliance and the presence of diabetic foot, where 72.1% were non compliants among patients who had diabetic foot the difference was statistically significant with (P=0.035**,** OR=0.406, C.I=(0.184-0.900)).

The non compliant rates were higher among those with neurological and ischemic heart disease and presented by 57.1% and 73.7% respectively but the result didn't reach the statistical significance.

On the other hand, non compliance rate was higher among patients without renal complication and lesser among those with renal complication, but the difference didn't reach statistical significant level (P=0.524). Regarding cerebrovascular accident it was found only one patient who exposed to CVA and was compliant.

In a study was done by Dietrich, 1996, he studied the attitudes of people with diabetes toward their disease and its treatment from their point of view, participants reported that when diabetes complications started their compliance improved and this result disagree with the result of the present study where the presence of diabetic complication increase the non compliance rate especially retinopathy complication and diabetic foot and the results was statistically significant.

5.24 Compliance and source of drug prescription and availability of drugs

Compliance rate varies in relation to source of drug prescription, among participants who got their drugs from governmental health centers, the non- compliance rate was higher than the compliance rate, it was 52.1%. While it was lesser among those who got their drugs from UNRWA, it was 40%. It didn't reach the statistical significance; (P=0.384).

Concerning the availability of drugs, patients who said drug is always available were more compliant, represented by 62.7%. While patients who answered that drug is sometimes available or said drug is not available were less complaint, presented by 72.4%, and 66.7% respectively. The result was strongly statistically significant as (P=0.000).

Referring to other options to get the drugs in case of unavailability, the non compliants were higher among those who mentioned that they can't get the drugs from private pharmacy and among those who remains without treatment, represented by 65.1%, and 88.6% respectively, the results reach strongly the statistical significance where P=0.001 and P=0.000 respectively. The result revealed that there was a positive relationship between compliance and capability to get the medicine from private pharmacy (OR=2.641, C.I=(1.496-4.661)), as well there was a negative relationship between compliance and remaining without treatment (OR=0.088, C.I=(0.033-0.2234)). This could be related to the low socioeconomic status or to the cost of the drugs that might be as a barrier to compliance.

The other options to get the drugs were from UNRWA, from another governmental health center, and from relatives, the compliants were higher represented by about 60.9%, 100%, and 53.8% respectively, although the result didn't reach the statistical significance but it also indicated to the same barriers and the factors that might lead to non-compliance such

as the socioeconomic status, as whenever there was another options to get medicine, the compliance increased too.

Table 5.26: The relationship between compliance and sources of drug prescription, availability of drugs and number of daily medication

Variable	Compliant		Non compliant		X^2	P –value
	No	%	No	%		
Sources of drug prescription						
Governmental health center	92	47.9	100	52.1	1.915	0.384
UNRWA	9	60.0	6	40.0		
Other sites	6	66.7	3	33.3		
Availability of drugs						
Always available	84	62.7	50	37.3	24.488	0.000
Sometimes available	21	27.6	55	72.4		
Not available	2	33.3	4	66.7		
Other sources to get drugs						
1- UNRWA clinic						
Yes	14	60.9	9	39.1	1.332	0.277
No	93	48.2	100	51.8		
2-Another governmental clinic						
Yes	2	100.0	0	0.0	2.056	0.244
No	105	49.1	109	50.9		
3- Private pharmacy						
Yes	78	58.6	55	41.4	11.490	0.001
No	29	34.9	54	65.1		
OR=2.641			**C.I=(1.496-4.661)**			
4-Use drugs from relatives						
Yes	7	53.8	6	46.2	0.103	0.782
No	100	49.3	103	50.7		
5-Remain without treatment						
Yes	5	11.4	39	88.6	32.210	0.000
No	102	59.3	70	40.7		
OR=0.088			**C.I=0.033-0.234)**			
Respect Diabetic Clinic appointments						
Yes	94	49.5	96	50.5	0.003	1.000
No	13	50	13	50		
Taking drugs other than antidiabetic drugs						
Yes	59	45.7	70	54.3	1.851	0.212
No	48	55.2	39	44.8		
No of daily drugs taken by patients						
One drug	30	90.9	3	9.1	42.333	0.000
Two-Three drugs	59	54.1	50	45.9		
> three drugs	18	24.3	56	75.7		

The result of the present study was congruent with Kem, 2003, as he said that patients typically cope with economic hardship by not having prescriptions filled, taking a smaller dose, or buying a cheaper over-the-counter product that is presumed to have a similar effect, and found that the out-of-pocket costs of medications have a profound impact on compliance (Kem, 2003).

Concerning the diabetic clinic visit commitment, the compliance rate was 49.5% among who respect their appointments, and it was 50% among who were not respect their appointments, and the result did not reach the statistical significance (P=1.000).

Regarding poly pharmacy, about 54.3% of patient who taking drugs other than diabetic were not compliants and higher than the compliants (45.7%) but the result didn't reach the statistical significance (P=0.212).

Considering number of daily drugs taking by the patients, the compliers were higher among patients who either take one drug or who take two-three drugs per day and represented by 90.9%, and 54.1% respectively. The compliance rate was decreased among patients who take more than three drugs daily (24.3%). There was a strong statistical significance between non compliance and polypharmacy, as the number of daily drugs increased, the compliance decreased too (P=0.000). This result agreed with Paes et al in1997, he found that compliance dropped from 79% for once-daily medications to 38% for medications taken 3 times a day. The result was congruent also with Winkler, et al. in 2002 as they found that once daily dosage led to significantly better adherence rates than two or three times daily regimens.

Similarly the results agreed with Jaser in 1999 in Palestine, as he found that the compliance rate was significantly higher among patients taking one type of hypoglycemic drugs and among patients on single daily dose (Jaser, 1999).

In contrast, Grant, et al. in 2003, found that patients reported very high medication adherence rates regardless of number of medicines prescribed.

Chapter 6

Conclusion and Recomendations

Conclusion

One ongoing challenge to diabetes care is maintaining compliance to the recommended treatment and lifestyle program that will reduce the risk of long-term complications. Diabetes is a chronic illness requiring extensive adjustments to daily living.

Patients often do not take their medication as prescribed, and the reasons for non-adherence to prescribed medication are very heterogeneous.

This study assess the non compliance in type2 diabetes patients, prevalence and associated factors. The results revealed that the prevalence of non- compliance among the study population was (50.5%), typical reasons cited by patients for not taking their medications included forgetfulness (66.4%), frustration (24.3%), feeling better without treatment(19.6%), polypharmacy (14%), and other causes such as fear from drug side-effect and unavailability of drugs which representing by 12.1%, 8.4% respectively.

According to HbA1c, the prevalence of controlled patients was only 24.5%, while the prevalence of uncontrolled was 75.5%. Glycemic control was strongly significantly affected by compliance, around five times as the non-compliance increased, poor glycemic control increased; (HbA1c more than 7%) .

As it was shown there was a difference between prevalence of non compliance (50.5%) and uncontrolled patients (75.5%). That difference could be related to that diabetic patient didn't comply to the non-pharmacological treatment in addition to their non compliance to

the regimen treatment, HbA1c values reflect the radical changes in diet or changes in other modes of therapy approximately 3 to 4 weeks after initiation of the change.

