SCHOOL OF PHARMACY

Use of medicines and devices by adults in the management of Type 2 diabetes in Kuwait

Thesis submitted in accordance with the requirements of the University College London (UCL) for the degree of Doctor of Philosophy by

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June 2016

Plagiarism statement

This thesis research conducted in the School of Pharmacy, University College London between January 2013 and June 2016 under the supervision of Professor Felicity Smith and Professor Kevin Taylor. I Zahra Alsairafi confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature: Date:

Acknowledgments

Firstly, I am grateful to thank God for the good health and wellbeing, which were necessary to complete this project. I would also like to extend my sincere gratitude to my supervisors Professors Felicity Smith and Kevin Taylor for their continued support of my study, their patience and encouragement. Without their great knowledge and guidance, the completion of this work would be impossible.

I would like to express my special thanks to my family for their endless love, support and prayers. My parents, brothers (Mohammed, Husain, Hasan and Ali) and my sister Batool, I am really grateful for supporting me throughout the PhD period. My husband, Adnan Alsairafi, I would like to express my gratitude for your great assistance since the beginning of this study to its completion. It is greatly appreciated.

To my lovely department (Research Department of Pharmacy Practice and Policy), to my best friends Zahraa, Dalal, Mona, Dalia, Naoko, and Julia, thank you for being with me at all stages of this thesis and for listening to me in my difficult times.

This study was conducted in diabetes outpatient clinics at the main hospitals in Kuwait. So, I am very grateful to all the team who collaborated with me in the data collection, and who participated in this study. Without their help, the data collection would be difficult. Particularly, I would like to express my deepest gratitude and thanks to pharmacist Mona Awad and the diabetologists: Abdulnabi Al Attar, Waleed Al Dahi, Ammar Al Mansour and Thaier Almuaili for their unconditional help. I would also like to acknowledge with great appreciation Dr Abdul-Mohsen Al-Shimmeri and Dr Fatima Alhaddad for helping me in the analysis and Professor Abdulghani Al-Bazzaz for helping me in the translation and in revising some chapters in this thesis.

Last but not least, I would like to thank all the patients who participated in this study and the Ministry of Health for providing me with this opportunity to achieve my dream, continue my education, and for the scholarship.

Abstract

Background

Diabetes is a threat to peoples' health and lives around the world. Particularly, there is a large increase in its prevalence in the Middle East, especially type 2 diabetes. Knowledge, beliefs and attitudes are the major contributing factors to medicine misuse and poor glycaemic control. Insulin is the last treatment option that patients with type 2 diabetes might require to control their disease. In addition to traditional injections, newer insulin delivery methods, such as pens and pumps are available, which may impact medicine use.

Aim

To identify factors that impact the management of type 2 diabetes by examining patients' experiences about their medicine/device use and lifestyle and exploring the perspectives of healthcare providers (HCPs) to inform service development.

Method

The study was conducted in hospitals in Kuwait. All patients (n=43) using medical treatment for the management of type 2 diabetes and HCPs (n=10) who were involved in management of those patients were invited to participate. Data were collected primarily through semi-structured interviews. Data analysis was performed using MAXQDA-11.

Results

Non-adherence to medicines was prevalent in this study. Interviews with patients revealed that poor health awareness, health beliefs and culture influenced health behaviour, in terms of medicine use and lifestyle. Some of the emergent beliefs were about the disease (downplaying its seriousness), medicines (disbelief in their efficacy) and self-beliefs. Using pens and pumps improved patients' adherence, quality of life and satisfaction. Interviews with HCPs revealed that some barriers affected management of the disease, such as lack of staff, incentives and equipment. Recommendations to inform healthcare provision were identified.

Conclusion

To improve the management of type 2 diabetes and health outcomes, many issues need to be considered. For example, addressing patients' beliefs, and the benefits of insulin pens and pumps and expanding their use. Taking into account concerns of HCPs would be valuable to inform service development.

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List of abbreviations

ADA	American Diabetes Association
BMI	Body mass index
BNF	British National Formulary
BP	Blood pressure
CAQDA	Computer Assisted Qualitative Data Analysis
Carb	Carbohydrate
CASP	Critical Appraisal Skills Programme
CSII	Continuous Subcutaneous Insulin Infusion
CS-SRM	Common Sense-Self Regulation Model
DAFNE	The Dose Adjustment for Normal Eating Project
DCCT	The Diabetes Control and Complications Trial
DDI	Dasman Diabetes Institute
DTSQ	Diabetes Treatment Satisfaction Questionnaire
DKA	Diabetic ketoacidosis
Dl	Decilitre
FPG	Fasting plasma glucose
GCC	Gulf Co-operation Council
HbA1c	Glycated haemoglobin A1c
HBM	Health Belief Model
HCP	Healthcare provider
HLOC	Health locus of control
IDDM	Insulin-dependent diabetes mellitus
IDF	International Diabetes Federation
IFG	Impaired fasting glucose
IGT	Impaired glucose tolerance
IMEMR	Index Medicus for the Eastern Mediterranean Region
IPQ	Illness Perception Questionnaire
Kcal	Kilocalories
KCPDG	Kuwaiti Clinical Practice Diabetes Guidelines
KD	Kuwaiti Dinar
KDCP	Kuwait Diabetes Care Programme
KDS	Kuwait Diabetes Society
KFAS	Kuwait Foundation for the Advancement of Sciences
Kg/m^2	Kilogram per square metre

KHN	Kuwait Health Network
MARS	Medication Adherence Rating Scale
MDI	Multiple daily injection
MENA	Middle East and North Africa
Mg	Milligram
Mm	Millimetre
MMAS	Morisky Medication Adherence Scale
Mmol/l	Mill moles per litre
MOH	Ministry of Health
N.A	Information was not available
NICE	National Institute for Health and Care Excellence
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIDDM	Non-insulin dependent diabetes mellitus
OGTT	Oral glucose tolerance test
OHAs	Oral hypoglycaemic agents
PCIS	Primary Care Information System
RPG	Random plasma glucose
SCT	Social Cognition Theory
SMAs	Shared Medical Appointments
SMBG	Self-monitoring of blood glucose
SRM	Self Regulation Model
S/V	Syringe and vial
TPB	Theory of Planned Behaviour
UAE	United Arab Emirates
UK	United Kingdom
UKPDS	United Kingdom Prospective Diabetes Study
WHO	World Health Organisation

Journal articles

(1) Patients' management of type 2 diabetes in Middle Eastern Countries: review of studies. Submitted to Dove Medical Press on 20 January 2016 and accepted for publication in Patient Preference and Adherence Journal on 24 March 2016.

Abstracts

(1) Alsairafi, Z., Smith, F., & Taylor, K. (2016). Use of Medicines and by Adults for the Management of Type 2 Diabetes Mellitus in Kuwait. *Diabetes Technology & Therapeutics,* 18, A100-A101.

(2) Alsairafi, Z.K., Smith, F.J., & Taylor, K.M.G. (2016). Use of medicines and by adults for the management of type 2 diabetes mellitus in Kuwait. *Diabetic Medicine,* 33, 120.

(3) Alsairafi, Z., Smith, F., & Taylor, K. (2016). Use of medicines and by adults for the management of type 2 diabetes mellitus in Kuwait. *International Journal of Clinical Pharmacy,* 38:516.

Presentations

(1) Use of Medicines and Devices by Adults for the Management of Type 2 Diabetes Mellitus in Kuwait. PhD Research Day, School of Pharmacy, UCL, London, September 2014.

(2) Use of Medicines and Devices by Adults for the Management of Type 2 Diabetes Mellitus in Kuwait. PhD Research Day, School of Pharmacy, UCL, London, September 2015.

Posters

(1) Use of Medicines and Devices by Adults for the Management of Type 2 Diabetes Mellitus in Kuwait. PhD Research Day, School of Pharmacy, UCL, London, September 2014.

(2) Use of medicines and devices by adults for the management of type 2 diabetes in Kuwait. 44th ESCP Symposium on Clinical Pharmacy. Medicines Information-Making Better Decision, Lisbon, Portugal, October 2015.

(3) Use of medicines and devices by adults for the management of type 2 diabetes in Kuwait. Pharmaceutical Science Poster Event, Royal Pharmaceutical Society, London, November 2015.

(4) Use of medicines and devices by adults for the management of type 2 diabetes in Kuwait. 9th ATTD International Conference on Advanced Technologies & Treatments for Diabetes, Milan, Italy, February 2016.

(5) Use of medicines and devices by adults for the management of type 2 diabetes in Kuwait. Diabetes UK Professional Conference, Glasgow, UK, March 2016 (Accepted).

Overview of the project

This project is a study of the management of type 2 diabetes with medicines and devices by adults living in Kuwait, and receiving healthcare services in the Ministry of health (MOH). The study was conducted in secondary-care units in Kuwait, including the main five hospitals in the five health regions: Mobarak Al-Kabeer, Amiri, Adan, Jahra and Farwaniya. Semi-structured interviews were conducted with adult patients and HCPs. In addition, the study involved the completion of MMAS-8 and BMQ-Specific by the patients, and their HbA1c levels were obtained from the medical notes. The study aimed to identify the factors that affected the management of type 2 diabetes in the region, in particular, it examined the role of health awareness, beliefs and culture in shaping the management behaviour of patients. In addition, as a relatively new delivery methods and options for type 2 diabetes in the MOH, the study investigated the advantages and problems of insulin pens and pumps, and their impact on patients' management behaviour and life. Types of support were also investigated from the perspectives of patients and were discussed with HCPs. HCPs reported the challenges facing better management of type 2 diabetes and provided their recommendations. The study will inform the decisions of policy makers, in order to propose service developments, inform healthcare provision and to improve health outcomes.

Organisation of the thesis

The thesis is divided into nine chapters, a description for each is provided below:

Chapter 1: Introduction and background
This chapter contains an overview of diabetes in the Middle East, an overview of the research subject (adherence), and a description of healthcare services in Kuwait, where this project was based.

Chapter 2: Systematic review of studies conducted on adherence of patients with diabetes
This chapter contains an overview of the literature from studies of the adherence of patients with diabetes in the Middle East, and this study aim and objectives.

Chapter 3: Methodology

The chapter describes the methods applied in order to achieve each of the study objectives and justification for selecting these methods.

Chapter 4: Response rate and sample characteristics

The chapter describes the response rate of the participants and their demographic and clinical characteristics.

Chapter 5: Medication adherence, health beliefs and the management of type 2 diabetes

This chapter contains the results of all the study participants (patients; n=43), and discusses their beliefs and other factors that affected their management behaviour.

Chapter 6: Management of type 2 diabetes with insulin injections (syringe/vial and pens)

This chapter includes the results of the participants (patients; n=26) who were using insulin injections (syringe/vial) and pens, and describes their views and experiences of pen use, advantages and problems.

Chapter 7: Management of type 2 diabetes with insulin pumps

This chapter describes the results of the participants (patients; n=8) who were using insulin pumps, and illustrates their views and experiences of pump use, advantages and problems.

Chapter 8: The perspectives of healthcare providers on the key findings and their recommendations

This chapter includes the results of semi-structured interviews with the HCPs (n=10), and describes their perspectives on the study findings and recommendations.

Chapter 9: Discussion and Conclusion

The chapter provides a discussion to the results of this study, a conclusion and proposals for future work.

Chapter 1: Introduction and background

This chapter provides a background for the project and explains the research subject. It includes five major sections, describing an overview of diabetes mellitus, particularly type 2 diabetes, the epidemiology of diabetes in the Middle East, medicine-taking behaviour, public health and policy of type 2 diabetes management in Kuwait and the use of technology in the management of diabetes.

1.1 An overview of diabetes mellitus

1.1.1 The pathology of diabetes mellitus

Diabetes mellitus is a chronic disease that involves lack of insulin secretion from pancreatic beta-cells and/or insulin resistance, which results in abnormal glucose levels in the blood (Alhyas et al., 2011). It is a major contributor of morbidity, e.g. kidney and cardiovascular diseases, limb amputations and blindness and mortality (Badawi et al., 2015). Diabetes is classified into two main types: type 1 diabetes or insulin-dependent diabetes (IDDM), which results from a complete deficiency of insulin secretion due to a destruction of pancreatic beta-cells and type 2 diabetes or non-insulin dependent diabetes (NIDDM). Type 2 diabetes occurs when the body has an inadequate insulin secretion that results in the insulin's inability to move blood sugar to cells for energy use, which is called a resistance to insulin. Unlike, individuals with type 1 diabetes, patients with type 2 diabetes have measurable levels of circulating insulin. **Figure 1.1** shows the pathophysiology of type 2 diabetes (Ozougwu et al., 2013). There are independent environmental factors in the pathogenesis of type 2 diabetes. These are aging, obesity, low activity levels, alcohol drinking and smoking. Obesity, particularly in individual's waist area is accompanied by a reduction in muscle mass resulting in insulin resistance. Poor diet, particularly increased fat and simple sugars intake and reduced starch and fibre intake cause obesity and glucose tolerance deterioration (Ozougwu et al., 2013). There is another type of diabetes, which is called gestational diabetes. This type involves glucose intolerance and is firstly diagnosed in women during pregnancy. Subclinical diabetes or 'pre-diabetes' is known as impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) (American Diabetes Association, 2014).
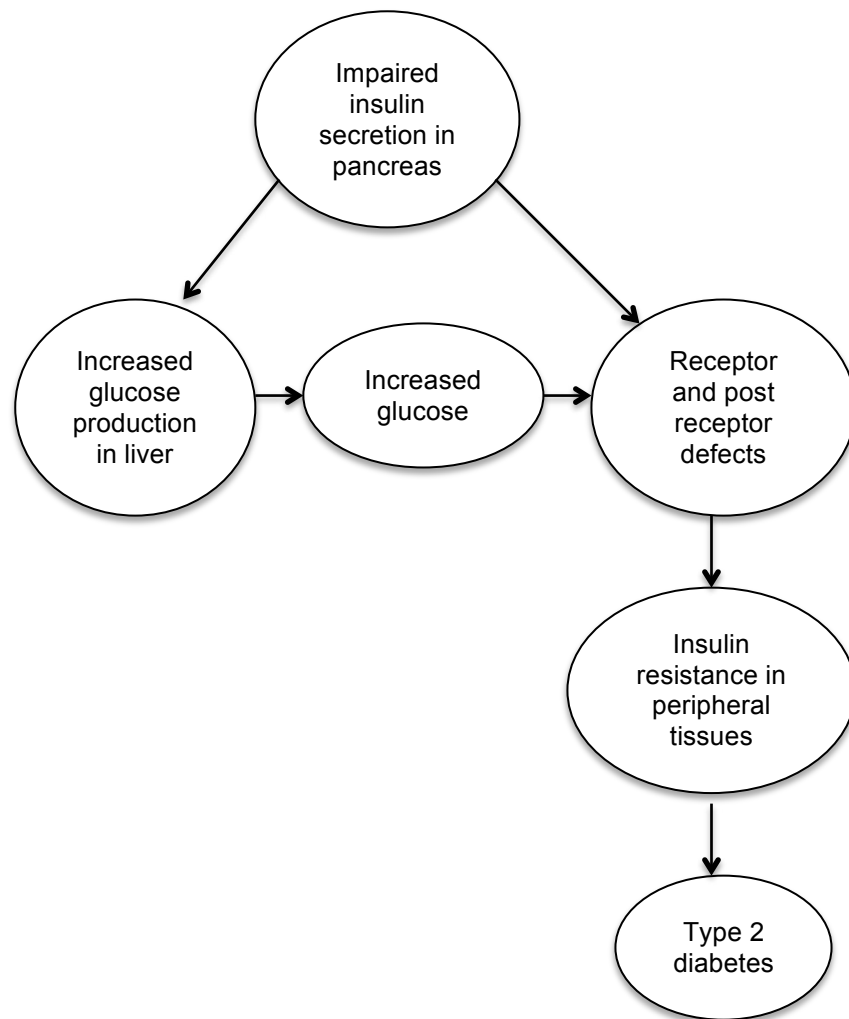
Figure 1.1: The pathophysiology of type 2 diabetes

1.1.2 Diagnosis and management of diabetes

The criteria for the diagnosis of diabetes, as published in the American Diabetes Association (ADA) in 2012 are shown in **Table 1.1**. Blood tests used in the diagnosis of diabetes and pre-diabetes are the glycated haemoglobin A1c test (HbA1c), a fasting plasma glucose test (FPG) test, an oral glucose tolerance test (OGTT) and the random plasma glucose (RPG). The RPG is used during regular check-ups, if an individual has 200 micrograms per decilitre in the RPG and shows symptoms of diabetes, such as increased thirst, increased urination and unexplained weight loss, then diabetes may be diagnosed. HbA1c test is used to detect type 2 diabetes and pre-diabetes but is not recommended to diagnose type 1 diabetes or gestational diabetes. It reflects the average of an individual's blood glucose levels in the past 3 months and it can be performed at any time of the day. A normal HbA1c level is below 5.7%, from 5.7 to 6.4% indicates pre-diabetes and a level of $\geq$6.5% indicates diabetes (ADA, 2014).

Table 1.1: Criteria for the diagnosis of diabetes

Blood Test Levels for Diagnosis of Diabetes and Prediabetes

	A1C (percent)	Fasting Plasma Glucose (mg/dL)	Oral Glucose Tolerance Test (mg/dL)
Diabetes	6.5 or above	126 or above	200 or above
Prediabetes	5.7 to 6.4	100 to 125	140 to 199
Normal	About 5	99 or below	139 or below

- A1c=glycated haemoglobin, which identifies average plasma glucose concentration, mg=milligram, dL=decilitre.
- For all three tests, within the pre-diabetes range, the higher test result, the greater risk of diabetes.

Source: ADA. Standards of medical care in diabetes-2012. Diabetes Care. 2012;35(Supp1):S12, table 2.

Patients with type 1 diabetes do not respond to interventions, such as dietary changes, exercise and oral hypoglycaemic agents (OHAs) other than insulin (Atkinson et al., 2014). In order to achieve target therapeutic goals, the medical treatment of type 2 diabetes starts with diet and exercise and ends with the requirement of insulin initiation. In type 2 diabetes, the function of pancreatic beta-cells drops over time due to cell exhaustion resulting from long-time insulin resistance, leading to elevated lipids and glucose that induce toxic effects on these cells (Inzucchi et al., 2015). This decline in glycaemic control make most patients require insulin treatment eventually even with good adherence to OHAs (Inzucchi et al., 2015). The aim of the treatment of both types of diabetes is to achieve glycaemic control and reduce the risks of micro and macro-vascular complications. It has been shown that improving glycaemic control has a role in decreasing rates of retinopathy, neuropathy and nephropathy. The findings of The United Kingdom Prospective Diabetes Study (UKPDS) showed that intensive glycaemic control (with a sulphonylurea or insulin) remarkably decreased the risks of micro-vascular complications compared to conventional glycaemic control (primarily with diet) in a group of patients with type 2 diabetes (Inzucchi et al., 2015). The UKPDS 41 has also shown that intensive glycaemic control significantly reduced the cost and increased the time free of complications (Gray et al, 2000).

1.2 Epidemiology of diabetes in the Middle East

Diabetes has become a major public health issue that affects 415 million adults worldwide and this number is expected to increase to 642 million by 2040 (International Diabetes Federation, 2013). In the Middle East and North Africa (MENA) region **(Figure 1.2)**, diabetes becomes one of the most rapidly growing non-communicable diseases. It affects approximately 35 million of adult population in the region and this number is expected to double to 68 million by 2030 (Badawi et al., 2015). Type 1 diabetes accounts for 5-10% of all diabetes cases, and usually presents in children and young people, although it can present at any age. Type 2 diabetes accounts for around 90% of all diabetes cases. It mostly affects adults and is associated with obesity, hyperlipidaemia and hypertension (Alhyas et al., 2012). Prevalence of type 2 diabetes has dramatically increased over the past 3-4 decades. The most prevalent type of diabetes in Middle Eastern countries is type 2 diabetes (IDF, 2013).

Source: www.iavireport.org

Figure 1.2: The MENA region

Diabetes has also become one of the leading causes of mortality in industrialised and developing countries (Alhyas et al., 2011). In 2011, diabetes contributed to 280,000 of deaths in the Gulf Co-operation Council countries (GCC). Kuwait, Lebanon, Qatar, Saudi Arabia, Bahrain, United Arab Emirates (UAE), Oman and Egypt are among the ten countries in the world with the highest prevalence of diabetes (Alhyas et al., 2012). A recent study reported that three of the ten countries with the highest prevalence of diabetes in the world are in the Arabian Gulf region. The estimated percentage of the prevalence of diabetes in each of these countries is 24, 23.3 and 22.9 for Saudi Arabia, Kuwait and Qatar respectively (Awad and Alsaleh, 2015). In a study by Alarouj et al. (2013), the prevalence of diabetes among

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Kuwaiti nationals aged between 20 and 65 years was 17.9%, which has exceeded the IDF projections for the year 2030. Diabetes also becomes one of the significant risk factors for cardiovascular diseases in the country (Alarouj, 2013).

According to a study in the UAE, the annual direct treatment costs of diabetes without complications was $1,605 (£1,115), which is 3.2 times higher than the per capita expenditure for healthcare in the country (Boutayeb et al., 2012). That cost increased 2.2 times in the presence of microvascualr complications, 6.4 times in the presence of macrovascular complicationas, while presence of both micro and macrovascualr complications increased the cost 9.4 times. Another study showed that the annual treatment costs for patients above 60 years old is higher compared to those between 20 and 60 years old. In that study, it has been shown that overall costs increase with age, duration of the disease, presence of other complications and are higher for patients using insulin compared to those using OHAs (Al-Maskari et al., 2010). In a more recent study, it has been estimated that patients with diabetes have healthcare expenditures ten times higher than what expenditures would be in the absence of diabetes (Alhowaish, 2013).

The Middle Eastern diabetes pandemic has been the result of several social and economic changes that have occurred in the region since the 1980s. Social changes occurring in the region are the population's adoption of elements of Western cultures, such as eating habits and urbanisation. Economic changes have resulted from the region's increased wealth resulting from increased oil production and demand from the United States and other countries around the world. Increased wealth has led to an increase in automobile purchases, decreased physical activity, increased obesity and smoking (Mabry et al., 2010; Williams, 2012). In particular, in the GCC countries, rapid socio-economic growth led to a shift towards sedentary lifestyles, increasing rates of obesity and diabetes in the population. Also, it has been noted that lack of health awareness, beliefs, attitudes and cultural factors contribute to the high prevalence of obesity and diabetes in the Middle East (Musaiger, 2004).

1.3 Medicine-taking behaviour

1.3.1 Definitions of medicine-taking behaviour

Several terms have been used to describe adherence to treatment, the most commonly used definitions are: compliance and adherence. At the end of the 1970's, compliance is defined as "*the extent to which a person's behaviour coincides with medical or health advice*" (Silva et al., 2011). Although this term is the most helpful in searching the literature, it has been criticised by some researchers, as it lacks patient involvement in the process (Vermeire et al., 2001). In 1997, the Royal Pharmaceutical Society of Great Britain introduced the term "concordance". This term describes process of achievement of an agreement with the healthcare professional in the whole process of medicine taking rather than describing the extent to which medication is taken (da Silva et al., 2011).

Adherence is "*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). This term signifies the patient's right to choose whether to follow the doctor's recommendations or not. It also removes the blame, which the term "compliance" brings on the patient for not following the treatment (Horne et al., 2005). As "adherence" requires the patient's agreement to the recommendations, it has been seen to be more respectful and will be used in this thesis. In this thesis, participants considered to have good medicine-taking behaviour when they were using their medicines in a way that suits them and was in line with their doctors' recommendations.

Adherence is a complex behavioural process that is influenced by the environment in which the patient lives, healthcare providers and the healthcare system. It is also affected by patients' health beliefs, motivation and confidence in managing their illness, and their satisfaction about the treatment outcomes (WHO, 2003). **Table 1.2** shows the factors that affect medication adherence. Researchers worldwide have identified some of these factors among patients with type 2 diabetes through different methods including qualitative interviews with patients and/or doctors. For example, Vermeire et al. (2003) have reported the deficit or inaccurate knowledge of diabetes and its complications, lack of motivation and the frustration due to failure to achieve control despite of perfect adherence. Hayes et al. (2006) and Aflakseir (2012) have reported the fear of side effects and the cost of treatment. The complexity of the treatment regimens has been reported by all the previous

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researchers. In Kuwait, Jeragh-Alhaddad et al. (2015) have identified cultural factors, such as social stigma, healthcare system-related factors, such as unavailability of medicines and HCP-related factors, such as discontinuity of care as barriers to adherence to treatment among patients with type 2 diabetes.

Table 1.2: Factors reported to affect patient's adherence

1. SOCIAL AND ECONOMIC DIMENSION	4. THERAPY-RELATED DIMENSION
Limited English language proficiency	Complexity of medication regimen (number of daily doses; number of concurrent medications)
Low health literacy	
Lack of family or social support network	
Unstable living conditions; homelessness	Treatment requires mastery of certain techniques (injections, inhalers)
Burdensome schedule	Duration of therapy
Limited access to health care facilities	Frequent changes in medication regimen
Lack of health care insurance	Lack of immediate benefit of therapy
Inability or difficulty accessing pharmacy	Medications with social stigma attached to use
Medication cost	
Cultural and lay beliefs about illness and treatment	Actual or perceived unpleasant side effects
Elder abuse	Treatment interferes with lifestyle or requires significant behavioral changes
2. HEALTH CARE SYSTEM DIMENSION	
Provider-patient relationship	**5. PATIENT-RELATED DIMENSION**
Provider communication skills (contributing to lack of patient knowledge or understanding of the treatment regimen)	**Physical Factors**
Disparity between the health beliefs of the health care provider and those of the patient	Visual impairment
	Hearing impairment
Lack of positive reinforcement from the health care provider	Cognitive impairment
Weak capacity of the system to educate patients and provide follow-up	Impaired mobility or dexterity
	Swallowing problems
Lack of knowledge on adherence and of effective interventions for improving it	**Psychological/Behavioral Factors**
Patient information materials written at too high literacy level	Knowledge about disease
Restricted formularies; changing medications covered on formularies	Perceived risk/susceptibility to disease
	Understanding reason medication is needed
High drug costs, copayments, or both	Expectations or attitudes toward treatment
Poor access or missed appointments	Perceived benefit of treatment
Long wait times	Confidence in ability to follow treatment regimen
Lack of continuity of care	Motivation
3. CONDITION-RELATED DIMENSION	Fear of possible adverse effects
	Fear of dependence
Chronic conditions	Feeling stigmatized by the disease
Lack of symptoms	Frustration with health care providers
Severity of symptoms	Psychosocial stress, anxiety, anger
Depression	Alcohol or substance abuse
Psychotic disorders	
Mental retardation/developmental disability	

Source: World Health Organisation, 2003

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1.3.2 Health Behaviour Models

Consideration of health behaviour models is crucial for this study, because patients' beliefs impact on their medicine-taking behavior and are associated with their adherence (Vermeire et al., 2003; Horne et al., 2013). Patients may intentionally choose not to adhere to their therapeutic regimens due to different beliefs regarding their medications (Horne et al., 2005). In a study of chronic conditions, there was a relationship between health beliefs and behaviour, as 60% of patients had intentionally stopped taking their medicines completely (Barber et al., 2004). In order to understand this relationship, it is crucial to study the socio-psychological approaches that explain the impact of health beliefs on behaviour (Glanz et al., 2002).

Different theories have been established, such as the Social Learning/Cognitive Theory (SCT; Bandura, 1997). This theory indicates that people go through different mental stages, e.g. problem solving and decision-making before changing behaviour (Bosworth and Voils, 2006). Furthermore, according to this theory, the individuals' attitude is influenced by beliefs in their capabilities to perform a specific action and motivation, which comes from the person's evaluation of the values/benefits of taking such action (Luszczynska et al., 2005). There are several Social Cognition Models that are based on the social cognition theory. For example, the Health Locus of Control (HLOC) theory has been used in several studies as a predictor of health behaviour (De Jesus and Xiao, 2014). Researchers used this theory to examine the medication adherence behaviour in patients with hypertension (Kretchy et al., 2014) and patients with diabetes (O'Hea et al., 2005). In patients with diabetes, the use of HLOC theory showed that patients with low internal HLOC beliefs and high external HLOC beliefs, such as beliefs in God, luck, HCPs or other people had poorer HbA1c levels as a consequence to poor adherence to medicines than those with high internal HLOC beliefs (Theofilou and Saborit, 2012).

However, Conner and Norman (2005) have pointed out the weakness of the HLOC theory in predicting health behaviour. In a study on a group of community-dwelling patients with rheumatoid arthritis and osteoarthritis, HLOC beliefs showed less influence on health status than self-efficacy (Cross et al., 2006). Likewise, in a study on 4,013 Latino adults, HLOC beliefs weakly impacted on healthcare use, while access factors, such as having health insurance coverage were more predictable for healthcare use than HLOC beliefs (De Jesus and Xiao, 2014).

Self-efficacy is the belief of someone regarding his/her ability to engage in a behaviour that is necessary to achieve a desired outcome. It is a part of a self-regulatory reciprocal process that interacts with personal, behavioural and environmental factors to determine behaviour (Cross et al., 2006). It may act as a mediator between personality components, such as negative affectivity and poor medication adherence (Molloy et al., 2012). There is some evidence that self-efficacy is correlated with illness perceptions, both of which are useful predictors of diabetes self-management behaviour. Patients with high self-efficacy are more likely to adopt health-related behaviour and consequently have better health outcome measures (Cross et al., 2006). Aljasem and colleagues (2001) have used this theory to predict medication adherence behaviour in patients with diabetes. The authors found that patients with high self-efficacy showed better medication adherence. On the other hand, low self-efficacy significantly correlated to high resistance to treatment (Mishali et al., 2010). Self-determination theory in contradiction to self-efficacy indicates that health-related self-regulation behaviour is dependent upon the development of a "sense of autonomy and competence", which is critical to the processes of "internalisation and integration" (Ryan et al., 2008).

Self-regulation models view the patient as central to the management of their disease; the more the patients are motivated to achieve a health-related goal, the more likely they will engage in actions that they believe will help to accomplish that goal (Clark and Zimmerman, 2014). According to the common-sense self-regulation model (CS-SRM), patients' illness/treatment representations can be categorised into five types of beliefs based on identity, cause, timeline, control and consequences (Cameron and Leventhal, 2003). These representations are dynamic and patients may adapt these beliefs through a better medical understanding of their condition and how to manage it (Phillips et al., 2012). The CS-SRM of illness perceptions has been used to predict health behaviour in type 2 diabetes and other chronic conditions (Ashur et al., 2015). It refers to the mental representations and personal beliefs that individuals have about an illness.

Illness Perception Questionnaire (IPQ) is used to measure patients' illness perception beliefs (Broadbent et al., 2015). Patients' drawings can also be used to visualise how they perceive their illnesses (Broadbent et al., 2004). Together with the variations of the IPQ, these have been used to support the illness perception model. According to this model, patients' self-management behaviour is guided by their cognitive representation of their illnesses (Petrie and Weinman, 2012). Phillips

et al. (2012) stated that greater adherence and more positive outcomes at a one-month follow-up were associated with greater use of CS-SRM behaviour by primary care providers to help patients have an adaptive understanding of their conditions.