Finding of this study showed that 38.9% did not follow any diet regimen, and 61.6% of respondents were not exercising at all, More over the non-compliance rate was significantly decreased among patients who did not follow any diet regimen. In conclusion the compliance towards diet and exercise is poor and it is important to focus on lifestyle intervention and to increase the education in this field congruent with medication to improve compliance.

Most of the study population was from Gaza 64.8%, followed by North Gaza 20.8%, and the lowest were from Mid-zone 14.4%. The mean age of patients participated in the study was 54.4 years, diabetic females were twice more than males. The majority of the study population (50.9%) were of low level of education, not working (89.8%), and with low income; about half of the sample population 46.3 their income was 2000 NS or less.

Non compliance rate was higher among females and increased among patients with high educational level as well with long duration of diabetes but the difference did not significantly affect the compliance. There was no significance difference in compliance rates regarding demographic factors, such as age, gender, locality, consanguinity, educational level and socio-economic status. Similarly associated chronic diseases showed no significance difference on compliance except the associated ischemic heart disease which showed a significant effect on non-compliance.

A positive family history; regarding the mother showed a negative significant effect on compliance, this could be explained as diabetic patients needs a social support which could be lost when the mother is also diabetic.

It was found that 64.4% Of the study population were on oral hypoglycemic agents (OHAs), 17.6% on insulin and 18.1% on mixed therapy (OHAs&Insulin). The non compliance rate was the highest, among those who were on insulin and on mixed treatment (OHAs and insulin), but the type of medicine did not show a significant association with compliance.

The results showed that 15.3% of the participants were taking only one drug therapy, more than half of study sample (50.5%) were taking two or three drugs per day, 34.3% of patients were taking more than three drugs per day. It was found a significant relationship between polypharmacy and non-compliance rate. The compliance rate was the highest among those who were on one drug treatment, and decreased gradually as the number of taking drugs increased.

The majority of patients who were on insulin treatment (35.6% of study population) had their injections by themselves represented by 74%, among them 93% had a training either by health providers (71.7%), or by family members (20.8%).

More than half of the study population had a knowledge and information about the disease; cure of diabetes and drug side-effects (58.8%, and 61.1% respectively). The main source of information was from the health providers (doctors and nurses). This result indicates that health providers have a good role in patient's knowledge about their disease. The results showed that increased knowledge of drug side-effect had a significant positive association with the compliance rate. And it was found that poor knowledge increase the risk of non compliace by about six times.

As shown in the results there was a positive attitude of some patients towards either using traditional remedies or using drugs prescribed to others but that attitude did not significantly affect the non compliance.

The results showed that patients had a negative attitude regarding taking of a missed dose and that attitude was highly significantly increasing the non compliance.

Patients' feeling regarding their medicine especially their feeling not to take their medicine and feeling in need for a rest period were significantly associated and increasing the non compliance rate, and feeling in need for rest period showed a negative association with compliance. Patients related the causes of their feeling regarding medicines to as follow; fear of drug side- effect at present or in future, fear from drug dependence or no confidence of drugs. There were a belief by some patients (38.4%) in that medicine is not needed, but it didn't significantly affect the compliance.

In conclusion, feeling and attitude had shown to have an effect on compliance, so that a better understanding of patients' feeling and attitudes may help physicians increase motivation, understanding, and compliance of diabetic patients.

Concerning patient practice; patients who were regular on taking their drugs as they had claimed had a highly significant higher compliance rate than those who were irregular. Moreover the compliance rate was highly significantly affected by the attitude of patients regarding taking of a missed dose.

The results revealed that 98.6% of study population believed in the benefit of exercise for their health, in spite that only 38.4% of the subjects was actually practicing exercise, and among them 18.1% of them were exercising 3 or more days per week, 15.3% were exercising one or two days per week and 5% were practicing little exercise. This indicated that there is a gap between attitude and behaviors, so that barriers must be assessed, and behaviour modification should be included, if diet and exercise programs are to be successful.

It was found that the majority of study population (92.6%) depending on themselves in remembering their doses time which is susceptible for forgetfulness.

Only 11.1% of study population checking the glucose level by themselves**,** self-monitoring of blood glucose (SMBG), It is important to focus on SMBG in order to achieve good glycemic control.

The majority of study population had associated risk factors; uncontrolled blood pressure (68.5%), hypercholesterolemia (64.8%), hyper triglyceridemia (68.5%), and obesity (63%). The non compliance rate in general was higher than the compliance rate regarding risk factors but hypertriglyceridemia and obesity were significantly increased among non compliance. This result indicated that non compliance is highly linked and significantly associated with obesity and hypertriglyceridemia.

It was found that 57.9% of the study population had complication, more over presence of complication was significantly increased in relation to non compliance rate in general, and in particular for ophthalmic and diabetic foot complication. Presence of complication; "co

morbidities" may increase or lead to depression and resulted in a negative effect on compliance.

Concerning the availability of medicine in the governmental health center, 62% of the study population certain that medicine is always available, and the results showed a strong statistical significance regarding the availability of drugs and increasing of compliance rate. It was shown in case of unavailability of medicine, The compliance rate had a significant positive association with the option of getting the medicine from private pharmacy and a strong significant negative association with the option of remaining without treatment. This result indicated that medicine availability and cost of medicine had a significance effect on adherence, as the patients who forced to get their drugs from private sources when their drugs are unavailable, the non compliance increases and remaining without treatment increased, this result reflect that socio-economic status had a negative impact on compliance as low socioeconomic status may put patients in the position of having to choose between competing priorities.

It was found in the results that 88% of study population keeping their appointment to the diabetic clinic, the proportion who did not omit their appointment related the causes to the increasing waiting time (77.8), doctors did not give the patients' his care or attention (14.8%) or unavailability of drugs (7.2%). It was found that commitment of the diabetic clinic appointment, source of getting the drug, and taking drugs other than ant diabetic drugs had no significant association with non compliance.

In conclusion, compliance to medications as well as to diet and exercise was poor.

Many factors affecting and lead to poor compliance; patient related factors (forgetfulness, poor knowledge, attitude, feeling, beliefs or socio-economic), regimen factors (polypharmacy), health system related factors (unavailability of drugs or increase waiting time), provider-based factors (the perception of providers as being warm and caring), and condition-related factors (social support, frustration, presence of complications of diabetes, associated chronic diseases). On the other hand socio-demographic factors (age, gender, locality, consanguinity, marital status, family size educational level and income) did not report a role on compliance.

Recommendations

Efforts to enhance compliance should target patient, provider and health care system related factors according to the following recommendations:

1- Helping the patients to increase their self awareness of their values, needs, and goals for diabetes care by directing efforts towards developing educational programs on consanguineous marriage and on diabetes knowledge, dietary practices, physical exercise, medication compliance, self-monitoring of blood glucose, and glycosylated hemoglobin.

2-Enhancing patients factors that could overcome forgetfulness by using adherence aids such as medication calendars, medication organizers, and electronic devices or alarms.

3-More efforts must be made to enhance the role of health provider by increasing motivation, understanding, and compliance of diabetic patients by focusing on understanding of patients' beliefs and attitudes that may help physicians to improve compliance and to overcome the gap between attitude and behaviors.