Another predictor of behaviour is the Theory of Planned Behaviour (TPB; Ajzen, 1991) (Ajzen, 2011). This theory refers to the extent to which people believe in their control over performing the behaviour. Such beliefs impact the individuals' motivation/intention (an immediate mediator of behaviour) (Ajzen, 2011). The theory has been used effectively to predict medication adherence in patients with diabetes (Jannuzzi et al., 2014). One such model that identifies motives that influence health-related actions is the HBM (Glanz et al., 2002). **Figure 1.3** summarises the dimensions of this model.
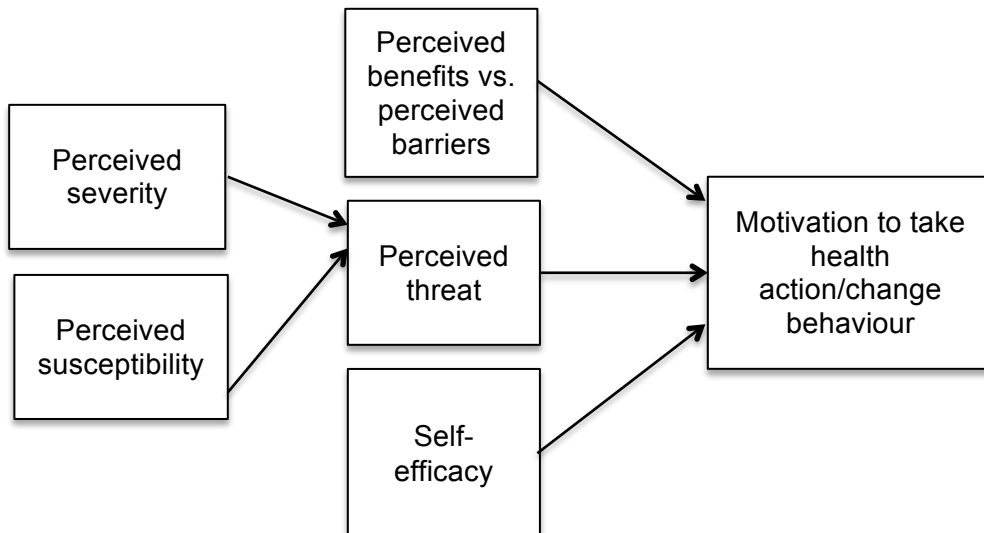
Figure 1.3: The dimensions of the HBM

The model was developed in 1950 by a group of psychologists (Hochbaum, Kegeles, Leventhal and Rosenstock) and has been widely used to predict health related behaviour for different conditions, such as hypertension, diabetes and coronary artery diseases (Kartal and Ozsoy, 2007). The HBM has become one of the most effective models of health education. Its use in adherence studies increases the understanding of the factors that affect the individuals' health behaviour and estimates the factors that are most influential and strong determinants of health behaviour (Dehghani-Tafti et al., 2015). The HBM clarifies that the interest of patients in taking a specific behaviour, e.g. medication adherence

is a function of their beliefs about the perceived (threat) of the disease and an evaluation of the value (benefits) of taking health action weighed against its psychological costs (barriers) (Green and Murphy, 2014). The perceived threat split into two dimensions, the perceived (susceptibility) and the perceived (severity). Perceived susceptibility indicates that the individuals must believe that they are susceptible to the disease. Perceived severity indicates that individuals should understand the seriousness of their disease (Dehghani-Tafti et al., 2015).

For example, if patients believe that diabetes is serious, they are vulnerable to its complications, following medical recommendations will reduce threats, their medications are effective and the benefits of using medicines properly outweigh their risks, they will have the appropriate motives to undertake recommended health-related actions, e.g. medication adherence. Self-efficacy construct was added to the original four beliefs of HBM in 1998 and recognised as an important predictor of health behaviour in diabetes management (Green and Murphy, 2014). It indicates the individuals' beliefs in their abilities to take an action required to achieve a certain goal (Bayat et al., 2013).

1.3.3 Adherence of patients with diabetes

1.3.3.1 Adherence to medicines

Adherence to therapeutic regimens is important in the management of type 2 diabetes but is often neglected (Bailey and Kodack, 2011). It has been concluded that a large proportion of patients with diabetes, using OHAs and/or insulin experienced difficulty in managing their disease. Complexity of the health regimen in this group and polypharmacy, as many as five medications or more daily, which are required to achieve good metabolic control constitute a significant barrier to effective use of medicines and adherence (Vermeire et al., 2003; Cramer, 2004; Khattab et al., 2010; Bailey and Kodack, 2011).

In a review of studies on medication adherence in Middle Eastern countries, it was found that non-adherence is prevalent among patients with chronic conditions including diabetes. Top reasons for patients' non-adherence ranged from forgetfulness to confusion about required medication duration to disbelief about the overall effectiveness or purpose of the medication (Al-Qasem et al., 2011). Studies have estimated an average adherence rate of 68% among patients with diabetes in Middle Eastern countries (de Villiers and Halabi, 2015). Poor adherence among

patients with diabetes has led to severe consequences in the region. For example, a study conducted in Saudi Arabia has found that poor adherence contributed to 54% of diabetic ketoacidosis (DKA) cases (Qari, 2002). Another study in the same country has recorded proteinuria cases among patients with poor scores of adherence (Al-Homrany and Abdelmoneim, 2004). In Jordan, depression was more prevalent among patients with diabetes who had increased barriers to adherence (Al-Amer et al., 2011). Because diabetes is a relatively new issue for the Middle Eastern areas, some of the healthcare systems do not have sufficient resources (e.g. educational services) for properly addressing the disease. As a result, almost half of the deaths that are caused by diabetes occur in people under age 60 because of late diagnosis due to lack of early detection. People in the Middle East are still not knowledgeable about the seriousness of the disease, its complications or early detection signs (IDF, 2013).

In Kuwait, although the policy of the Ministry of Health (MOH) has focused on establishing diabetes-specialised clinics in primary and secondary healthcare units, the prevalence of type 2 diabetes is sharply increasing. Despite the availability and accessibility of healthcare serveries to all patients with diabetes, the intended medical care targets are difficult to achieve. The majority (60%) of patients who manage their type 2 diabetes with insulin could not achieve glycaemic targets of HbA1c$\leq$7%; the mean HbA1c level among patients was 8.1% (Amiri Hospital Statistics, 2013). The same result was also reported in Jordan, where more than half of patients with type 2 diabetes exceeded target HbA1c levels (HbA1c>7) (Al-Khawaldeh et al., 2012). Failure in attaining treatment goals and the sharp increase in the prevalence of diabetes suggests a defect in the disease management process, which could be attributed to patients' non-adherence to their treatment regimens (Blackburn et al., 2013). Al-Qazaz et al. (2010) have reported a significant association between the eight-item Morisky Medication Adherence Scale (MMAS) scores and HbA1c levels in patients with type 2 diabetes. Use of insulin has shown to be a statistically significant predictor of glycaemic control (Al-Khawaldeh et al., 2012). It has been indicated that each 10% reduction in patients' medication adherence was associated with a 0.14 increase in HbA1c levels (Pladevall et al., 2004).

In the context of medication adherence in Kuwait, it has been found that patients with chronic diseases experience difficulties in adhering to their medications. This includes patients with psychiatric disorders (Fido and Husseini, 1998; Al-Saffar et

al., 2003; Al-Saffar et al., 2005), hypertension (Al-Mehza et al., 2009) and diabetes (Jeragh-Alhaddad et al., 2015). This paucity of medication adherence studies highlights the need for research to be performed in this field, particularly for a highly prevalent disease, such as diabetes. Specifically, patients with type 2 diabetes who manage their disease with insulin should be targeted because it has been shown that non-adherence rates to insulin (20-40%) are higher than those of OHAs among this group (Wallia and Molitch, 2014). In addition, there is little known about interventions that can improve adherence to insulin regimens (Doggrell and Chan, 2015). Therefore, targeting those patients will help to inform policy about the needed interventions that help patients to improve their health outcomes.

1.3.3.2 Adherence to lifestyle modifications

Following healthy lifestyle, such as healthy diet, maintaining normal body weight, regular exercise and smoking cessation is crucial for prevention and management of type 2 diabetes (de Villiers and Halabi, 2015). Unfortunately, in the Middle East, poor adherence among patients with type 2 diabetes extends to healthy lifestyle behaviour and constitutes a barrier to achieving glycaemic control in the region (Al-Kaabi et al., 2008). The majority of patients with diabetes in the Middle East neither followed a diet plan nor regularly exercised (Khattab et al., 1999; Abahussain and El-Zubier, 2005; Khattab et al., 2010; Al-Amer et al., 2011). Most patients with diabetes are physically inactive as a consequence of their obesity (Musaiger, 2004). Qualitative studies have reported that adherence to an appropriate diet and healthy lifestyle among patients with diabetes is more difficult than taking medications (Vermeire et al., 2003). Recent studies have shown that patients with diabetes experienced difficulty in applying multiple self-care behaviours simultaneously and that patients adhere better to medications compared with lifestyle interventions (Mishali et al., 2010; de Villiers and Halabi, 2015).

In the GCC countries, people highly consume energy-dense foods rich in fat, free sugars, sodium content and deficient in complex carbohydrates. It has been found that daily energy intake exceeds 3,000-kcal/per capita (Musaiger, 2004; Al-Sarraj et al., 2010; Sibai et al., 2010; Badran and Laher, 2012; Elliott et al., 2013). In particular, people in Kuwait experience difficulty in following a regular diet due to lack of motivation and awareness and frequent social gatherings (Badran and Laher, 2012; Karageorgi et al., 2013). Moreover, people in the GCC countries are considered physically inactive (Mabry et al., 2010). People spend much of their time in sedentary activities, e.g. watching television, playing video games, etc.

Furthermore, the availability of housemaids and sophisticated household appliances also limits physical activity. Extreme climate conditions, e.g. being very hot in the summer and very cold in the winter limits outdoor activities and encourages using cars instead of walking (al-Mahroos and al-Roomi, 1999; Benjamin and Donnelly, 2013). A study in Kuwait in 2013 reported the prevalence of obesity among Kuwaiti nationals aged between 20 to 65 years to be 48.2% and 62% of participants had a sedentary lifestyle (Alarouj et al., 2013).

Smoking which contributes to an increased risk of coronary artery diseases is highly prevalent in the MENA region. Smoking rates in the region ranged from 15.3% in Morocco to 53.9% in Lebanon (Khattab et al., 2012). In a study among Kuwaiti nationals aged between 20 and 65 years, 17.8% of participants were smokers (Alarouj et al., 2013). Although it increases risk of micro-vascular complications, some patients with diabetes decide to smoke or continue smoking cigarettes. In Libya, it has been found that 26.7% of patients with diabetes are smokers (Roaeid and Kablan, 2007). Approximately the same percentage (27.6%) has been reported in Egypt (Kamel et al., 1999). The rate of smoking in each of these countries has been raised to 45% in Libya and 46% in Egypt (WHO, 2015).

1.4 Public health and policy of diabetes management in Kuwait

Kuwait is a small country located in the northeast of the Arabian Peninsula. It has a population of approximately 3,695,316, of which 33% are Kuwaiti and 67% are from different origins (e.g. Arabian, Asian, African, European, American and Australian). Most of Kuwait's areas are urbanised and about 97% of people have access to safe water and sanitation (Central Statistical Bureau, 2013). Kuwait is divided into five governorates: Capital, Hawalli, Ahmadi, Jahra and Farwaniya **(Figure 1.4)**. In terms of health, the MOH regulates the delivery of healthcare services via primary health care centres, general and specialised hospitals. The healthcare delivery system is regionalised; each region comprises a general hospital and a number of primary healthcare centres that refer to it. **Table 1.3** shows the healthcare facilities in the MOH by health region (Health, Kuwait, 2010).
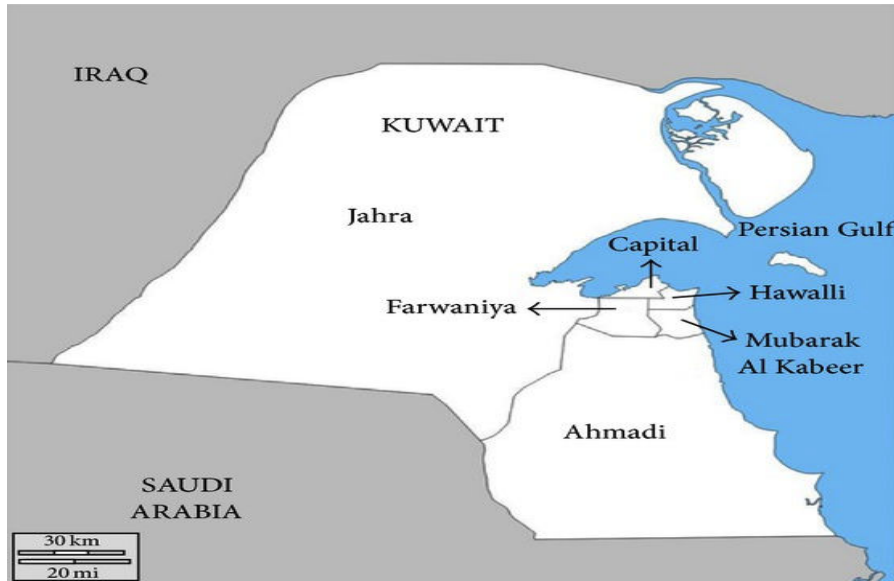
Source: Karageorgi et al., 2013

Figure 1.4: The map of Kuwait including the main five health districts

The delivery of healthcare services is free of charge for all Kuwaiti nationals and all other nationalities from the Arabian Gulf (e.g. Saudi Arabia, Bahrain, Qatar, Oman and United Arab Emirates). Non-Kuwaiti nationals from other than Arabian Gulf countries have to pay a small standard administration fee, about 1-2 KD (equivalent to £2-4) for admission to polyclinics and hospitals. This fee covers consultations as well as medications.

Table 1.3: Health care facilities in the MOH by health region, Health, Kuwait, 2010

Health regions	General hospitals	Primary health care centres				
		Diabetes care	General health & child care	Maternal health care	Dental care	Preventive care
Capital	1	**17**	22	5	19	12
Hawalli	1	**8**	15	5	14	13
Ahmadi	1	**15**	17	7	18	15
Jahra	1	**7**	13	8	10	9
Farwaniya	1	**12**	19	9	17	17
Total	**5**	**59**	86	34	78	66

The MOH has provided all primary care units with an electronic system, the Primary Care Information System (PCIS) to store patients' medical records. By using the PCIS software, physicians can access patients' data including: past medical history, drug history and allergies. Also, it provides physicians with clinical measurements of patients, such as body mass index (BMI), blood pressure (BP), HbA1c and other

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laboratory results. Patients' prescriptions are sent electronically to the pharmacy by physicians. However, in diabetes care, paper records are still used in some settings and in hospitals as well.

In addition to primary-care units and hospitals, Kuwait established the Islamic Medicine Centre in 1978, which is part of the MOH. A national programme for the regulation of herbal medicines was created in 1989. The Centre supplies herbal medicines to all patients in Kuwait free of charge and it includes medicines for the treatment of 15 different diseases, such as rheumatoid arthritis, asthma, kidney diseases and diabetes. Herbal medicines are available in different forms, such as capsules, granules, powders, creams, ointments and liquids. No referral letters are required for patients to receive treatment in the Centre but the patients have to show blood tests or other laboratory investigations relevant for their disease (WHO, 2005).

1.4.1 Diabetes care

Diabetes is managed in Kuwait through diabetes clinics that are available in primary healthcare settings and they provide patients with consultation and treatment. Hospitals provide outpatient diabetes care, annual eye and feet check-ups as well as inpatient services. Patients with diabetes are usually managed in their local polyclinics. The MOH provides most of the specialised polyclinics with a wide range of anti-diabetic medications. Patients are usually seen every 2-3 months for a follow-up and to dispense their prescriptions. In cases where patients fail to achieve glycaemic control in the polyclinic or if they need medicines that are not provided there, the physician refers the patient to the hospital. In hospitals, patients go for further investigations by a diabetologist, who follows their case. Patients then are managed in the hospital and collect their prescriptions from the outpatient pharmacy of the hospital. **Figure 1.5** shows number of patients with diabetes in each health region.
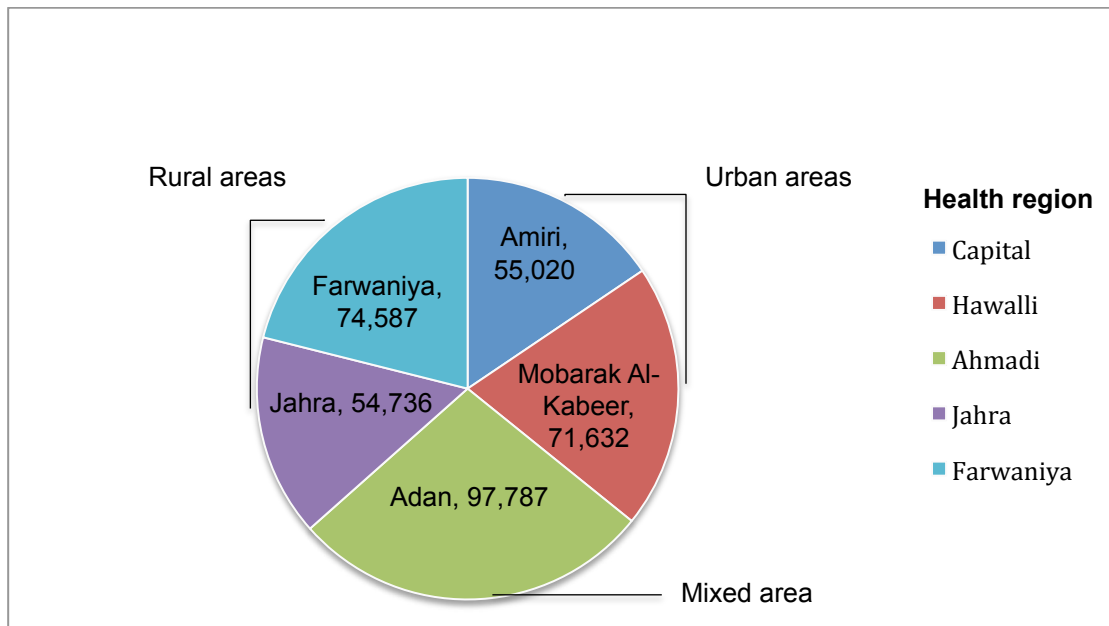
Figure 1.5: Number of patients with diabetes in each health region, Health, Kuwait, 2010

In 1999, the Kuwait Diabetes Care Programme (KDCP) was established. The aim of this programme was to improve the quality of care provided to patients with diabetes in primary care settings. Briefly, the programme involved the development of clinical guidelines, standards of care, training courses and monitoring system (Al-Wotayan, 2011). It has been shown that the implementation of KDCP was associated with improvements in diabetes care quality (Al-Adsani et al., 2009).

In 2006, Sheikh Sabah Al-Ahmad, the current Amir of Kuwait, inaugurated the Dasman Diabetes Institute (DDI), one of the leading centres of diabetes research in the Middle East. The project was funded by the Kuwait Foundation for the Advancement of Sciences (KFAS). The main aim of the Institute was to improve quality of life of patients with diabetes through preventing, controlling and alleviating the impact of diabetes in Kuwait by conducting research, training programmes, education and health promotion (Dasman Diabetes Institute, 2016). One of the important achievements of the Institute was the Kuwait Health Network (KHN) Informatics system. This system provides education to students and clinical decision-making tools to HCPs. It also links all primary healthcare polyclinics and hospitals in the Capital region through electronic records (Ben Nakhi and Morris, 2014). In 2010, DDI collaborated with DAFNE UK, the Dose Adjustment for Normal Eating project (Alozairi, 2011). In 2011, the Institute, in collaboration with University of Dundee, officially started to deliver a joint Masters course in Diabetes Care and

Education. The Institute receives referrals from all Kuwait's governmental hospitals, when patients fail to achieve clinical targets, although referrals are not strictly defined. **Figure 1.6** summarises the pathway of patients for the management of diabetes.
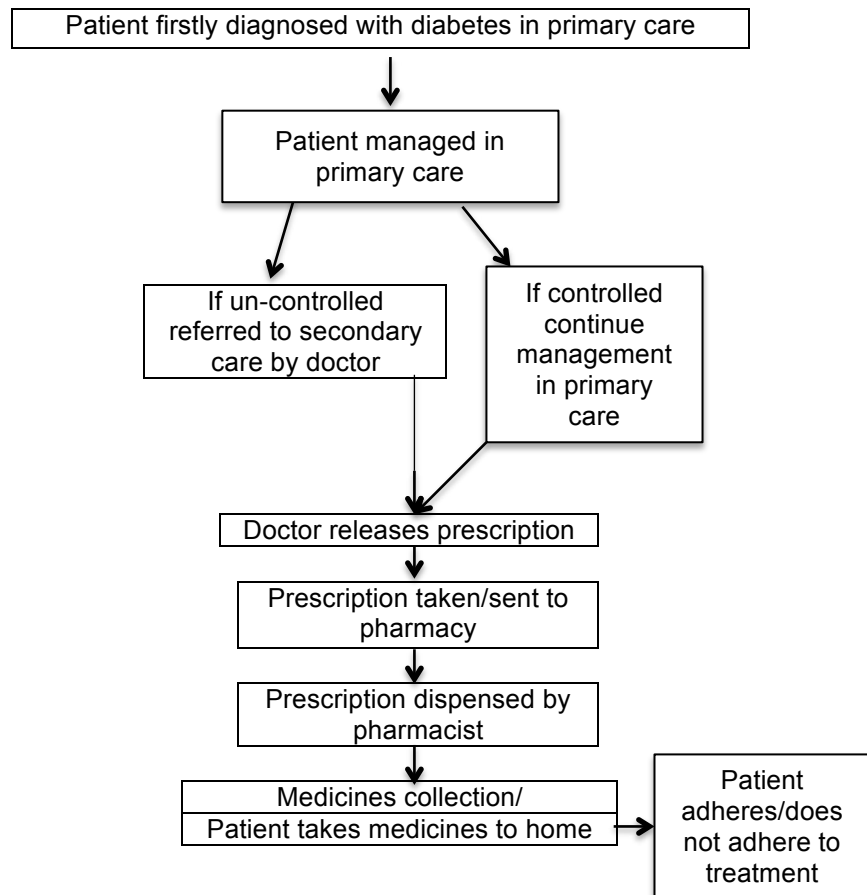
Figure 1.6: Pathway of patients for diabetes management

1.4.2 Pharmaceutical care

Different types of OHAs in addition to insulin injections are distributed regularly to pharmacies of all governmental primary healthcare units and hospitals by medical stores. Examples of OHAs that are available in Kuwait are: metformin and sulfonylureas, such as glibenclamide, gliclazide, glimepiride and glipizide. Different types of insulin are provided to all primary healthcare units along with traditional syringes, which are also provided to hospitals along with insulin pen devices. In addition, the MOH supports patients with diabetes by providing them with blood glucose meters, stripes and lancets at half price, available at Kuwait Diabetes Society (KDS). Very recently, the MOH has introduced a new option for treating people with diabetes; insulin pumps. However, the use of insulin pumps is still limited in Kuwait. This limitation can be attributed to the restrictions presented in the

KDCP guidelines, which enforce complex procedures for prescribing insulin pumps. According to these guidelines, candidates for pump therapy should have type 1 diabetes and be evaluated by a diabetes consultant in a well-established unit. The diabetes consultant should also assess the patient's understanding, willingness and ability to undertake self-care behaviour, e.g. frequent SMBG, carbohydrate counting and dose adjustments. Then, two diabetes-specialists must sign the form for dispensing the pump from Medical Stores. However, during the preliminary fieldwork for this study, which was conducted in February 2013, it was found that the use of insulin pumps has been extended to patients with type 2 diabetes, but they are very few compared to patients with type 1 diabetes. In addition to conventional medicines for the treatment of diabetes, Kuwait created a national programme for the regulation of herbal medicines, which are supplied to patients as over the counter medicines by the Islamic Medicine Centre. Herbal medicines are also sold in private pharmacies and herbal shops as over the counter medicines without restriction (WHO, 2005).

Regarding pharmacy education in Kuwait, there is one School of Pharmacy at Kuwait University, where students spend 5 years to obtain a bachelor academic degree. Clinical pharmacy is taught in the final 2 years of study, but in practice clinical activities are still limited. Extensive search in databases have not revealed any national research that covers pharmaceutical care plans in Kuwait. There are only three studies that discuss general pharmacy practice in governmental hospitals and describe barriers to implementation of pharmaceutical care and the enthusiasm of motivated pharmacists to be involved in the process. Unfortunately, the shift towards introducing clinical activities into pharmacy practice in Kuwait has been discussed for many years with no success of it being achieved yet. Pharmacists are still perceived by some doctors and patients as dispensers only. The role of pharmacists is limited to dispensing prescriptions and clarifying to patients how to use their medicines. In most cases and particularly during rush hours, some pharmacists do this job by only swiping with pens on the medicine package and avoid oral interactions with patients (Awad et al., 2006; Al-Taweel et al., 2014; Katoue et al., 2014).

1.4.3 Management of type 2 diabetes

According to the Kuwaiti Clinical Practice Guidelines for diabetes (Al-Wotayan, 2011), once a diagnosis of type 2 diabetes has been confirmed, the patient is assessed for the need for an inpatient management. If inpatient management is not

needed, the patient is allocated for non-pharmacological therapy (e.g. diet, exercise and weight management). If treatment goals have not been met, the patient starts the pharmacological treatment. The management algorithm starts with metformin as a first-line treatment, unless medically contraindicated. If treatment goals have not been met with the mono-therapy with metformin, a second OHAs is added or insulin. In addition to pharmacological therapy there is a surgical option for patients with type 2 diabetes called bariatric surgery. The criteria for the surgery are adults with type 2 diabetes with BMI>35 kg/m^2 especially, in patients with co-morbidities. It is recommended when all non-surgical measures have been tried but failed to achieve or maintain adequate weight loss for at least 6 months, the patient is generally fit for anaesthesia and surgery and there is a commitment for long-term follow-up and medical monitoring. **Figure 1.7** describes the management algorithm.

```
┌──────────────┐      ┌──────────────┐      ┌──────────────┐
│   Patient    │      │ Does patient │      │ If yes,      │
│  diagnosed   │─────▶│ needs inpatient│────▶│ recommend    │
│ with type 2  │      │ management?  │      │ hospital     │
│  diabetes    │      │              │      │ admission    │
└──────────────┘      └──────┬───────┘      └──────────────┘
                             │
                             ▼
                      ┌──────────────┐
                      │ If no,       │
                      │ recommend:   │
                      │ *Diet        │
                      │ *Physical    │
                      │ activity     │
                      │ *Weight      │
                      │ management   │
                      │ *Smoking     │
                      │ cessation    │
                      │ *General     │
                      │ diabetes self-│
                      │ management   │
                      │ education    │
                      └──────┬───────┘
                             │
                             ▼
                      ┌──────────────┐      ┌──────────────┐
                      │ Initiate metformin,│ │ AND assess need│
                      │ unless medically │──▶│ for:         │
                      │ contraindicated │   │ antihypertensive,│
                      │              │      │ statin and aspirin│
                      └──────┬───────┘      └──────────────┘
                             │
                             ▼
                      ┌──────────────┐      ┌──────────────┐
                      │ Are treatment│      │ If yes, on-going│
                      │ goals met?   │─────▶│ management   │
                      │ (HbA1c<7)    │      │ and follow-up│
                      └──────┬───────┘      └──────────────┘
                             │
                             ▼
                      ┌──────────────┐
                      │ If no, consider:│
                      │ *Maximal     │
                      │ tolerated dose│
                      │ *Add 2nd OHA │
                      │ *Insulin     │
                      │ therapy      │
                      └──────────────┘
```

Figure 1.7: The management algorithm for type 2 diabetes

1.5 Use of technology in diabetes management

Despite the extensive studies on the importance of early insulin treatment in patients with type 2 diabetes, and its efficacy in delaying complications, insulin is still considered as the last resort for treating this group of patients in the Middle East (Lakkis et al., 2013). Different reasons may contribute to the delay of insulin initiation, such as fear of injections and weight gain. In correlation with the increased

rates of type 2 diabetes in the world and its severe complications, the optimisation of glycaemic control has become a fundamental aspect of diabetes management. Different researchers have reported higher adherence rates among patients using OHAs compared to those using insulin only or as a concomitant therapy (Cramer, 2004; Lee et al., 2006). A recent review showed that adherence to OHAs reached 93% in patients remaining on treatment for 6-24 months and adherence to insulin was 62% and 64% for long-term and new-start insulin users respectively (Garcia-Perez et al., 2013). So, adherence to insulin continues to be a challenge for optimum diabetes management. However, it has been suggested that simplifying the insulin delivery method can overcome barriers to insulin use and improve patients' adherence. Technological devices, such as insulin pens and pumps have been introduced as insulin delivery methods instead of traditional injections (syringe and vial) **(Figure 1.8)**. The aim of using insulin pens and pumps is to help insulin-dependent patients to cope with their disease and treatment, and to make it easier for them to take better care of their condition (Shaghouli et al., 2009).

An insulin pen is a device that contains a cartridge of insulin and a needle (dial a dose cartridge injector); it may be reusable or disposable **(Figure 1.9)**. Most insulin pens have been designed to be socially accepted, ease the use of the injection and reduce injection pain. Therefore, they play a pivotal role in insulin delivery by providing patients with convenience compared to conventional insulin syringes (Luijf et al., 2010). An insulin pump is a mechanical device that connected to a tubing system (cannula) **(Figure 1.10)**, which is inserted under the skin and used to continuously (24 hours a day) deliver the insulin (usually a rapid-acting insulin). The cannula remains *in situ* and should be changed every 2-3 days. Insulin pumps have the feature of delivering basal insulin (increased or decreased based on the patient's activity) and bolus insulin (calculated according to carbohydrate intake) that simulate physiological insulin delivery (Nicholls and Partridge, 2015).

Source: cornerstones4care.com   *Source: bd.com*

Figure 1.8: Syringe and vial   **Figure 1.9:** Insulin pen
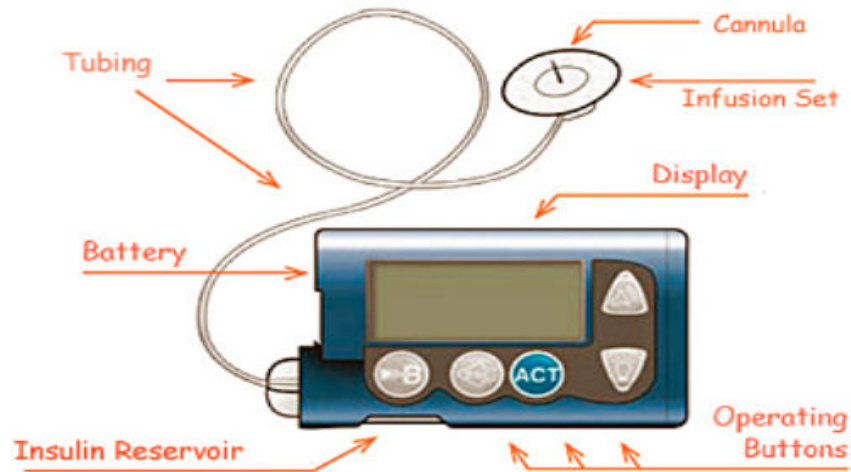
Figure 1.10: Insulin pump

In the 1920s, when insulin was firstly discovered, the only delivery method available for clinical use was syringe and vial. Then, the first manufactured insulin pump was introduced in the 1970s and the first manufactured insulin pen (NovoPen[R]) was introduced in 1985 (Selam, 2010). Subsequently several insulin pens have been manufactured to deliver rapid- and long-acting insulin and insulin premixes. Newer types of insulin pens have more advantages than older ones by having finer needles and requiring lower injection force, e.g. FlexPen[R]. In addition, many patients find the disposable prefilled pens more convenient than the reusable ones (Selam, 2010). To enhance convenience for patients, many improvements have been made since the introduction of the first pump 35 years ago (Alsaleh et al., 2010). Technological advances in the 1990s have transferred continuous subcutaneous insulin infusion (CSII) into a practical alternate to MDIs (Lepore and Tommaselli, 2015). Pager-sized pumps have taken the place of the brick-sized old ones. OneTouch[R] and MiniMed Paradigm[R] are examples of the currently available insulin pumps. A newer type of insulin pumps is the patch or tubeless pump **(Figure 1.11)** that is attached directly to the skin. It consists of a patch (a reservoir of insulin and a tiny pump) attached to the skin with the smart calculator and glucose monitor as a separate device connected by Bluetooth (Selam, 2010). As technology in diabetes management is rapidly progressing, a new generation of insulin pumps (OmiPod[R]) have been developed (glucose sensor-augmented insulin pump), providing a continuous glucose monitors resulting in the adjustment of insulin delivery based on detected variability of blood glucose levels (Cengiz et al., 2011).
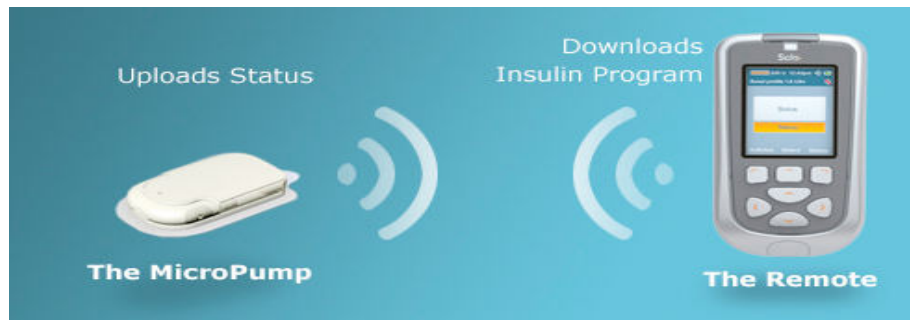
Figure 1.11: The patch pump

The cost-effectiveness of insulin pens and their acceptability by patients with type 2 diabetes have been reported in several studies (Lee et al., 2006; Chandran et al., 2015). In the United States, the improved adherence among patients with type 2 diabetes who used insulin pens reduced the diabetes care costs when compared with the use of traditional injections (Chandran et al., 2015). The use of insulin pumps has been examined worldwide and their efficacy in achieving glycaemic control compared with optimised insulin injection therapy has been shown in both types of diabetes (Bode, 2010; Pickup, 2014). Furthermore, physiological continuous delivery of insulin provides control using less insulin and thus, reduces weight gain and hypoglycaemic events, which improves patients' quality of life and wellbeing (Lepore and Tommaselli, 2015). However, insulin pump therapy is primarily considered for patients with type 1 diabetes who have suboptimal glycaemic control despite maximum control using multiple daily injections (MDIs) (Nicholls and Partridge, 2015). The routine use of insulin pump therapy in patients with type 2 diabetes is not usually recommended and it differs between countries (Roze et al., 2015). In a review of studies, it has been shown that CSII is cost-effective in patients with type 1 diabetes who have poor glycaemic control and/or problematic hypoglycaemia with MDIs (Roze et al., 2015). In type 2 diabetes, the cost-effectiveness of CSII versus MDIs has been shown in the Netherlands, in patients who continue to have poorly controlled HbA1c despite optimisation of MDI (Roze et al., 2016).