4-Encouraging and enhancing specific training in adherence management for practitioners and the health care systems include educating staff nurses and setting up standards of patient care, protocols for the prevention and care of diabetes-related complications of the eyes, lower extremities, and cardiovascular system as well as educating patients.

5-Simplification of the dosage regimen**;** simplification of the dosage regimen may include conducting a drug utilization review to decrease the number of medications a patient is taking, decreasing the number of daily doses by switching to extended-release formulations.

6-Increasing efforts by policy makers for creation and adoption of chronic care models of service delivery, for improving access to medicines and health care, decreasing waiting time and to offer medications for all patients.

Further researches:

1-More researches needed at the national level including other health providers.

References

Abu Mosa, H., (1999), " *Magnitude of Diabetes Mellitus in Gaza Strip*", UNRWA-Gaza.

Abu Ramadan,M., (2004), "*Risk Factors of Diabetes Mellitus Type 2 In Gaza Strip* ", School of Public Health, Al -Quds University, Gaza, Palestine.

Adrienne Blount, B.S., Maureen Harris, M.S., R.D., Anna Hodgson, M.A., and Pat M.,(1998), Clinical Guidelines On The Identification, Evaluation, And Treatment Of Overweight And Obesity In Adults. The Evidence Report. *Obesity Education Initiation*, National Institute of Health, NIH publication, 98-4083.

Albaz RS. (1997), *Factors affecting patient compliance in Saudi Arabia*. Journal of Social Sciences, Vol. 25:5-8.

Aljasem., LI., Peyrot, M., Wissow, L., and Rubin, RR., (2001), *The impact of barriers and self-efficacy on self-care behaviors in type 2 diabetes*. Diabetes Educator. Vol. 27:393-404.

Alwan A.S., (1994), Management Of Diabetes Mellitus Standers of Care and Clinical Practice Guidelines, *Diabetes prevention and control*, World Health Organization Regional Office for the Eastern Mediterranean, Alexandria, Egypt.

Al-Saeedi, M., Elzubier, AG., Bahnassi, AA., and Al-Dawood, KM., (2003), *Patterns of belief and use of traditional remedies by diabetic patients in Mecca*, Saudi Arabia. East Mediterranean Health Journal. Jan-Mar,9(1-2):99-107.

American Diabetes Association (ADA), 2002, *National Diabetes Fact Sheet*, Available at http://www.diabetes.org/diabetesstatistics/ national-diabetes-fact-sheet.jsp (accessed in1st of august,2006).

American Diabetes Association (2003), *Economic Costs of Diabetes in the U.S. in 2002*. Diabetes Care Vol.26(3):917-932.

American Diabetes Association,(2005), *Diagnosis and classification of Diabetes Mellitus*, Diabetes Care 28:S37-S42, 2005.

American Diabetes Association, (2006), *Standards of Medical Care in Diabetes*, Diabetes Care 29:S4-S42, 2006.

American society of consultant pharmacist Journal (ASCP), supplement 4, 2001: Clinical consult, *Oral Therapy for Management of Diabetes Mellitus in the Elderly*, Vol.16.

Anderson, R. & Kirk, L. (1982), *Methods of Improving Patient Compliance in Chronic Disease States*. Archives of Internal Medicine, 142, 1673-1675.

Anthony. S., Odgers, T., and Kelly, W., (2004), *Health promotion and health education about diabetes mellitus*, Diabetes Care Centre, J R Soc Health. Mar;124(2):70-3, England.

Asim, A.J., (2004), *Adherence to HIV Treatment Regimens: Recommendations for Best Practices* APHA – www.apha.org/ppp/hiv - June (accessesd on 3rd Sep.2006)

Astrup, A., (2001*), Healthy lifestyles in Europe: prevention of obesity and type II diabetes by diet and physical activity*, Public Health Nutr. Apr;4(2B):499-515.

Balkrishnan, R., (1998): *Predictors of Medication Adherence in the Elderly*. Clinical Therapeutics, 20; 4: 764-771.

Brown, JB., Harris, SB., Webster-Bogaert S., Wetmore, S., Faulds, C. and Stewart, M., (2002), *The role of patient, physician and systemic factors in the management of type 2 diabetes mellitus.* Family Practice,Vol. 19: 344–349.

Cameron, C., (1996): *Patient compliance: recognition of factors involved and suggestions for promoting compliance with therapeutic regimens*. Journal of Advanced Nursing, 24: 244-250.

Ciechanowski, PS., Katon, WJ., Russo, JE., and Walker, EA., (2005), *The patient-provider relationship, attachment theory and adherence to treatment in diabetes*. Am J Psychiatry. 158:29-35.

Christophersen ER, Mortweet SL., 2005, Treatments that Improving Adherence in the Primary Care or Specialist Care Setting, *How to improve adherence to medical regimens using behavior principles* , Washington, D.C.: APA Books, 2001.

Clark, E., Oswald, D., Kreuter, M. & Bull, F. (1999). Understanding How People Process Health Information: *A Comparison of Tailored and Nontailored Weight-Loss Materials.* Health Psychology, 18, 487-494.

Centers for Disease Control and Prevention, CDC, (2003): National Center for Chronic Disease Prevention and Health Promotion, *National diabetes fact sheet:* general information and national estimates on diabetes Department of Health and Human Services, United States .

Centers for Disease Control and Prevention, CDC, (2005): National Center for Chronic Disease Prevention and Health Promotion, National diabetes fact sheet: general information and national estimates on diabetes Department of Health and Human Services, United States .

Cramer, J., (1991), Identifying and improving compliance patterns*. Patient compliance in medical practice and clinical trials*. New York: Raven Press, Vol. 387-92.

Deborah, J.C., Cert, D.N.,and coleman,R., August (2005), *Medication compliance in the elderly*, JCN journal, Vol. 19, Issue 08.

Dietrich, UC., (1996), *Factors influencing the attitudes held by women with type II diabetes*: a qualitative study, Patient Educ Counc, Oct;29(1):13-23.

Dunbar, J., Shumaker, S., and Eleanor, B., (1990), Predictors of patient adherence, *Patient Characteristics*. The Handbook of health behavior change. New York, NY, USA: Springer Publishing Co, Inc.

Dunn, FL., (1992): *Management of hyperlipidemia in diabetes mellitus*. Endocrinol Metab Clin North Am. Jun;21(2):395-414.

Ferzacca, S.(2000), "Actually, I don't feel that bad", *Managing diabetes and the clinical encounter*. Medical Anthropology Quarterly 14(1):28-50.

Germendy, G., (2003), *Is type-2 diabetes mellitus preventable*? Orv Hetil, Sep 28;144(39):1909-17

Gonen, BA., Rubinstein, AH., and Rochman, H., (1997), *Hemoglobin A1: An Indicator of the Metabolic Control of Diabetic Patients*. The Lancet Oct 8,2(8041):7347. http://diabetes.bio-rad.com/html/story.html#hba1c,(accessed on 6th Sep).