Studies examining the psychosocial impact of insulin pump therapy on patients have reported improved patient' satisfaction, preference and acceptance over the years (Lepore and Tommaselli, 2015). Other studies have also indicated a preference for insulin pumps in adults with type 2 diabetes (Bode, 2010; Rubin et al., 2010). Overall, both insulin pens and pumps offer advantages to patients by improving their

convenience, preference, adherence and health outcomes (Selam, 2010). However, it has been shown that most patients with type 2 diabetes had not been offered insulin pens by their doctors (Rubin and Peyrot, 2008). This could be due to the lack of awareness of doctors about the benefits of such devices. Improving awareness of physicians about the benefits of theses devices is the key for better diabetes management. However, although there are many advantages for the use of insulin pens and pumps, there are many disadvantages (Dansinger, 2015). These are discussed compared to traditional injections in **Table 1.4**.

The use of insulin devices among adults in the Middle East has not been widely investigated. Five studies examined the use of insulin pens and pumps among adults in Lebanon, Israel and Egypt **(Chapter 9, Sections 9.2.2, 9.2.3)**. In Kuwait, insulin pumps have recently been provided to patients in the MOH (since 2006). The Medtronic Company provides a definite number of insulin pumps every year to the Medical Stores of the MOH, where patients can obtain their pumps. Number of adults using this delivery method is expanding but unfortunately, information on how these devices are being used in this population and their advantages and problems in use is lacking.

Table 1.4: The advantages/disadvantages of the different insulin delivery systems

Pros/cons	Syringe and vial	Insulin pen	Insulin pump
Cost	A box of 100 syringes= £7-10	Costs £21-28	Costs £2000-3000
Preparation	-Mix different types of insulin in one injection -Inaccurate mixing is probable	-Inability to mix preparations -Some types of insulin are not available	-No preparation is needed
Administration	-Complex administration procedures -Dosing inaccuracy is probable	-Ease of administration -More dosing accuracy	-Automatic delivery of doses -Avoid frequent injections
Carrying burden	Carry several items	Carry less items	Constant wear
Requirements	-Simple skills are required -Needs to know how to calculate doses	-Simple skills are required -Needs to know how to calculate doses	-Advanced education and skills are required for proper use -Needs carb counting -Automatic doses calculation
Risks	-Pain/ bruising/ bleeding at injection site	-Less pain/ bruising/ bleeding at injection site	-Irritation/ inflammation at cannula insertion site -Equipment breakdown/ blocked needle/ folded catheter
Efficiency	Requires larger amounts of insulin to provide control	Requires larger amounts of insulin to provide control	Provide control with less amount of insulin

Summary of what is known about the topic?

Non-adherence to medicines among patients with chronic conditions including type 2 diabetes is a problem in a number of Middle Eastern countries. Many factors have been identified, through questionnaires and interviews, as contributors to poor adherence. The HBM is effective in assessing health-related behaviour and is useful in explaining factors that influence patients' behaviour. The use of technology in diabetes management has not been widely discussed in Eastern Mediterranean literature. However, use of insulin pens and pumps had some advantages among patients with type 2 diabetes. Use of insulin pens improved patients' quality of life and insulin pumps improved patients' glycaemic control.

What this thesis adds?

In the context of wider diabetes management in the Middle East, some adult patients with type 2 diabetes poorly manage their disease. This includes improper use of medicines and insulin devices. In relation to factors that influence patients' health behaviour, describing these in the context of the HBM helped in organising patients' beliefs, explaining the relation between patients' attitudes and health-related behaviour and evaluating the most influential beliefs on behaviour. In addition, barriers to appropriate insulin devices use were also investigated.

Overall, this thesis aims to identify gaps in knowledge of patients using different therapies and to compare between the use of technology and the traditional methods of insulin delivery. Also, this study aims to identify different factors that influence patients' behaviour, in terms of healthcare profession and system, in order to design the most practical interventions that address patients' beliefs and attitudes. This thesis provides an evidence-based guidance for future service development and to inform policy and practice implications to the MOH, Kuwait. Therefore, it was important to conduct a literature search regarding how patients with diabetes manage their disease in similar populations (in the Middle East). Literature review of the studies is discussed in the next chapter.

Chapter 2: Systematic review of studies on adherence of patients with diabetes

2.1 Introduction

This chapter describes the literature search process, which was conducted to review the published studies relating to diabetes management in Middle Eastern countries and discussing patients' adherence. Studies that discuss cultural factors affecting people with diabetes were also reviewed. Because it has been noted that some patients with diabetes lack knowledge of their disease, and that patients' beliefs played a role in their ability to use medicines (Vermeire et al., 2003), patients' medication adherence in the region is still challenging. As this project is based in Kuwait, the aim of this review was to: reveal areas of research in the context of diabetes management among adults in the Middle East, consider local literature in which adherence of adults with type 2 diabetes have been discussed from the perspectives of patients, review evidence regarding the association between patients' knowledge, beliefs, cultural factors and health behaviour, and identify methods that have been employed to assess patients' beliefs/adherence.

A systematic search was undertaken using electronic databases. The literature search was conducted in the beginning of this study (January 2013) and continued until the completion of this thesis (April 2016).

2.2 Methods

2.2.1 Search terms and strategy

A systematic search of studies relating to medicine use and medication adherence in diabetes in the Middle East was performed using the following databases: Embase, PubMed, Web of Science and Index Medicus for the Eastern Mediterranean Region (IMEMR). The search was selected for the period from 1990 to 2015. The search terms were: (diabetes AND adherence or compliance AND medicine use AND Middle East or Kuwait or United Arab Emirates or Saudi Arabia or Bahrain or Qatar or Oman or Jordan or Egypt or Lebanon or Syria or Iraq or Iran or Palestine or Israel or Turkey or Libya), with or without the combination of the search terms: (health beliefs, lifestyle, patient behaviour, insulin). Studies that discussed medicine use during the holy month of Ramadan were searched using the search terms: (Ramadan fasting AND diabetes mellitus). In addition, the Google search engine was used to identify clinical journals in Middle Eastern areas. These

journals were searched for relevant papers and the bibliographies of relevant papers were hand searched for additional articles. In addition, an expert in diabetes in the area was contacted to help in identifying relevant articles. This helped in identifying the most recent studies that conducted among patients with diabetes in Kuwait.

2.2.2 Inclusion/exclusion criteria

The electronic database search yielded 833 studies and nine studies were identified from other sources, such as contact with an expert (n=2), searching reference lists (n=4) and Google search engine (n=10). Removing duplicates yielded a total of 822 studies. The summary of the literature search process is illustrated in **Figure 2.1**. Titles and abstracts were evaluated to determine eligibility for full screening. Studies that employed acceptable quantitative (e.g. questionnaire) and qualitative methods (e.g. interviews), including randomised controlled trials and observational studies (e.g. cross-sectional, experimental and interventional) and review articles were included. The inclusion criteria were adults (18 years and above) with diabetes, and from an Eastern Mediterranean country (e.g. Kuwait, Iran, Saudi Arabia, Turkey, Palestine, Israel, Jordan, Oman, Libya, Egypt and UAE). Studies that involved all sexes and ethnicities, urban and rural, residents and expatriates, and all socioeconomic and educational backgrounds were included. In addition, the review includes studies at different healthcare levels.

Overall, all studies with topics of interest (n=39), discussing the management of diabetes among adults in the Middle East were reviewed. All studies wherein patients' self-management behaviour, and determinants of this behaviour were explored from the perspectives of patients were eligible for inclusion. The views and experiences of HCPs on the management of diabetes in the region, and factors affecting this management were also included. As the requirements and experiences varied from those of adults, studies related to young people, adolescents and pregnant women were beyond the scope of this research and were not reviewed. In addition, case studies were excluded from this literature review.

2.2.3 Data extraction

Once all relevant studies had been identified, full-text manuscripts were retrieved as hard copies for assessment. The quality of each study was assessed using checklists adapted from the Critical Appraisal Skills Programme (CASP). The researcher used the relevant checklist for each type of study (e.g. systematic review checklist for review articles). Another researcher (A.A) undertook the quality

assessment process for the identified papers. Then, the researchers met and any disagreements were discussed and resolved. Information was extracted into a *pro forma*, this enabled identification of papers which addressed specific topics and issues relevant to the study objectives, and facilitated the retrieval of information. The *pro forma* included primary author name, date of publication, setting, country of the study, number of participants, study design, and the main study findings about the determinants of adherence to medicines and lifestyle among patients with diabetes in the Middle East, and socio-cultural factors relevant to the prevalence and management of type 2 diabetes in the region **(Appendix 1)**.

Records identified through database searching (n=833):
-Embase (n=127)
-PubMed (n=565)
-Web of Science (n=119)
-IMEMR (n=22)

Additional records identified through other sources (n=16):
-From contact with an expert (n=2)
-From searching reference list (n=4)
-From Google search engine (n=10)

Records after duplicates removed (n=822)

Records screened (n=822)

Records excluded (n=784)

Full-text articles assessed for eligibility (n=47)

Full text articles excluded (n=8):
-Full access to the study unavailable (n=3)
-Data analysis (n=3)
-Excluded subjects (e.g. pregnant women) (n=2)

Reasons:
-Articles were not on medicine-taking behaviour, e.g. on efficacy of a drug, or specific to the disease complications (clinical trial)
-Articles were not in a Middle-Eastern country, e.g. Canada or England
-Articles were on diseases other than diabetes, e.g. depression, hypertension, heart diseases, hypercholesterolaemia, hyperparathyroidism or hyperkalaemia
-Articles were on adherence to medicines other than anti-diabetics, e.g. statins, anti-hypertensive, laxatives
-Articles were on surgery
-Articles were on children with type 1diabetes

Studies included in the review (n=39)

Quantitative studies (n=28)
Qualitative studies (n=3)
Mixed methods studies (n=3)
Review articles (n=5)

Figure 2.1: Summary of literature search process for this review

2.3 Results

A total of 39 studies were identified from all regions of the Middle East: Kuwait (2 studies), Iran (3), Saudi Arabia (7), Turkey (1), Palestine (3), Israel (3), Jordan (2), Oman (6), Libyan Arab Jamahiriya (2), Egypt (3) and United Arab Emirates (4). Three studies were across Middle Eastern countries and one focused on the GCC countries.

Thirteen of the 39 studies discussed issues related to type 1 and type 2 diabetes (Kamel et al., 1999; Khattab et al., 1999; Al-Saeedi et al., 2002; Turan et al., 2002; Al-Saeedi et al., 2003; Salti et al., 2004; Abahussain and El-Zubier, 2005; Roaeid and kablan, 2007; Al-Kaabi et al., 2008; Elis et al., 2008; Mishali et al., 2010; Jamous et al., 2011; Yekta et al., 2011), whilst 17 focused on type 2 diabetes only (Abdulhadi et al., 2006; Abdulhadi et al., 2007; Ali et al., 2010; Hui et al., 2010; Khattab et al., 2010; Shams and Barakat, 2010; Al-Shookri et al., 2011; Aflakseir, 2012; Al-Khawaldeh et al., 2012; Badran and Laher, 2012; Alhyas et al., 2013; Elliott et al., 2013; Jimmy et al., 2014; Sweileh et al., 2014; Ashur et al., 2015; de Villiers and Halabi, 2015; Jeragh-Alhaddad et al., 2015). Six of the studies addressed other long-term diseases alongside diabetes (Serour et al., 2007; Biderman et al., 2009; Al-Qasem et al., 2011; Ibrahim et al., 2011; Aflakseir, 2013; AlHewiti, 2014), and one focused on lifestyle issues and obesity (Mabry et al., 2010). All of the studies were conducted among adult populations ($\geq$18 years of age). The settings of the research studies were primary healthcare centres (n=14), hospitals (n=5) and diabetes centre/clinic (n=13), and retirement club (n=1). The sample sizes of the reviewed studies ranged from 91 to 41,936 participants for the quantitative studies, and from 9 to 75 for the qualitative ones.

Most studies (n=28) employed survey methods to collect data and applied quantitative analytical procedures to explore the determinants of patients' medicine-taking behaviour, such as health awareness and beliefs. Only three studies applied qualitative methods (focus groups and interviews) (Abdulhadi et al., 2007; Ali et al., 2010; Alhyas et al., 2013). These studies investigated factors that affected patients' management behaviours from the perspectives of patients themselves (n=2), and from the perspectives of healthcare professionals (n=1). Three studies combined quantitative and qualitative methods (questionnaires and interviews) (Kamel et al., 1999; Shams and Barakat, 2010; Al-Khawaldeh et al, 2012). All of the studies were

original articles except five, which were reviews (Hui et al., 2010; Mabry et al., 2010; Al-Qasem et al, 2011; Al-Shookri et al., 2011; Badran and Laher, 2012).

The main findings about determinants of medication adherence among the studies were lack of knowledge, illness perceptions, treatment misconception and satisfaction, self-efficacy, beliefs about necessity/safety of medicines, beliefs about herbs, forgetfulness and beliefs about HCPs. Determinants of adherence to lifestyle modifications were poor health awareness, lack of social support and lack of time. Details about each determinant are provided below.

2.3.1 Lack of health awareness about diabetes

Knowledge is a prerequisite of preventive health behaviour and it motivates patients to take actions for treating their illnesses (van den Arend et al., 2000). Because patients with type 2 diabetes are responsible for their self-control behaviour, it is important that they understand the disease and how to treat it (Saadi et al., 2010). Many studies have discussed the knowledge of patients with diabetes in the Middle East. Overall, poor knowledge levels have been recorded in all of these studies. For example, Roaeid and Kablan (2007) have reported poor knowledge among patients about the effects of diabetes on the eye and kidney, and about the symptoms of hypoglycaemia and its treatment. Further, a study in Oman revealed that a significant proportion of people had no information regarding preventive measures needed to cope with diabetes (Al Shafaee et al., 2008). Another study has noted that a substantial number of patients did not mention any signs of abnormal glucose levels or did not know how to detect hypoglycaemia (Elliot et al., 2013).

2.3.1.1 Health awareness and medicine use

Kamel et al. (1999) in Egypt reported that 90% of patients had poor knowledge about diabetes; 83.7% had poor knowledge about its complications and 96.3% had poor awareness of how to control the disease. Another study by Al-Saeedi et al. (2002) concluded that patients thought that cure from diabetes could be expected after a short course of treatment, and that they could eat whatever they want as long as medications were taken. It was reported that patients demonstrated better treatment adherence when they received sufficient information on the disease, medicines, dosage, complications and their prevention (Kamel et al., 1999; Al-Saeedi et al., 2002; AlHewiti, 2014). Other studies have shown that knowledge and health awareness may encourage patients to be serious in following their therapeutic regimens (Pinhas-Hamiel and Zeitler, 2003; Jamous et al., 2011).

Abahussain and El-Zubier (2005) reported poor knowledge of general diabetes characteristics and low perceptions of its consequences among patients. However, in that study the authors noticed that some patients used herbs to control their diabetes and abstained from their conventional medical treatment. This could be because patients lacked the awareness of the importance and role of their medicines. Other authors have also reported a significant relationship between knowledge about diabetes and adherence to treatment, in which poor diabetes-related knowledge led to poor adherence to treatment (Shams and Barakat, 2010; Sweileh et al., 2014; Ashur et al., 2015). In one study, it was reported that the patients had poor glycaemic control and had developed diabetes-related complications, as a consequence to poor knowledge and low treatment adherence (Ashur et al., 2015).

Poor knowledge levels not only affected patients' compliance but also contributed to dangerous actions practised by patients, which might affect their glycaemic control. For example, Roaeid and Kablan (2007) reported that some patients omitted their insulin evening doses, did not keep their insulin in a refrigerator or did not shake it before use, did not change the injection site and used the insulin syringe more than once. Another study by Elliot et al. (2013) reported that one-third of patients using insulin, self-adjusted their doses when eating smaller or larger meal portions, or if experiencing frequent hyper or hypoglycaemic attacks. In that study it was also reported that one in five patients using insulin adjusted their doses according to their physical activity. Although such behaviour could be good practice, and it is recommended for patients to self-adjust their insulin doses according to their lifestyle (Leontis and Hess-Fischl, 2016), patients in that study reported dangerous responses. The responses of those patients were against their blood glucose requirements, for example they were increasing doses of oral anti-diabetics or insulin or going to sleep when experiencing hypoglycaemia. Other responses were drinking juice or eating sour food to counteract hyperglycaemia. Other practices that could be fatal were not taking any corrective measure for an abnormal glucose level or when a hypoglycaemia was detected (Elliot et al., 2013).

However, there were contributing factors to poor knowledge among patients. Some of these factors were illiteracy and frequency of visits to healthcare services. Literacy levels of patients were associated with their understanding of diabetes and willingness to adhere to anti-diabetic medications. Most patients with a high level of education were found to comply with their treatment plans and achieve target

outcomes (Alhyas et al., 2013). Aflakseir (2013) in his study has concluded that the majority of older adults who had low education levels did not adhere to their medications. Illiteracy affects the ability of patients to comprehend the information provided by multiple resources and constitutes a barrier for good communication and management. In a qualitative study in Oman, it has been found that some patients did not perceive diabetes as a serious disease due to the lack of symptoms, and because they were inadequately educated about the disease (Abdulhadi et al., 2007). In addition, patients who had first-degree relatives, who were diagnosed with diabetes, showed better adherence to their therapeutic regimens because they shared the experiences, which improved their knowledge (Al Shafaee et al., 2008). Patients who frequently visited educators and doctors have been found to have better adherence because information was reinforced during each visit (Khan et al., 2012).

2.3.1.2 Health awareness and self-care behaviour

Management behaviours, which form the cornerstone of diabetes care, were mentioned in three studies. In all these studies, it was reported that good knowledge led to good management behaviours. For example, patients' knowledge about hypertension as a diabetic complication motivated them to have regular blood pressure checks. Knowledge about retinopathy was associated with patients' attendance at eye screenings, and knowledge about foot ulcer also encouraged patients to have regular foot check-ups. Only a small proportion of insulin-dependent patients were found to regularly monitor their blood glucose levels. This was because patients lacked an understanding of the importance of this practice, or simply they did not know how, and did not have the desire to do so. Also, it has been reported that some patients did not know that they could buy the blood monitoring device themselves, and believe it is only sold to healthcare professionals. Patients with more knowledge are motivated to control their disease, linking their symptoms with readings of their blood glucose and hence monitor their blood glucose regularly (Kamel et al., 1999; Roaeid and Kablan, 2007; Elliot et al., 2013). This in turn may impact on patients' adherence to treatments and motivate them to make other appropriate behavioural changes such as healthy eating (Abdulhadi et al., 2007).

2.3.2 Health beliefs and its impact on patients' behaviour

Patient adherence is believed to be significantly affected by health beliefs, and it is believed that there is a relationship between beliefs and behaviour (Alhyas et al.,

2013). Psychologists have studied this relationship extensively, revealing several socio-psychological approaches that may be used to explain the impact of health beliefs on patients' behaviour (Horne et al., 2005). Vermeire et al. (2003) have noted that patients with diabetes might intentionally misuse their medicines or not adhere to their therapeutic regimens as a result of their beliefs. However, the Middle Eastern population has unique beliefs that impact on their behaviour as discussed below.

2.3.2.1 Religious beliefs

Despite the cultural diversity among the Middle Eastern countries, Islam is the most practised religion in the region. Because Muslim people constitute the predominant portion of the Middle Eastern population, medical practices are based on Islamic beliefs. Religious beliefs indicate that death is part of God's plan, making explanations about the seriousness and urgency of making lifestyle changes and taking appropriate actions challenging. In other words, diabetic patients in the Middle East are highly affected by their religious beliefs specifically fatalism (Khoury, 2001; Klautzer et al., 2014). Fatalism is a psychological mechanism that identifies the relationship between people's control over their lives and destinies clarifying that "belief that events are controlled and predetermined by Allah, and that humans have little, if any, control over their destinies" (Khoury, 2001). Severe untreated cases of diabetes can lead to death but religious beliefs about God's control can discourage patients from engaging in activities that are perceived as against God's will. This may also be an issue associated with patients' medication non-adherence. It has been found that strong religious beliefs of patients in God's locus of control, and a reduced level of trust in scientific medical knowledge prevented them from committing to a course of oral anti-diabetic drugs (Bener et al., 2009; Ashur et al. 2015; de Villiers and Halabi, 2015).

Another study has reported that a proportion of Middle Eastern patients did not adhere to their medications because of instilled cultural beliefs. In the Middle Eastern culture, there is a strong belief in the "evil eye", which refers to the belief that an envious party inflicts negative events, such as illnesses and accidents on individuals or their families out of jealousy or envy (Lipson and Meleis, 1983). Often, patients prefer seeing religious and spiritual healers for the removal of the "evil eye" that they assume is causing their illness. Because removal of the misfortune plays a role in Middle Eastern culture, patients do not adhere to their medications until they are certain that other healers cannot assist with their situation (Yahia et al., 2012).

The association between religious beliefs and patients' health behaviour can be explained by HLOC theory. According to this theory, when patients have high external HLOC beliefs, and that an external factor is responsible for their cure (e.g. God, healers), they are less likely to adhere to their medications.

2.3.2.2 Beliefs about Ramadan fasting

Despite the Islamic exemption from fasting for ill individuals, which may provide some level of relief for patients and physicians, most patients with diabetes exempt themselves from this rule. Patients during Ramadan prioritise the religious obligations over the advice of doctors and religious authorities (Salti et al., 2004). This is supported by findings of Hui et al. (2010), who noted that patients' views of fasting were based extensively on religious faith and perception of God. Some patients perceived religious, spiritual and psychological benefits of observing fast during the holy month of Ramadan were viewed to outweigh the risks of diabetes complications.

So, patients' beliefs in the beneficial effects of fasting in Ramadan affect their medicine-taking behaviour. Since fasting during Ramadan obliges people to abstain from eating and drinking from sunrise to sunset, patients may change their insulin or oral anti-diabetic use without consulting their doctors. Some patients think that their medicine-taking behaviour during Ramadan is a private issue and there is no need to consult their doctors about it (Hui et al., 2010; Mygind et al., 2013). A study by Salti et al. (2004) revealed that 19.7% of patients using oral anti-diabetic drugs and 36.7% of patients using insulin changed their doses during Ramadan. For instance, some patients reported that they reduced their oral anti-diabetic doses because they believed that as long as they were not eating traditional foodstuffs, they did not need to take their medicines. Another study by Lawton et al. (2005) reported that patients think that their oral anti-diabetic drug will affect and expose them to more side effects if they take them as usual.

A qualitative study by Mygind et al. (2013) has reported some practices of patients regarding their medicine use during Ramadan. Some patients reported taking doses as usual, but delaying the evening doses and taking the morning ones earlier. Other patients reported missing their morning doses because they believed that taking their medicines without eating would further reduce their blood glucose level and affect their health. However, feeling normal even when not taking morning doses

was the main concern of those patients that encouraged them not to take their morning doses. In addition, some patients believed that insulin counteracts the effect of sugar; so they ate large portions of sweet in their Iftar; the meal in which Muslims break their fast, and then compensate for that by increasing their insulin doses.

The association between beliefs about Ramadan fasting and patients' health behaviour can be explained by the HBM. According to this model, when patients perceive barriers (e.g. fear of hypoglycaemia) to outweigh the benefits (e.g. maintaining glucose control), they become less motivated to take a health action (e.g. medication adherence).

2.3.2.3 Beliefs about the efficacy and necessity of medicines

Several studies have mentioned beliefs about the necessity and efficacy of the treatment. For instance, in the studies of Jamous et al. (2011), Alhyas et al. (2013), Jimmy et al. (2014) and Sweileh et al. (2014), it has been concluded that these types of beliefs, along with beliefs that the benefits of medicines outweigh their costs and risks resulted in better medication adherence. According to the HBM, patients might undertake a specific behaviour, e.g. medication adherence, when they believe that their medicines are effective (Bosworth and Voils, 2006). Therefore, beliefs about the necessity of treatment and quality of care provided are associated with important health outcomes (Stack et al., 2011; Petrie and Weinman, 2012; Alhyas et al., 2013).

However, other studies have concluded that beliefs about the efficacy of medicines negatively impact on other aspects of diabetes management. A qualitative study among Emiratis with type 2 diabetes has revealed that patients who believed that their condition could be managed only with drugs did not spend sufficient time with their healthcare professionals to discuss other important behaviours (Alhyas et al., 2013).

On the other hand, patients who believe that their medications are no longer effective might stop taking their medicines. This is supported by findings of Khattab et al. (1999), Khattab et al. (2010) and Ibrahim et al. (2011) who have found that patients with longer duration of diabetes and more complications were non-adherent to their medications. Also, it has been found that concerns about the negative effects of medicines prevented patients from complying with their treatments

(Aflakseir, 2012; AlHewiti, 2014). The same result was reported by Aflakseir (2013), where patients who had fear of side effects had poor adherence to their treatments. In addition, belief in the efficacy and safety of traditional herbs is highly prevalent among Middle Eastern patients with diabetes, especially the elderly. This type of belief has been mentioned in many studies, which reported that many patients abstained from their conventional medical treatments and used herbs to control their disease (Al-Saeedi et al., 2003; Abahussain and El-Zubier, 2005; Alhyas et al., 2013).

2.3.2.4 Perceptions about healthcare system/provider
Three studies have reported the role of beliefs about the quality of care in affecting the medicine-taking behaviour of patients. A study by Abdulhadi et al. (2007) has reported better glycaemic control among patients who attended hospitals than those attended primary care clinics. In that study, patients who attended hospitals believed that care provided in secondary care settings was better. Therefore, they adhered to their appointments and treatments and consequently achieved their glycaemic control. Also, it has been concluded that patients who continued their care with one primary care provider had better glycaemic control mediated by changes in patients' behaviour (Abdulhadi et al., 2007). Patients preferred to be seen by the same doctor because they believed that they would get better advice regarding their problems. Also, some patients perceived the continuity of care with the same HCP as a salient element in building their confidence and trust and improving their relationship with doctors. Patients' lack of belief in the competence of doctors and nurses significantly impacted on health outcomes (Abdulhadi et al., 2007).

The same finding was reported by Alhyas et al. (2013), who found that patients who had confidence in diabetes specialists only, discontinued their appointments when they were seen by doctors, in which their diabetes management was affected. Aflakseir (2013) has also concluded that a poor relationship between doctor and patient was associated with medication non-adherence. The association between patients' perception about healthcare system/provider and medication adherence can be explained by the CS-SRM. According to this model, when patients have negative perceived consequences of their illness, they will be less likely to engage in self-management behaviour. For instance, according to findings of this review, patients lack trust in primary-care units and in HCPs other than specialists. As a result, they became less satisfied with the services provided. The less satisfaction

level and the more negative perceived consequences they would get from the system/provider lead to poor management behaviour (Jin et al., 2008).

2.3.2.5 Self-efficacy and coping with diabetes

Self-efficacy, which refers to patients' beliefs in their ability to change and succeed, has been mentioned in two studies. In two studies, it was noted that self-efficacy was significantly associated with patients' adherence to treatment recommendations (Mishali et al., 2010; Al-Khawaldeh et al., 2012). Another study by Yekta et al. (2011) has reported that patients might not adhere to their medical treatments due to their belief that their self-care practices, such as maintaining sufficient levels of physical activity and controlling dietary intake are effective. However, despite having such belief, not all patients were found to follow such practices. Results revealed that only 52% of patients maintained physical activity levels that were sufficient for controlling diabetes and 65% monitored and controlled their dietary intake. On the other hand, believing that healthy lifestyle behaviour, e.g. diet and exercise do not result in immediate better health outcomes could discourage patients from making essential changes.

Besides the role of beliefs and self-efficacy in influencing the medicine-taking behaviour, coping with diabetes and satisfaction with treatment are essential in improving medicine use. Patients, particularly with type 2 diabetes, perform most of their disease management without consulting HCPs (Alhyas et al., 2013). Thus, they have to cope with challenges that they face in their daily lives In addition, coping with diabetes played a crucial role in improving patients' adherence to medications and glycaemic control especially in insulin-treated patients (Turan et al., 2002). Aflakseir (2012) noted that patients who believed that diabetes would last a long time had better medication adherence. In addition, patients who perceived that they had control of their medicines, better adhered to the therapeutic regimens (Aflakseir, 2013). On the other hand, patients with negative attitudes towards diabetes had more barriers to adherence and poor glycaemic control (Khattab et al., 2010).

According to the SRM, patients monitor their health behaviour, in order to transfer themselves from a current status (disease) to a future goal (control/cure) (Bosworth and Voils, 2006). Thus, medication adherence is the coping response in which patients achieve their goal (e.g. cure/controlled disease). However, the lack of immediate threat to life could discourage patients from complying with medications and lifestyle changes (Pinhas-Hamiel and Zeitler, 2003). Treatment satisfaction of

patients with diabetes in the Middle East has been studied by Biderman et al. (2009). The authors concluded that insulin-treated patients were the least satisfied with their treatments and thus, had more difficulties in taking medications. Patients of all ages have the fear of injections and there is a common belief that is "insulin means the deterioration of health status" (Kunt and Snoek, 2009).

2.3.3 Cultural factors & its impact on patients' behaviour

2.3.3.1 Social norms

Several studies have shown that cultural patterns and infrastructure prevent the achievement of target glycaemic control in patients with diabetes. For instance, according to a cross-sectional survey in Saudi Arabia, medication adherence differed between males and females (Khan et al., 2012). The reason for this was not established; however, one possible explanation could be that, in this region, females are predominantly housewives and this may enable them to monitor their medicine intake better than men. Furthermore, it has been reported that cultural factors prevent females from travelling alone to the diabetic care centres, and lack of adequate means of transport between rural and urban areas of Saudi Arabia prevent routine checks of blood glucose levels (Azab, 2001; Khan et al., 2012).

Individuals in the Middle East associate diabetes with impotence and infertility, both men and women are ashamed of their diagnosis and avoid engaging in conversations about diabetic medications, changing their eating habits from society's norms and engaging in activities that may result in weight loss (Khoury, 2001).

2.3.3.2 Family support

Family ties ranks highly on the values list among Middle Eastern people. Middle Eastern cultures consider family involvement almost mandatory for individual decisions. Also, according to Islam, societies are characterised by 'dependent collectivism', where people are combined into strong, connected in-groups from birth onwards. These groups are usually extended families, which continue supporting patients in exchange for unquestioning loyalty (Abdulhadi et al., 2007; Al-Shookri et al., 2011). Demanding behaviour is common in Middle Eastern culture and it is associated with the requirement for family to show that they care for patients, will never leave the patient alone and to show care and attention for their well-being. Most patients rely heavily on other people during times of crisis and illness. This is

often evident during medical care visits, where patients are frequently accompanied by one or more people, who are present during interviews and examinations to listen and answer questions for the patient.

The role of family support in affecting the management of diabetes has been obtained in three studies. In one study, it was reported that patients with severe symptoms, whom their family or doctors were concerned about their health, showed higher responsibility and adherence towards their medications (Elis et al., 2008). Another study concluded that effective self-management behaviours would be impossible without support of other family members. High prevalence of unhealthy lifestyles among family members constituted a barrier to effective treatment of patients with type 2 diabetes (Pinhas-Hamiel and Zeitler, 2003). Abdulhadi et al. (2007) in their qualitative study concluded that families were not supportive in terms of cooking and preparing food and they suggested education programmes to address family members. In that study, some patients blamed themselves and their families for not following their doctors' advice. This was because families were not supportive and always makes sweets like dates available in their homes. However, family support is dependent on the family members' interest in providing social support or pressure (Lipson and Meleis, 1983).