Grant, RW., Devita, NG., Singer, DE., and Meigs, JB.(2003*), Polypharmacy and medication adherence in patients with type 2 diabetes*, Diabetes care. May;26(5):1408-12. USA. rgrant@partners.org

Harris R., Linn MW., and Pollack L., (1984), *Relationship between health beliefs and psychological variables in diabetic patients*. Diabetes Care Sep.57 (Pt 3): 9-253

Haynes, R.B., Taylor, D.W., Sackett, D.L. (1979): *Compliance in Healthcare*. The John Hopkins Press, London.

Hays, LM., and Clark, DO.,(1999): *Correlates of physical activity in a sample of older adults with type 2 diabetes*, Diabetes Care, May;22(5):706-12.

Hertz, RP., Unger, AN. And Lustik, MB., (2005), *Adherence with pharmacotherapy for type 2 diabetes*: a retrospective cohort study of adults with employer-sponsored health insurance. Clinical Therapy, Pfizer Inc., New York, Vol.27(7):1064-73.

Hunt, Linda M., Jacqueline P., and Miguel V., (1998), *How patients adapt diabetes self-care recommendations in everyday life*. The Journal of Family Practice 46(3):207-215.

Jaser, NA., (1999)," *Compliance of Diabetic Patients with the treatment regimen at UNRWA health centers in Gaza strip*", School of Public Health, Al Quds University, Gaza, Palestine.

Jenny, J. (1986), Differences in Adaptation to Diabetes Between Insulin-Dependent and Non-Insulin Dependent Patients: *Implications for Patient Education*. Patient Education and Counseling, 8, 39-50.

Joel, S., Mohan, N., and John, V.,(2002), *The Association Between Diabetes Metabolic Control and Drug Adherence in an Indigent Population*, Diabetes Care 25:1015-1021.

Joyce A.C., (2004), *Systematic Review of Adherence With Medications for Diabetes*. Diabetes Care. 27:1218-1224.

Justin J. S., (2005), *The Impact of Smoking and Quitting Smoking on Patients With Diabetes*. Diabetes Spectrum, Vol. 18:202-208.

International Diabetes Federation (2004), *Creating a European Framework for Diabetes Prevention, Diagnosis and Control*. Information Paper – June 2004.

Kamel, NM., Badawy, YA., El-Zeiny, NA., and Merdan, IA., (1999), Socio-demographic determinants of management behavior of diabetic patients Part II. *Diabetics' knowledge of the disease and their management behavior*, EMHJ, Vol. 5:5, 974-983.

Kell,y J., (1995): *Making sense of drug compliance by patients.* Nursing Times, 91; 40: 40-41.

Kem, P., Krueger, Bill, G., Felkey, and Bruce, A. Berger,(2003), Improving Adherence and Persistence: *A Review and Assessment of Interventions and Description of Steps Toward a National Adherence Initiative*, Journal of the American Pharmacists Association Vol.43:668–79.

Kumar, P. and Clark, M., (2002), *Clinical Medicine*, Forth edition, W. B. Saunders,London.

Kusserow, R., Dufresne, J., and Greene,V., June (1990), *Medication regimens,"Causes of non-compliance"*. Office of Inspection General (OIG), Office of Evaluation and Inspection(OEI)-04-89-89121.

Manson, JE., Stampfer, MJ., Colditz, G., Liu, S., Solomon, CG., Willett, WC.,(2001), *Diet, lifestyle, and the risk of type 2 diabetes mellitus in women*. New England J. Med. Sep 13;345(11):790-7.

Mark H., Robert S. P., Thomas V. J., Justin L. K., Michael B., (2006),The Merk Manual of Diagnosis and therapy, *Section 2. Endocrine and Metabolic Disorders*, Diabetes Mellitus, Published by Merck Research Laboratories, Merck & Co., Inc. Whitehouse Station, N.J.

McCord, EC. and Brandenburg, C., (1995), *Beliefs and attitudes of persons with diabetes. Family and Community Medicine*, USA, Apr;27(4):267-71.

McGill, M. (2001 Sep-Dec), Diabetes education: *a keystone in the management of diabetes.* Papua New Guinea Medical Journal, 44(3-4), 131-4.

McKevith, B.,(2005), *Diet and healthy ageing*, J Br Menopause Soc. Dec;11(4):121-5.

Medical practice guidelines (MPG), 2006, *Monitoring test options*. http://www.diabetes-tests.com/Monitoring_Test_Options.html#Top(accessed on 10th Oct.2006).

Michael H., (2004), Improving Adherence in the Polypharmacy Management of Disease, Business Briefing: *Pharmatech, Technology and Survices*. www.touchbriefings.com/pdf/890/scolr.pdf (accessed on 20th Oct.).

Ministry of Health, (2002), Health status in Palestine, Annual Report (2001), State of Palestine, Ministry of Health; *Health Management Information Center* (HMIS).

Ministry of Health, (2004), Health status in Palestine, Annual Report (2003), State of Palestine, Ministry of Health; *Health Management Information Center* (HMIS).

Ministry of Health, (2004), Health System Development Project Quality Improvement Program, *Palestinian Guideline For Diagnosis and Management Of Diabetes Mellitus*, Palestinian National Authority.

Ministry of Health, (2005), Health status in Palestine, Annual Report (2004), State of Palestine, Ministry of Health; *Health Management Information Center* (HMIS).

Mojtabai, R., and Olfson, M., (2003): *Medication costs, adherence, and health outcomes among Medicare beneficiaries.* Health Aff. Vol. 22:220-229.

National Health System (NHS), 2006: *Guide To The Management Of Diabetes For Primary Care Practitioners*, Primary Care, West Hertfordshire.

Osterberg L., and Blaschke., T., (2005), *Adherence to Medication*, The New England Journal Of Medicine., August 4,Vol. 353:487-497.

Paes, AH., Bakker, A., and Soe-Agnie, CJ.,(1997), *Impact of dosage frequency on patient compliance.* Diabetes Care.;20:1512-1517.

Paul M., Rachel P. W., Kristi R., Karen B. D., Jing C., and Vivian F.,(2005), *Relationship Between HbA_{1c} Level and Peripheral Arterial Disease*, Diabetes Care 28:1981-1987

Palestinian Central Bureau of Statistics, (2004): *demographic status of the Palestinian in the Palestinian Territory*, Palestinian National Authority: Author.

Palestinian Central Bureau of Statistics, (2006): *demographic status of the Palestinian in the Palestinian Territory*, Palestinian National Authority: Author.

Pannacciulli, N., Pergola, D., Ciccone, M., Paolo Rizzon, R., Giorgino, F., and Giorgino, R., 2003: Effect of Family History of Type 2 Diabetes on the Intima-Media Thickness of the Common Carotid Artery in Normal-Weight, Overweight, and Obese Glucose-Tolerant Young Adults Diabetes Care 26:1230-1234

Petty, R.E. and Cacioppo, J. T. (1981), Attitudes and persuasion: *Classic and contemporary approaches*. Dubuque, IA: William C.Brown.

Platt, F.W., Tippy, P.K. & Turk, D.C. (1994, October 30). *Helping patients adhere to the regimen.* Patient Care, 43-52.

Polonsky WH., Fisher L., Dowe, S., and Edelman S., (2003), *Why do patients resist insulin therapy?* Diabetes. 52(suppl 1),A417.