2.3.3.3 The doctor-patient relationship

Cultural differences in Middle Eastern countries result in patients and physicians having different relationships from those expected in Westernised cultures. Patients in the Middle East have their cultural issues such as requirements to communicate certain types of news to families, respect, honor and shame. Unlike Westernised cultures where physicians disclose illness diagnosis to patients only to protect their privacy, this practice is not adopted in the Middle East. Physicians in Middle Eastern countries engage patients' families in the communications about illnesses. This is because of the family-oriented model and values that require family members to play a significant role in all aspects of people's lives. This role also allows the family to dictate if a patient should be informed about certain types of illnesses. For that reason, when patients are diagnosed with diabetes, their family members may be aware of the diagnosis before the patient. In some instances, patients are never informed about the diagnosis because physicians are required to establish relationships with certain family members, and their preferences override those of the physicians (Rosner, 2004; Back and Huak, 2005; Mobeireek et al., 2008).

In addition, in Muslim communities, cultural heritage affects the relationship between physicians and patients. Physicians are considered the main source of information for patients seeking advice and they are responsible for patients' wellbeing. Some patients have concerns about taking responsibility for their own health, and not depend too much on doctors (Abdulhadi et al., 2007; Al-Shookri et al., 2011). In a study by Mohamed et al. (2013), it was noted that patients who changed their locus of control from an external one to an internal one, and took control of their own disease had improvements in diabetes knowledge, attitude and practice. This in turn improved their adherence to treatments and follow-ups and consequently, their clinical outcomes and psychological well-being.

The growing diabetes pandemic in the Middle East has led to discussions about adjusting healthcare systems to allow physicians to use a patient-centred approach that could reduce costs, mortality rates and prevalence of the disease. A patient-centred approach is the concept of promoting the partnership between the patient and the healthcare team, where patients are given full information about their disease (e.g. history of the disease, its signs and symptoms, results of investigations, and how the diagnosis has been reached) (Abdulhadi et al., 2007).

2.3.3.4 The lack of a multidisciplinary approach

The lack of a multidisciplinary approach in patients' care has been reported in several studies. Three studies concluded that HCPs, such as dieticians, chiropodists or ophthalmologists did not see patients after their diagnosis (Abdulhadi et al., 2006; Roaeid and kablan, 2007; Al-Kaabi et al., 2008). Another qualitative study reported comments made by patients during interviews; these raised concerns about not being referred to dieticians or health educators since their diagnosis (Abdulhadi et al., 2007). In Kuwait, pharmacists identified barriers to the delivery of pharmaceutical care to patients with type 2 diabetes, such as pharmacist-physician interaction, pharmacist's confidence and pharmacist's image by patients and physicians as a dispenser only (Al-Taweel et al., 2014). A study by Biderman et al. (2009) reported that physicians are the most involved HCPs in diabetes care. However, doctors usually concentrate on the disease rather than the whole person and neglect the importance of patient's perceptions and satisfaction. Patient's dissatisfaction is a major factor contributing to medicine misuse and non-adherence (Vermeire et al., 2003). Competent professionals must cooperate in order to provide patients with the required skills for maintaining untraditional and desired behaviours. The involvement of other team members such as counselors, physical therapists

and psychologists is considered essential for effective behavioural change (Dean, 2008).

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In addition to the above cultural factors that impacted patients' behaviour, it was found that HCPs in the Middle East had specific beliefs, which might impact the disease management as well. Alhyas et al (2013), have found that beliefs and attitudes of some HCPs might constitute an obstacle in the management of diabetes in the Middle East. For example, HCPs who believed that diabetes is a complex disease, needs intensive care and that the complications are hard to control once they have occurred had reduced motivation to get involved in patients' care. Some healthcare professionals perceived the poor compliance of patients to treatment plans and not achieving the target goals as barriers to their motivation and contribution to the management process and to the provision of high quality of diabetes care.

The culture in Middle Eastern society has a direct effect on physicians' beliefs about the necessity of insulin and other anti-diabetic medications. In a study by Elliot et al (2013), it was found that most physicians in the Middle East believe that insulin is a treatment of last resort. Another study also found that some Middle Eastern physicians are hesitant to prescribe insulin and other medications to patients despite their knowledge of the benefits and necessity (Lakkis et al., 2013). In that study, the authors examined the attitudes of physicians towards insulin therapy for type 2 diabetes. Results revealed that more than 73% of physicians preferred delaying insulin initiation until other methods were proven ineffective. However, the majority of physicians admitted that they were reluctant to initiate or suggest insulin as a treatment option because of perceived patient reluctance. Surprisingly, almost 74% of the participated physicians believe that the benefits of insulin outweighed the risk of hypoglycaemia and weight gain and approximately 14% have neutral responses in this area.

In addition, Middle Eastern physicians have preferences for the type of pharmacological therapy that is most effective and poses less threat and complications for patients. Metformin, an oral anti-diabetic medication that addresses insulin resistance in the liver and skeletal muscle and reverses hyperglycaemia by reducing hepatic glucose production, is one of the favoured medications. Several factors contribute to the physicians' preference to prescribing

metformin. One factor is the lack of the full distribution of this medicine in the body and targeting only one area, in such that side effects are reduced. Some studies have found that patients may experience gastrointestinal symptoms such as increased weight loss and diarrhoea, which can be minimised with low doses. Additionally, metformin is inexpensive, making it more affordable for patients and reducing the government's overall health costs. Patients can also safely combine the medication with other anti-diabetic drugs such as insulin, incretin enhancers and incretin mimetics (Al-Maatouq et al., 2010).

Another medication that is preferred by Middle Eastern physicians is acarbose, an alpha glucosidase inhibitor. Physicians prescribe acarbose for diabetic patients who have/or at risk of developing cardiovascular problems. This therapy is preferred because it reduces postprandial blood glucose, cardiovascular events and provides glycaemic control when combined with sulfonylurea and biguanides. Physicians also prefer this drug due to the reversal of impaired glucose tolerance and the low incidence of adverse effects. Like metformin, patients do experience gastrointestinal symptoms such as diarrhoea and flatulence but the occurrence of these effects is rare and can be controlled by minimising the dosage (Shihabi et al., 2013).

Non-pharmacological treatments, such as bariatric surgery that promotes weight loss, has recently become an option for treating type 2 diabetes in the Middle East. However, such treatment is considered as the last option for managing poorly controlled patients (Keidar, 2011). Because the problem of type 2 diabetes relates to high fat levels in the pancreas, and that reducing calorie intake by losing weight would help in reducing fat levels, there is a debate that the surgery may be regarded in the future as a medical emergency (Hobbs and Taylor, 2013). Whether the emergency concept of the surgery will be familiar in the Middle East is still unclear.

2.3.4 Patients' lifestyle

Poor knowledge affects patients' engagement in self-care behaviours, such as diet and exercise. Literate subjects have been found to adopt healthier lifestyle, e.g. increased physical activity (Alarouj et al., 2013). People with higher literacy levels are more aware of the risk factors and more able to avoid and prevent them from affecting their health (Shah et al., 2010). It has been noted that patients who do not fully understand the necessity of exercise and healthy diet to either control or reduce their chances of acquiring diabetes may adhere to one healthy behaviour only; either diet or exercise. A study in the UAE revealed that 48% of participants

exercised to maintain or lose weight, 36% changed their eating habits, while only 26% participated in both activities as a preventive measure for controlling diabetes (Booz Allen Hamilton, 2012). In Saudi Arabia, most of females with diabetes in one study were overweight or obese and they lacked the awareness of the importance of diet and exercise (Abahussain and El-Zubier, 2005).

2.3.4.1 Physical inactivity

Wealth and increased income contribute to high obesity rates in the Middle East. The direct association between being overweight and increased income is that wealth decreases individuals' motivation to engage in weight loss activities (Klautzer, et al., 2014). Despite the general awareness about health complications arising from obesity, patients in the region have difficulties following healthy lifestyle patterns. Several social environmental barriers have been identified, for example, households in the Middle Eastern countries like Saudi Arabia, Qatar and Kuwait have a common practice of employing household maids which further reduces physical activity associated with domestic chores (Bener et al., 2009). This has also been highlighted by Ali et al. (2010) in their qualitative study, where participants found that dependence on housemaids resulted in their weight increasing. Patients with type 2 diabetes in Kuwait reported several cultural barriers that interfere with their engagement in recommended levels of physical activity. The main barriers were lack of time, co-existing diseases, extreme weather conditions, abundance of maids and excessive use of cars (Serour et al., 2007). Another study reported physical inactivity due to another reason. Badran and Laher (2012) have noted that after marriage, couples become less active and consume more food during cultural joint meals.

Cultural barriers also restrict women's access to outdoor activities, and the availability of culturally acceptable exercise facilities is limited and expensive, thereby increasing women sedentary time (Musaiger, 2004). This is supported by the findings of Ali et al. (2010), where some participants raised their concerns about the unavailability of exercise places and the unacceptability of walking in the street alone. Women, in particular, face objections from their husbands if they walk outside alone, but if there is a closed place (e.g. gym), it is usually accepted. In addition, there are some traditional cultural norms that oblige couples to have a high number of children, which means high pregnancy rates of women and short spacing between pregnancies. This in turn further limits women's physical activity and increases their chances of obesity (Musaiger, 2004).

2.3.4.2 Dietary habits

Dietary habits in the region have undergone drastic changes with low dietary fibre and high fat intake leading to obesity and diabetes (Al-Nozha et al., 2004; Klautzer et al. 2014). In addition, in Arab-speaking countries, the social processes of gatherings require consumption of mainly meat, fat, rice and carbohydrates (Badran and Laher, 2012). Hospitality and generosity are high on the list of Islamic values. This value requires individuals to engage in rituals where hosts serve guests large amounts of food as a sign of hospitality and demonstration of honor. During these meals, guests are often encouraged and persuaded to consume more than normal portions of food as an appreciative and friendly gesture. Guests who refuse food that is offered may raise suspicions that they have some form of illness or diabetes, or are exhibiting a poor gratitude (Khoury, 2001). Regarding this, Ali et al. (2010) have reported that some participants found it difficult to control their weights due to having many guests all the time. Other individuals found it difficult to keep eating healthy food when they visit their relatives and friends, because they might get upset if they do not eat everything they put for them on the table. Serour et al. (2007) have reported some barriers to following a healthy diet as perceived by patients. These barriers were unwillingness, stress, traditional food, difficulty to adhere to a diet different from other family members and the high frequency of social gatherings.

In some Middle Eastern countries, especially the GCC countries, people strongly believe in the nutritional and economic value of dates, which they consume frequently with coffee during the day as part of their culture. Consuming large amounts of dates may affect the glycaemic control of patients with diabetes due to their high sugar content (Abdulhadi et al., 2007; Al-Shookri et al., 2011; Alhyas et al., 2013). In addition, the Middle Eastern population lacks knowledge on nutrition and healthy food eating which is crucial for type 2 diabetes management. In relation to this, Ali et al. (2010) in their qualitative study reported that some participants did not know how to cook healthy food, while others needed a programme which helps them to lose and maintain weight. A study by Al-Kaabi et al. (2008) reported that patients with diabetes could not calculate their calorie intake, and only a small proportion of them read food labelling. The majority of patients were also unable to distinguish between low and high carbohydrate index food items.

2.4 Discussion

The results of this review indicate that the problem of non-adherence to treatment is prevalent among patients with type 2 diabetes in the Middle East. This review has investigated the determinants of such patients' behaviour, in order to propose services and recommendations targeted at those determinants, and help in counteracting such behaviour, leading to improved health outcomes in the region. The review revealed that lack of health awareness, health beliefs and culture had a significant influence on patients' adherence to treatment and lifestyle measures. Different methodologies were employed to obtain the results of the reviewed studies; most studies used questionnaires to collect data, while a few studies applied interviews and focus group. All the reviewed studies were conducted with adult patients with diabetes (predominantly type 2 diabetes), one study was conducted with participants at high risk of type 2 diabetes, and two studies conducted with healthcare professionals.

In studies that covered the knowledge of patients and their awareness regarding the seriousness of the disease and its related complications, it was found that lack of health awareness was common among patients with diabetes (Kamel et al., 1999; Al-Saeedi et al., 2002; Roaeid and kablan, 2007; Al Shafaee et al., 2008; Elliott et al., 2013; Shams and Barakat, 2010; AlHewiti, 2014; Sweileh et al., 2014; Ashur et al., 2015). This lack of health awareness was associated with different practices that impacted patients' management behaviour, such as use of herbs instead of conventional treatment (Al-Saeedi et al., 2003; Alhyas et al., 2013). Also, lack of health awareness of the role of diet and exercise led to difficulties in weight management and obesity (Abahussain and El-Zubier, 2005; Al-Kaabi et al., 2008; Ali et al., 2010). Some beliefs which were specific to Middle Eastern population were also identified in this review, such as religious beliefs in God's control and in the 'evil eye', beliefs about fasting in Ramadan, self-beliefs, and beliefs about necessity of treatment and in the healthcare providers. From the studies that discussed these beliefs, it was clear how these beliefs impact patients' behaviour and the management of diabetes (Khattab et al., 1999; Khoury, 2001; Salti et al., 2004; Lawton et al., 2005; Abdulhadi et al., 2007; Biderman et al., 2009; Mishali et al., 2010; Shams and Barakat, 2010; Yekta et al., 2011; Aflakseir, 2012; Al-Khawaldeh et al., 2012; Petrie and Weinman, 2012; AlHewiti 2014; Jimmy et al., 2014; Sweileh et al., 2014; de Villiers and Halabi, 2015). Cultural factors that were found to influence patients' adherence to lifestyle measures, e.g., diet and physical activity which led to high obesity rates in the region and consequently poor health outcomes

were also identified (Musaiger, 2004; Serour et al. 2007; Ali et al., 2010; Al-Shookri et al., 2011; Badran and Laher, 2012; Klautzer et al., 2014).

There was a factor which repeatedly appeared in the literature that might contribute to the poor knowledge in the region, which is the lack of sufficient diabetes education and educators (Klautzer et al., 2014). For instance, Al-Elq (2009) found that in Saudi Arabia, 63-86% of patients with type 2 diabetes were not screened for complications for a year in the given period of time. In Kuwait, diabetic retinopathy has been identified as the main cause of visual impairment (Dean, 2008). Alhyas et al. (2013) concluded that patients with diabetes do not attend appointments with podiatrists because they misunderstand their role. One suggestion made by patients that could benefit those with poor health literacy is to provide continuous education about diabetes complications and anti-diabetic medications by appropriate audio-visual aids especially in patients' waiting areas (Abdulhadi et al., 2007). Al-Nozha et al. (2004) noted that service providers were underperforming in providing adequate levels of information to patients and their families, such that patients felt the lack of support from society. This was consistent with the findings of Abdulhadi et al. (2006), that the performance of doctors and diabetes nurses in Oman was suboptimal and needed improvements. Also, it has been found that patients with type 2 diabetes were dissatisfied with primary healthcare services provided in Oman in terms of providing sufficient information (Abdulhadi et al., 2007).

Therefore, enhancing educational efforts by healthcare professionals to improve health awareness and modify health beliefs of patients, and addressing socio-cultural factors would play a great role in improving patients' behaviour regarding their medicine use and other management responsibilities, and consequently improving the management of type 2 diabetes in the region and health outcomes. In addition, implementing strategies for assessing and improving the quality of healthcare services provided may have an impact on patients' decision-making by enhancing their trust in the quality of healthcare services (Alhyas et al., 2013; Sweileh et al., 2014; Badawi et al., 2015). Also, at the governmental level, reinforcing and strengthening strategies for prevention and early diagnosis of type 2 diabetes should be taken into consideration.