Primary Health Agency of Canada (PHAC),(2003), Risk factors associated with diabetes. "Eat well. Be active. Have a fun"., *You can prevent type-2 diabetes*, www.phac-aspc.gc.ca/ccdpc-cpcmc/diabetes-diabete/english/risk/index.html - 21k-(accessed on 16.oct.2006).

Rajaei DZ., MacPherson, G., (1997): *Drug-related problems in older people*. Nursing Times, 93; 28: 54-56.

Rapoff, M.A., (1999), *Adherence to pediatric medical regimens*. New York: Kluwer Academic/Plenum.

Rhee, MK., Slocum, W., Ziemer, DC., Culler, SD., Cook, CB., El-Kebbi, IM., Gallina, DL., Barnes, C., and Phillips, LS.,(2005), *Patient adherence improves glycemic control*. Diabetes Educucation, Mar-Apr.31(2):240-50.

Ruggiero, L., Spirito, A.,, Bond A., Coustan, D., and McGarvey, S., (1990), *Impact of social support and stress on compliance in women with gestational diabetes*. Diabetes Care. Vol. 3:441-443.

Scott,R.V., and Anne, L.P., (2004), *Diabetes Mellitus, Type 2 - A Review*, Emedicine.

Searle, MS., and Ready, AE.,(1991), *Survey of exercise and dietry knowledge and behaviour in persons with type2 diabetes*, Can J Public Health, Sep-Oct;82(5):344-8.

Sha'at,O., (2000), "*Diabetes Mellitus Status Among Registered Pregnant Women in Primary Health Care Centers in the Southern of Gaza Province, Palestine"*, School of Public Health, Al Quds University, Gaza, Palestine.

Sheeri, L. K., Victoria, S. D., David, W. B., (2002), *Controlling Hypertension in Patients with diabetes.* American Academy of Family Physicians (AAFP). October 1,Vol.66, No.7.

Show, J.,and Chisholm, D., (2003), *Epidemiology and prevention of type 2 diabetes and the metabolic syndrome*, National prevention programs are needed, but GPs can contribute through screening and lifestyle advice, MJA 179: 379–383.

Shultz, JA., Sprague, MA., Branen, LJ., and Lambeth, S. (2001), *A comparison of views of individuals with type 2 diabetes mellitus and diabetes educators about barriers to diet and exercise*, J Health Commun. Apr-Jun,6(2):99-115.

Society for vascular surgery(SVS),(2006):*Patient and Family Health Information*, hyperlipidemia.
www.vascularweb.org/_CONTRIBUTION_PAGES/Patient_Information/NorthPoint/Hyperlipidemia.html - 17k-(accessed on 16th Aug.2006).
Swift, CS., Armstrong, JE., Beerman, KA., Campbell, RK., and Pond-Smith D., 1995, *Attitudes and beliefs about exercise among persons with non-insulin-dependent diabetes*, Diabetes Education, Nov-Dec., 21(6):533-40.

Tracy, JK., 2006, Diabetes Update, *High Post Meal Blood Sugars Destroy Nerves Before Diagnosis*, Kings College, London. diabetesupdate.blogspot.com/2006/08/, (Accessed on 10th Nov)

World Health Organization WHO,(1993), Khalil, S., Ruznamaji, N, Sherif, I, Khatib, O, Mukhtar, ED, MacKinnon, M., Alwan, A. and King, H,(1993), *Diabetes prevention and control*, Health Education For People with Diabetes. Alexandria, 10—14 November 1993.

World Health Organization, (1998), World Health Report (1998*), Life in the 21st Century*: A Vision for All. WHO: Geneva.

World Health Organization, (2003), *Adherence to long-term therapies: evidence for action.*, WHO Library Cataloguing-in-Publication Data,WHO, 20 Avenue Appia, 1211 Geneva 27, Switzerland.

World Health Organization, (2005), *WHO Global Strategy on Diet, Physical Activity and Health.*

Wild, S., Roglic, G., Green, A., Sicree, R., & King, H. (2004), *Global Prevalence of Diabetes*: Estimates for the year 2000 and projections for 2030. Diabetes Care, 27, 1047-1053.

Wichowski, H. and Kubach, S. (1997), *The Relationship of Self-Perception of Illness and Compliance with Health Care Regimens.* Journal of Advanced Nursing, Vol. 25, 548-553.

Wilson, Hanson and Glasgow(1986), *Psychosocial predictors of self-care behaviors (compliance) and glycemic control in non-insulin-dependent diabetes mellitus*. Diabetes Care 9:614-622.(Building compliance in diabetes)

Winkler, A., Teusche, A., Mueller, B., and Diem, P.(2002), *Monitoring adherence to prescribed medication in type 2 diabetic patients treated with sulfonylureas*, Swiss Medical Weekly (SMW), Vol. 132:379–385

Yusef J.I., (2000), *Management of diabetes mellitus and hypertension at UNRWA primary health care facilities in Lebanon*, Eastern Mediterranean Health Journal. Vol.6: 378-390

Zimmet, P. (2003 Sep), *The burden of type 2 diabetes: are we doing enough?* Diabetes Metababolism, 29(4 Pt 2), 6S9-18.

Annex 1

Body Mass Index

Body Mass Index	**Weight Status**
Below 18.5	Underweight
18.5-24.9	Normal
25.0-29.9	Overweight
30-39.9	Obese
=>40	Morbid obese

Annex 2

Map of Palestine

Annex 3

Map of Gaza Strip

Annex 4

Palestinian National Authority
Ministry of Health
Helsinki Committee

السلطة الوطنية الفلسطينية
وزارة الصحة
لجنة هلسنكي

Date: 30/10/2005

التاريخ: 2005/10/30

Mrs./ Amal Zaqout

السيدة: أمل زقوت

I would like to inform you that the committee has discussed your application about:

نفيدكم علماً بأن اللجنة قد ناقشت مقترح دراستكم حول:-

Non – compliance in Type 2 Diabetes Patients: Prevalence and Associated Factors in Gaza Strip.

In its meeting on October 2005 and decided the Following:-

To approve the above mention research study.

و ذلك في جلستها المنعقدة لشهر أكتوبر 2005

و قد قررت ما يلي:-

الموافقة على البحث المذكور عاليه.

Ministry of Health Helsinki Committee

Signature
توقيع

Chairperson

Member
عضو

Member
عضو

Conditions:-

- Valid for 2 years from the date of approval to start.
- It is necessary to notify the committee in any change in the admitted study protocol.
- The committee appreciate receiving one copy of your final research when it is completed.

Gaza Etwam – Telefax 972-7-2878166

Annex 5

وزارة الصحة

جامعة القدس

كليـة الصحـة العامـة

School of Public Health

القدس - فلسطين

2005/12/27

الأخ/ د. علي قويدر المحترم

مدير عام الرعاية الأولية – وزارة الصحة

تحية طيبة وبعد،،،

الموضوع: مساعدة الطالبة أمل زقوت

تقوم الطالبة المذكورة أعلاه بإجراء مشروع بحث بعنوان:

"Non-compliance of type -2 diabetes patients: prevalence an associated factors in Gaza strip"

كمتطلب للحصول على درجة الماجستير في الصحة العامة علماً بأن الطالبة قد حصلت على موافقة لجنة هلسنكي لأخلاقيات البحوث و ستكون المعلومات متوفرة لدى الباحثـة فقـط. و عليه نرجو التكرم للإيعاز لمن ترونه مناسب لتسهيل مهمة الطالبة في جمع البيانات الخاصة.

موافقتكم دعماً للمسيرة الأكاديمية

و تفضلوا بقبول فائق الاحترام ،،،

د. سوزان شعشاعه

عميد كلية الصحة العامة المساعد

نسخة: الملف

كلية الصحة العامة / غزة
رقم الصادر: 2005 – 340
تاريخ الصادر: 2005/12/27

Annex 6

موافقة على إجراء استبيان حول دراسة:

" العوامل التي تؤدي إلى عدم التزام مرضى الداء السكري من النوع الثاني بالعلاج ودراسة معدل انتشار هذه الظاهرة"

أنا الباحثة " أمل عبد العزيز زقوت" طالبة في برنامج ماجستير الصحة العامة في جامعة القـدس – أبو ديس- فلسطين.

إنني أقوم بعمل بحث علمي هو جزء من دراستي في الجامعة يهدف إلى " دراسة العوامل التـي تؤدي إلى عدم التزام مرضى الداء السكري النوع الثاني بالعلاج ودراسة معدل انتشار هذه الظاهرة" حيث أن نتائج هذه الدراسة قد تؤدي إلى تحسين الالتزام بالخطة العلاجية ومعالجة العوامـل التـي تحول دون الالتزام بذلك.

هنالك خيارات للإجابة عن كل سؤال، الرجاء اختيار الإجابة الأقرب لك ولممارستك الواقعية، مـع الملاحظة أنه لا يوجد إجابات خاطئة وإجابات صحيحة المشاركة في هذا البحث تطوعية ولك الحق في الانسحاب في أي وقت تشاء.

تعبئة الاستبيان تستغرق من 10 إلى 15 دقيقة، مع التأكيد على أن الحفاظ على السرية تؤخذ بعين الاعتبار ولا حاجة لكتابة اسمك على الاستبيان.

أقدر عالياً مشاركتك بالبحث

وتفضلوا بقبول جزيل الشكر

Annex 7

بسم الله الرحمن الرحيم

الرقم المتسلسل :.....

معلومات من مقابلة المريض :

1- الجنس : ذكر ☐ أنثى☐

2- الحالة الاجتماعية:
أعزب / عزباء ☐
متزوج / متزوجة ☐
مطلق / مطلقة ☐
أرمل / أرملة ☐

3- العمر:.....

4- العنوان: .....

5- المهنة : يعمل ☐ لا يعمل☐

إذا كان يعمل :
مؤهلون (أطباء ، محامون ، محاسبون ، كيميائيون ..)☐
مهنة متوسطة (مديرون – مدرسون ، .....)☐
تاجر ، ملاك ☐
أصحاب مهارات (رئيس العمال ، طباخ ، بقال ، .....)☐
أنصاف المهرة (عامل التلفون ، محصل التذاكر ،..)☐
غير المهرة (العتال ، عامل النظافة،....)☐
أخرى .....☐

6- عدد سنوات التعليم:- .....

7- عدد الأفراد في المنزل : .....

8- دخل العائلة الشهري من كل مصادر الدخل :

رفض الإجابة☐ شيكل < 2000 ☐ شيكل 1000-2000☐ شيكل >1000 ☐

9- صلة القرابة بين الوالدين:

درجة أولى (أبناء العم/ العمة – أبناء الخال/الخالة). ☐

درجة ثانية (قرابة من بعيد "من العائلة").☐

لا يوجد قرابة.☐

10- هل يعاني أحد أفراد أسرتك من داء السكرى ؟

إذا كانت الإجابة نعم فحدد: لا☐ نعم ☐

العم/العمة ☐ الابن/الابنة ☐ الأخ/الأخت☐ الأم ☐ الأب ☐

الخال/الخالة☐ الجد/ الجدة ☐

11- هل أنت مدخن ؟

لا ☐ نعم ☐

توقف عن التدخين (أكثر من 6 أشهر)☐

الشيشة:☐ السجائر ☐للمدخنين:

عدد السجائر في اليوم: ..... عدد مرات التدخين .....

مدة التدخين: ..... مدة التدخين: .....

12- هل تعاني من أمراض مزمنة أخرى ؟

نعم ☐ لا ☐

إذا كانت اجابتك نعم حدد:

ارتفاع ضغط الدم الشرياني ☐

نوبة قلبية (تصلب الشرايين التاجية)☐

أمراض في الجهاز التنفسي ☐

أمراض في الجهاز البولي / التناسلي ☐

أمراض في الغدد الصماء☐

النوبة الدماغية (الفالج الشقي)☐

أخرى .....☐

13- كيف بدأت العلاج بهذا المرض؟

حقن بالأنسولين☐ علاج دوائي بالفم "أقراص"☐ حمية ☐

مختلط (أنسولين + علاج دوائي)☐

14- ما نوع العلاج الحالي الذي تأخذه :

حقن بالأنسولين☐ علاج دوائي بالفم"أقراص"☐ حمية ☐

مختلط (أنسولين + علاج دوائي).☐

15- يطلب من المريض أن يحدد الجرعة الدوائية التي يتناولها فإذا كانت نفس الخطة العلاجيـة الموجودة في ملفه فإن المريض ملتزم ونشير إلى ملتزم واذا كان غيرذلك فنشيرالى غير ملتزم.

غير ملتزم ☐ ملتزم☐

اذا كان المريض ملتزم انتقل إلى سؤال رقم "17"

16- لماذا لم تلتزم بالعلاج حسب الخطة العلاجية ؟

لا☐ نعم ☐ بسبب النسيان . ☐

لا☐ نعم ☐ العلاج غير متوفر دائماً. ☐

لا☐ نعم ☐ أشعر بالتحسن من دون العلاج . ☐

لا☐ نعم ☐ كثرة الأدوية التي أتناولها . ☐

لا☐ نعم ☐ لم أفهم الخطة العلاجية بشكل واضح من الطبيب. ☐

لا☐ نعم ☐ أخشى الآثار الجانبية للعلاج. ☐

أسباب أخرى.....☐

.....

.....

17- هل لديك معلومات عن الأدوية التي تأخذها والآثار الجانبية لها ؟

لا ☐ نعم ☐

إذا نعم من أين حصلت على هذه المعلومات :

الكمبيوتر ☐ الأهل أو الجيران ☐ التمريض☐ الطبيب ☐

وسائل الإعلام☐ النشرات الدوائية☐

أخرى .....☐

18- ما هو مكان صرف العلاج ؟

مركز صحي حكومي.☐

وكالة ☐

أخرى.....☐

19- هل يتوفر علاج الداء السكري الموصوف لك في المركز الصحي ؟

لا يتوفر☐ نعم أحياناً ☐ نعم دائماً ☐

20- إذا لم يتوفر علاج الداء السكري فمن أين تحصل عليه ؟

أخرى).☐ وكالة ☐ حكومة ☐ من مركز صحي آخر: (☐

من صيدلية خاصة ☐

أستعمل علاج أحد الأقارب☐

أبقى بدون علاج ☐

أخرى.....☐

21- هل تستعمل أدوية لعلاج داء السكري قد تم وصفها للجيـران أو الأهـل أو الأصـدقاء دون الرجوع للطبيب ؟

لا☐ أحياناً ☐ نعم ☐

22- هل تتناول الآن أدوية لأمراض مزمنة غير أدوية الداء السكري ؟

لا ☐ نعم ☐

إذا نعم حدد عددها .....

23- هل تتناول أدوية الداء السكري بالجرعات الموصوفة لك وفي المواعيد المحددة لها ؟

لا ☐ أحياناً☐ نعم ☐

24- إذا لم تتناول أحد الجرعات في موعدها فهل تأخذها فيما بعد ؟

نعم قبل النوم ☐ نعم مع الجرعة التالية ☐ نعم فوراً ☐

لا أتناولها☐

25- كيف تتذكر موعد أخذ الجرعات ؟

بالاعتماد على النفس ☐

بالاعتماد على الآخرين ☐

باستعمال المنبة☐

على التساهيل☐

غير ذلك .....☐

26- في حالة انتظام مستوى السكر في الدم عندك وتحسن صحتك من أعراض الـداء السـكري التي كنت تعاني منها، هل ؟ :-

تستمر في أخذ العلاج بانتظام ☐

تخفض الجرعة ☐

تتوقف عن استعمال العلاج ☐

تستشير الطبيب☐

أخرى حدد .....☐

.....

27- هل تشعر أنك قد لا تكون بحاجة لتناول العلاج ؟

لا ☐ أحياناً☐ نعم ☐

28- هل تشعر أنك لا ترغب في تناول العلاج ؟

لا☐ أحياناً☐ نعم ☐

إذا نعم فما هو السبب ؟

لوجود أعراض جانبية عند تعاطي الدواء ☐

الخوف من الأعراض الجانبية للدواء في المستقبل☐

الخوف من الإدمان على تعاطي الدواء ☐

عدم الثقة في الأدوية الموجودة في المركز الصحي ☐

آخرى .....☐

.....

29- هل تشعر بأنك تحتاج إلى فترة راحة لا تستعمل فيها العلاج ؟ علماً بأنك طبياً في حاجة إليه.

لا ☐ نعم ☐

30- هل تعالج بالأنسولين؟

لا ☐ نعم ☐

إذا كانت الإجابة لا انتقل إلى سؤال رقم (36)

إذا كنت تعالج بالأنسولين:-

31- من يقوم بإعطائك الحقن؟

أحد أفراد الأسرة☐ بنفسك ☐

أذهب إلى العيادة☐ أذهب إلى صيدلية خاصة ☐

غير ذلك .....☐

32- إذا كانت إجابتك بنفسك، هل تم تدريبك على ذلك؟

لا ☐ نعم ☐

إذا كان نعم، من قام بتدريبك؟

تم تدريبي في المركز الصحي ☐

الأهل أوالأقارب ☐

غير ذلك .....☐

33- إذا كان من يعطيك الأنسولين أحد أفراد الأسرة فهل تم تدريبك على ذلك؟

لا ☐ نعم ☐

إذا نعم من قام بتدريبه؟

تم تدريبه في المركز الصحي ☐

الأهل أو الأقارب ☐

غير ذلك.....☐

34- هل تعتقد أنه من الضروري تناول الطعام بعد الحقن بالأنسولين؟

☐ نعم ☐ لا

35- إذا كانت الجابة نعم فهل:-

☐تتناول الطعام مباشرة بعد الحقن.

☐تتناول الطعام مباشرة بعد نصف ساعة.

☐تتناول الطعام مباشرة بعد ساعة.

☐أكثر من ذلك حدد .....

36- الداء السكري من الأمراض التي :

☐يمكن الشفاء منها تماماً

☐ لا يمكن الشفاء منها تماماً

☐ لا أعرف

37- هل تعتمد على الوصفات الشعبية في علاج السكري ؟

☐ نعم

☐ سابقاً

☐لم أتناولها مطلقا

38- في حال تناول الوصفات الشعبية هل كنت تتوقف عن أخذ العلاج الموصوف لك في المركـز الصحي ؟

☐ نعم ☐ لا

39- هل تعتقد أن ممارسة الرياضة قد تفيدك في علاج الداء السكري عندك ؟

☐ نعم ☐ لا

40- هل تمارس الرياضة؟

☐ نعم ☐ لا

إذا كانت الإجابة نعم

ما نوع الرياضة التي تمارسها: .....

41- ما هي كيفية الممارسة:

(يقوم بالرياضية 3 أيام/ أسبوعياً أو أكثر) ☐

(يقوم بالرياضية أقل من 3 أيام/ أسبوعياً).☐

42- هل تتبع نظام حمية معين ؟

نعم ☐ لا ☐

إذا كانت الإجابة نعم من أين حصلت على نظام الحمية؟

الأهل أو الأقارب☐ نشرات توعية خاصة ☐ من التمريض ☐ من خلال مقابلة الطبيب ☐

غير ذلك حدد .....☐

43- هل أنت ملتزم بمواعيد زيارة طبيب العيادة كما هو محدد لك ؟

نعم ☐ لا ☐

إذا كانت الاجابه لا فاذكر السبب

الخوف من أعراض نقص السكر عندي☐ مدة الإنتظار طويلة ☐ العلاج غير متوفر ☐

الطبيب لا يعيرني اهتمامه بشكل جيد☐ الطبيب قد لا يأتي دائماً ☐

أسباب أخرى حدد .....☐

44- هل يوجد مضاعفات عندك نتيجة الداء السكري؟

نعم ☐ ☐ لا أعرف☐ لا

إذا نعم حدد

العيون .....☐

الكلى .....☐

القدم .....☐

نوبة قلبية (تصلب الشرايين التاجية)☐ إعتلال الأعصاب الحسية ☐

اخرى.....☐ فالج دماغي (تصلب الشرايين الدماغية) ☐

45- هل تقوم بفحص مستوى سكر الدم بنفسك عن طريق جهاز فحص سكر الدم (الجلوكوميتر) ؟

☐ نعم ☐ لا

اذا كانت الاجابة نعم،فهل تقوم بفحص مستوى السكر في الدم:

☐ يوميا ☐ أسبوعيا ☐ شهريا ☐ اخرى.....

معلومات من ملف المريض

رقم ملف السكر: .....

سنة اكتشاف المرض ..... **المدة(بالسنة):**.....

الخطة العلاجية: .....

.....

.....

من تاريخ اخر زيارة لعيادة السكر:(FBS)آخر قراءتين لتحليل سكرالدم الصيامي

mg/dl..... mg/dl.....

) في الدم خلال سنه من تـاريخ اخـر HbAlcآخر قراءتين لتحليل مخزون السكر (زيارة لعيادة السكر:

....

آخر قراءتين لتحليل مستوى الكوليسترول و الدهون الثلاثيه في الدم خلال سنه

Total cholesterol:……. TG……mg/dl

Total cholesterol:……. TG…… mg/dl

قياس ضغط الدم (اربع قراءت خلال السنه)

BP …… BP…… BP…… BP…… mmHg

الوزن: kg.....

الطول: cm.....

BMI :kg/m2 .....

Non – Compliance in type 2 Diabetes
Patient – questionnaire

Data from patients Questioning

1- Sex ☐ Male ☐ Female

2- Marital Status ☐ single ☐ Married
☐ Widow ☐ Divorced

3- Age ……..

4- Address …….

5- Occupation ☐ work ☐ Didn't work

- If work: 1- Profesional (physician , lawyer, accountant,chemist.….)
  2- Managerial (manager, headmaster, teacher, …)
  3- Marcher.
  4- Skilled worker (chief worker, chief, groceryer, printer …).
  5- Partly skilled (telephone worker, fruit worker, …).
  6- Unskilled worker (cleaner).
  7- Unemployed.
  8- House wife.

6- Years of education ……...

7- Number of family members……..

8- Family income

☐ < 1000 NS ☐ 1000-2000 NS

☐ > 2000 NS ☐ Refuse the answer

9- Consanguinity

☐ First degree ☐ Second degree ☐ No

10- Have any one in your family ever had diabetes?

☐ Yes ☐ No

- If yes:

☐ Father ☐ Mother ☐ Brother/sister

☐ Son/daughter ☐ uncle ☐ grandfather

11- Smoking

☐ Yes ☐ No

☐ Stop smoking (for more than 6 months).

- For smokers: - No. of cigarette ……

- Duration ……..

12- Associated chronic diseases

☐ Yes ☐ No

* If yes:

☐ Hypertension

☐ Ischemic Heart Disease.

☐ Respiratory Diseases.

☐ Endocrine Disease.

☐ Stroke.

☐ Others.

13- How did you start your treatment?

☐ Diet ☐ Doanil ☐ Insulin ☐ Mixed

14- What is your treatment now?

☐ Diet ☐ Doanil ☐ Insulin ☐ Mixed

15- Are you compliant (the patient was asked to mention his/her management plan, and it was compared with the management plan which had been written in his/her file).

☐ Yes ☐ No

- If compliant, go to question 17

16- Why not compliant?

☐ Forgetfulness	☐ yes	☐ No
☐ Drug is not always available	☐ yes	☐ No
☐ Feel better without treatment	☐ yes	☐ No
☐ Polypharmacy	☐ yes	☐ No
☐ Could not understand the management plan.	☐ yes	☐ No
☐ Fear from drug side-effect	☐ yes	☐ No
☐ Others	☐ yes	☐ No

17- Do you have information about the medicines you are using and their side effects?

☐ Yes ☐ No

*If yes: From Where did you get this medicine information?

☐ Physician ☐ pharmacist

☐ Relatives ☐ Neighbors

☐ Media ☐ Others.

18- From where do you get your medicine (the anti – diabetic drug)?

☐ UNRWA. ☐ Governmental health center

☐ Others.

19- Is the anti-diabetic drug you are using available at the health center (Governmental)

☐ Yes always ☐ Yes, some times ☐ Not available

20- If not available, where do you get the drug from?

☐ another health center.

☐ private pharmacy.

☐ I use drugs from relatives.

☐ I remain with out treatment.

☐ Others.

21- Do you use drugs for diabetes that has been prescribed to relatives or neighbors?

☐ Yes, always.

☐ Yes, sometimes.

☐ NO.

22- Are you taking drugs for other chronic diseases?

☐ Yes ☐ No

23- Do you take the anti diabetic drugs regularly as prescribed?

☐ Yes ☐ sometimes ☐ No

24- If you miss a dose of anti diabetic drugs, do you take them later on?

- ☐ Yes, immediately.
- ☐ Yes, with the next dose.
- ☐ Yes, at bed time.
- ☐ I don't take it.

25- How do you remember the time for drugs administration?

- ☐ self reliance
- ☐ Relying others
- ☐ using an alarm
- ☐ No particular method

26- In case of improvement (from DM), you?

- ☐ Continue taking the drug
- ☐ Decrease the dose
- ☐ Stop the drug.
- ☐ Consult the physician.
- ☐ Others ……..

27- Do you feel that you do not like to take the drug?

- ☐ Yes
- ☐ sometimes
- ☐ No

28- Do you belief that you need the treatment?

- ☐ Yes
- ☐ sometimes
- ☐ No

- If yes, what is the cause?

- ☐ Because of drug side-effects.
- ☐ Fear from drug side-effect in future.
- ☐ Fear of dependence.
- ☐ No confidence with medicines.
- ☐ Others ……..

29- Do you feel that you want to take a period of rest from medicine?

☐ Yes ☐ No

30- Do you take Insulin?

☐ Yes ☐ No

- If No, shift to question no. (36)

31- Who give you the injection?

☐ myself ☐ member of the family

☐ I go to pharmacy ☐ go to the health center

☐ others

32- Are you trained for insulin injection?

☐ Yes ☐ No

- If yes, who trained you?

☐ I had trained in the center.

☐ I had trained by other member in the family.

☐ Others .

33- If a member of your family give you the injection, is he trained?

☐ Yes ☐ No

- If yes, who trained him

☐ In the health center.

☐ Others.

34- Do you think, it is necessary to eat after insulin injection?

☐ Yes ☐ No

35- If yes:

☐ De you eat directly after the injection.

☐ Do you eat after an hour.

☐ More than an hour

36- Diabetes is:

☐ A curable disease

☐ Partially curable disease.

☐ I don’t know

37- Do you depend on traditional remedies?

☐ Yes

☐ Yes, in the past.

☐ Never use it.

38- In case of depending on traditional remedies, do you stop treatment?

☐ Yes ☐ No

39- Do you think that practicing exercise is useful for the control of diabetes?

☐ Yes ☐ No

40- Do you practice any exercise?

☐ Yes ☐ No

41- How often do you practice exercise?

☐ >= 3days / week

☐ < 3days / week

42- Do you follow any diet regimen?

☐ Yes ☐ No

43- Do you respect your clinic appointment?

☐ Yes ☐ No

* If no, mention the cause

☐ Drug is not available

☐ Increase waiting time

☐ Fear of hypoglycemia

☐ Physician don’t come regularly

☐ Physician don’t give me his care.

☐ others

44- Do you have any complication?

☐ Yes ☐ No ☐ I don’t know

- If yes,

☐ Retinopathy .

☐ Renal disease.

☐ Diabetic foot.

☐ Neurological disease.

☐ IHD.

☐ Stroke.

☐ Others.

45- Do you measure your blood sugar by your self?

☐ Yes ☐ No

- If yes, how often

☐ Daily ☐ Weekly

☐ Monthly ☐ Others

Information from Patient file

a. No. of file ……

b. Date of diabetes discovery ……

c. Duration ……..

d. Management plan ……

- Last two reading of FBS during the last year

…….. mg/dl ……... mg/dl

- Last two reading of (HBAIC) during the last year

……

Last two reading of total cholesterol and triglyceridemia during the last year

Chol ……. TG ……

Chol ……. TG ……

- BP …… ……. …….. ……

- weight: ……

- Hight ……...

- BMI ……....