2.5 Practice implications

The increased prevalence of type 2 diabetes and the poor glycaemic control among the Eastern Mediterranean population calls for further research, particularly to identify the determinants of patients' behaviour. For better management of this disease, a collaborative approach between patients, their families, healthcare professionals and government should be adopted. Physicians, educators and other government health officials can provide forms of relief and decrease the recurrence of diabetes. The health awareness of patients, which is a determinant of their behaviour should be improved by increasing education efforts, modifying physician-patient communication to accommodate health beliefs and culture and implementing strategies that allow patients to understand both the benefits and risks associated with the disease and their culture. Because a lack of cultural understanding of health beliefs may affect the quality of diabetes care, it is crucial to provide healthcare professionals with knowledge about culture-specific health beliefs related to diabetes through culturally sensitive training programmes (Saadi et al., 2010; Alhyas et al., 2013).

Alhyas et al (2013) found that the beliefs and attitudes of some HCPs might constitute an obstacle in the management of diabetes in the Middle East. For example, HCPs who believed that diabetes is a complex disease, needs intensive care and that the complications are hard to control once they have occurred had reduced motivation to get involved in patients' care. In addition, poor compliance of patients to treatment plans and not achieving the target goals reduced the motivation of some HCPs and contribution to the management process to provide high quality of diabetes care. Therefore, stressing the need for continuous education and training for HCPs, and applying a system for credit and qualifications would motivate them to feel more responsible in providing better management.

The lack of a multidisciplinary approach in patients' care has been reported in several studies. Four studies concluded that healthcare professionals such as dieticians, chiropodists, ophthalmologists and health educators did not see patients following their initial diagnosis (Abdulhadi et al., 2006; Abdulhadi et al., 2007; Al-Kaabi et al., 2008; Saadi et al., 2010). Biderman et al. (2009) reported that physicians are the most involved healthcare providers in diabetes care in all health sectors. However, doctors usually focus on the disease rather than the whole person and neglect the importance of patient's perceptions and satisfaction. Patient's dissatisfaction is a major factor contributing to medicine misuse and non-

adherence (WHO, 2003). Competent professionals should cooperate in order to provide patients with the required skills for maintaining non-traditional and desired behaviour. Therefore, implementing behavioural strategies, psychological interventions and services that incorporate healthcare professionals other than doctors, such as dieticians, nurses, pharmacists and psychologists in the management process would potentially have a great influence on patients' behaviour and health outcomes. Pharmacists can assist patients in linking their therapeutic regimens to their routine activities (Al Mazroui et al., 2009; Jarab et al., 2012). Individualisation of care, taking into consideration the patient and societal, cultural, and economic variables would also be paramount in helping patients to initiate and maintain behavioural change, particularly in lifestyle aspects (Elis et al., 2008).

2.6 Strengths of this review

The strengths of the review were that it incorporated data related to the wider management of diabetes in the Middle East, and not only focused on the adherence studies. It is the first review that provides a mixture of all factors such as knowledge, health beliefs and cultural issues that might affect patients' behaviour and the management of diabetes in the region. A description of the applied healthcare system in the region and how this system affects the management of the disease is also outlined. Previous studies described either knowledge and health beliefs or the culture and lifestyle behaviours. In addition, findings provided here could be considered adequate to comment on the potential implications for type 2 diabetes care in the Middle Eastern region.

2.7 Limitations of this review

Identification of papers was through electronic databases, and hand searching. All of the reviewed studies were published in English. One limitation of this review was related to the heterogeneity of the reviewed studies. The studies were of different populations (although they were mostly from Eastern Mediterranean countries), from varied levels of healthcare provision, used different methodologies, adherence measurements and follow-up duration, and reported variable outcome measures (e.g., some studies covered both type 1 and type 2 diabetes, while others focused on type 2 diabetes only). In addition, due to the lack of published studies, this review did not include data from all the Middle Eastern countries. Therefore, the outcomes of the review are of a broad nature and their relevance to population groups in other countries, societies and contexts is unclear.

2.8 Conclusion

Managing diabetes is challenging specifically in Middle Eastern countries, where people's religious, social and cultural beliefs are strong and heavily practised by the patients. This review affirms that lack of health awareness, beliefs, attitudes and culture play an important role in patients' decisions regarding medication adherence and lifestyle interventions. This has implication at a governmental and health professional level for treatment outcomes in diabetes. Educational interventions that address patients' beliefs and culture may play a role in improving health awareness, behaviours and outcomes.

2.9 Aim and objectives of the main study

Rationale for this study

Non-adherence to medicines is a common problem among patients with diabetes. Particularly, patients with type 2 diabetes in the Middle East had poor management behaviour. In Kuwait, the rate of non-adherence among adults with type 2 diabetes was 43% (Alhaddad, 2010). Statistics about diabetes are still increasing and diabetes has become a pandemic (a leading cause of morbidity and mortality) in the Arab world, especially the GCC countries. Based on information from preliminary fieldwork, patients with type 2 diabetes in Kuwait are still experiencing difficulties in achieving glycaemic control, and they have poor health outcomes (Amiri Hospital Statistics, 2013).

2.9.1 Research aims

1. This study aims to explore experiences of adults with type 2 diabetes in managing their disease with different therapies (e.g. OHAs, insulin injections, pens and pumps) and to identify ways in which health awareness, beliefs and culture impact patients' behaviour.

2. To examine the extent to which using insulin pens and pumps improves patients' behaviour and quality of life, and enables health targets (e.g. normal HbA1c levels) to be achieved. Also, it aims to identify the most practical targeted interventions that could be employed in the MOH.

This will reveal the requirements and problems that arise in the context of the wider disease management from the perspectives of patients, allow evidence-based recommendations to be made and barriers to implement such recommendations, from the perspectives of HCPs, to be identified. Thus, findings of this study will help to:

- ➲ Inform healthcare provision
- ➲ Identify gaps in patients' knowledge
- ➲ Target educational interventions
- ➲ Inform guidelines modifications regarding insulin pumps
- ➲ Inform prescribing decisions for insulin pens and pumps
- ➲ Identify which group of patients should be offered insulin pumps and when
- ➲ Inform HCPs' concerns regarding the disease management
- ➲ Inform better utilisation of healthcare resources

2.9.2 Research objectives

There were five objectives for this study:

1. To identify, within the context of socio-cultural life, how adults with type 2 diabetes manage their disease in terms of medicine use and lifestyle modifications, and what problems they are experiencing, in order to inform recommendations.

2. To identify ways in which knowledge, beliefs and culture influence patients' medicine-taking behaviour, lifestyle and treatment outcomes, in order to recommend targeted interventions for improving patients' management behaviour.

3. To identify whether the use of insulin delivery technology (pens and pumps) has an impact on medicine use and treatment outcomes by exploring patients' views and experiences, in terms of satisfaction and quality of life compared to their previous therapeutic regimens, in order to inform recommendations for improving patients' care.

4. To investigate how the use of insulin pens and pumps affects the daily social lives of patients and other family members, and to identify problems associated with their use, in order to inform recommendations for improving patients' care.

5. To gain the perspectives of HCPs regarding the key findings of the study, assess the practicality of required recommendations and obtain barriers to optimum diabetes management in the MOH, in order to inform policy implications and propose service development.

Methods employed to achieve these objectives are described in the next chapter.

Chapter 3: Methodology

This chapter describes the methods employed to meet the study aim and objectives, and justifies the selection of specific measures and instruments. It starts with describing the preliminary fieldwork, the methodological design, the sampling and recruitment procedures, the development of the instruments, the translation procedures and piloting of the instruments, the procedures of data protection and ethical considerations, the data processing and analysis and finally, the measures used to ensure the validity and reliability of the data.

3.1 Preliminary fieldwork

3.1.1 Aims of preliminary fieldwork

There were four aims for conducting the preliminary fieldwork:

- To determine the most appropriate sites for data collection, discuss methods of patients' recruitment and realise how patients' medical records could be accessed for obtaining clinical data.
- To demonstrate priorities of local stakeholders to include them in the main study.
- To investigate the procedures and duration required for attaining ethics approval for the study.
- To gain insight into the procedures applied to dispense insulin devices (pens/pumps) to patients with type 2 diabetes and obtain an estimate about number of adults currently using such delivery methods.

3.1.2 Meetings with healthcare authorities and providers

Meetings were arranged with different HCPs (e.g. doctors and pharmacists), working in different authorities (e.g. Ministry of Health, Dasman Diabetes Institute and Kuwait Diabetes Society), in addition to academic staff at Kuwait University to discuss the focus of the main study. The individuals highlighted a number of priorities and concerns, from which the study objectives emerged. The discussions involved the management procedures of patients with type 2 diabetes in the MOH, in terms of available treatment regimens and policies for dispensing medicines/devices to patients. The most crucial areas in the context of management of type 2 diabetes in adults, the most convenient methods for recruiting participants to the study and accessing their medical notes and the ethical considerations were also discussed.

3.1.3 Impact of preliminary fieldwork on the main study

The preliminary fieldwork helped in designing the structure of the main study and planning the most appropriate sites and methods for patients' recruitment **(Figure 3.1)**. Also, it aided in addressing the priorities and concerns of HCPs in Kuwait. However, a decision on the appropriateness of the settings and justifications for the selection is provided for each study site as follows:

- Kuwait Diabetes Society, which was considered as a recruitment site at the beginning, was excluded. It was found that including patients from the Society might introduce bias to the results, because patients who are regularly visiting the Society are more likely to be highly motivated and adhere to their treatment and self-care behaviour, such as SMBG, and they might not experience any problems or barriers as others who do not visit the Society.

- The Ministry of Health, including the main five hospitals in Kuwait was chosen for conducting this study. Approaching these five hospitals granted the coverage of all health districts of Kuwait.

3.2 Methodological design

In order to achieve the study aim and objectives, a cross-sectional study design using mixed methods (qualitative and quantitative) was employed. An explanation of each employed method is provided below.

Methodological design → A cross-sectional study, using qualitative approach and quantitative measures

Setting → Main 5 governmental hospitals, MOH, Kuwait. Ethics approval was received

Sampling and sample recruitment → **Package** (invitation letter + information leaflet + consent form) → Given at clinic visits/other convenient time → **Population** (Adults with type 2 diabetes aged 18 years and older)

↓ Response

Sample 43 patients → Grouping →

8 patients use traditional insulin injections

9 patients use OHAs only

8 patients use insulin pumps

18 patients use insulin pens

Data collection* →

Semi-structured interviews

Questionnaires (MMAS-8 + BMQ-S)

Medical records (HbA1c readings)

Data processing and analysis → Transcribe interviews → Upload interview transcripts in MAXQDA11 → Generation of themes/sub-themes & Constant comparative and interpretive analysis

*Final stage of data collection: -Semi-structured interviews

-Same setting, in addition to Medical Stores and Management Department

-Invitation letter and information leaflet sent by e-mail or given at clinic working hours

-Population: HCPs: physicians, pharmacists, dieticians, nurses and psychologists

-Response: 10 HCPs

-Similar procedure for HCPs' interview transcripts

Figure 3.1: Overview of structure of the main study

3.2.1 Qualitative methods

Qualitative methods involved conducting semi-structured interviews with patients and HCPs. The study objectives (from 1 to 4) required exploration of the real determinants of medicine-taking behaviour and the role of newer insulin delivery methods in improving health behaviour. This was achieved by exploring patients' views and experiences regarding their medicine/device use in the management of their disease, obtaining information regarding their knowledge and beliefs and identification of the problems experienced. Objective 5 required discussion of the issues identified, in order to gain the perspectives of HCPs, include their recommendations and address their needs to propose service development.

Semi-structured interviews allowed to gain the most valuable data by asking patients open questions that allowed them to explain their perceptions and enabled the researcher to explore further the responses. In addition, semi-structured interviews allowed the HCPs to discuss freely the issues, highlight their recommendations, and the barriers envisaged for initiating them. This flexibility would not have been achieved if structured interviews, which lack the flexibility in two-way communication between the interviewer and the interviewee, were employed. Employing unstructured interviews also would not ensure the covering of topics of interest to all participants (Pope and Mays, 2007).

3.2.2 Quantitative instruments

The quantitative procedures involved the completion of two questionnaires and accessing medical records of patients to collect clinical data (e.g. HbA1c).

3.2.2.1 Self-report questionnaires

In order to achieve objectives 1 to 4 (exploring how patients manage their disease in terms of medicine use), a questionnaire that examined patients' adherence to medications was used (Morisky Medication Adherence Scale, MMAS) (Morisky et al., 2008). A part of objective 2, concerning identification of how beliefs affect medicine-taking behaviour necessitated the use of a questionnaire that examines patients' beliefs (Beliefs about Medicines, BMQ) (Horne et al., 1999).

However, questionnaires could not reveal the meanings behind the participants' responses and did not enable to get a complete picture about the barriers to adherence. For instance, although MMAS is considered suitable for measuring adherence, it was not designed to describe a patient's long-term continuity on

therapy, which is an important factor in the long-term management of type 2 diabetes and it may overestimate adherence or underestimate non-adherence. Therefore, the interviews were essential and used in this study.

3.2.2.2 Clinical data (HbA1c)

In order to fulfil objectives 1 to 4 (to identify the impact of medicine use on treatment outcomes), collection of HbA1c levels was considered. This would help to relate these readings to the qualitative data and to that obtained from self-report questionnaires. Also, this would help to assess the clinical effectiveness of using insulin devices, such as pumps in the management of type 2.

Using all those methods to collect data was a form of triangulation. Triangulation involves employing a range of methods to obtain information on different aspects and is recommended (Smith, 2002). In addition, obtaining data to describe the same issue using different methods is a way of data validation, and allowed retrieval of deeper information about the area under investigation. **Table 3.1** summarises the methods employed to achieve each of the study objectives.

Table 3.1: The methods applied to achieve the study objectives

Study objective	Methods used to achieve the objective
(1) To identify how patients manage their type 2 diabetes in terms of medicine use	-Semi-structured interviews with patients -MMAS-8 -HbA1c levels
(2) To identify the impact of knowledge, beliefs and culture on medicine-taking behaviour and treatment outcomes	-Semi-structured interviews with patients -MMAS-8 -BMQ-Specific -HbA1c levels
(3) To identify the role of insulin pens and pumps in improving medicine use and treatment outcomes through exploring patients' views and experiences	-Semi-structured interviews with patients -MMAS-8 -HbA1c levels
(4) To identify problems associated with the use of insulin pens and pumps	-Semi-structured interviews with patients
(5) To gain the perspectives of HCPs on the key findings and obtain their recommendations	-Semi-structured interviews with HCPs

3.3 Sampling and recruitment

3.3.1 Sampling strategy and sample size

All adults with type 2 diabetes were using medical treatment for the management of their disease, and treated at the main five hospitals in Kuwait (Mobarak Al-Kabeer, Amiri, Adan, Farwaniya and Jahra) were considered eligible for this study. Since the

secondary-care units are the major centres in Kuwait providing adults with type 2 diabetes with different treatment regimens, such as OHAs, traditional insulin injections, insulin pens and pumps, approaching the main five hospitals allowed to recruit patients using different therapies and to achieve all the study objectives. Moreover, in secondary-care units, all the healthcare team required for the management of type 2 diabetes can be approached. Therefore, to meet objectives 1 and 2, all adults receiving any medical treatment for the management of type 2 diabetes were eligible. To meet objectives 3 and 4, adults using insulin pens and pumps, and for different durations were eligible. Accordingly, all patients who met the eligibility criteria and visited the diabetes outpatient clinics during the data collection period were invited to participate. To achieve objective 5, HCPs who were involved in the management of adults with type 2 diabetes, and worked in the MOH were invited to take part. In addition to the main five hospitals, the Management Department and Medical Stores of the MOH were also included as sites for the recruitment of HCPs.

All the five hospitals have diabetes outpatient clinics. Number of diabetologists in each hospital ranged from 1-11. Number of other HCPs, such as nurses (mean=5), dieticians (mean=5), pharmacists (mean=34), and psychologists (mean=1) who were involved in the management of type 2 diabetes varied between hospitals. Number of eligible patients registered with a diagnosis of type 2 diabetes, and prescribed medicines and/or devices, differs between the hospitals (mean=2,200).

Approaching the main five hospitals in Kuwait ensured the generalizability of the results to all patients with type 2 diabetes receiving care in the MOH. In addition, covering all the health districts allowed patients from different socio-cultural backgrounds and geographical areas (e.g. rural and urban) to be recruited, which ensured the coverage of different perspectives and experiences. All patients regardless of their origins (e.g. White and Black) were invited to participate.

Regarding the sample size, the researcher continued interviewing patients and HCPs until no new experiences and perspectives were raised. This is called data saturation level, which was reached within 43 interviews with patients and 10 with HCPs. This sample size would allow analysis of the clinical data.

The study aimed to recruit adults aged 18 years or older, who were diagnosed with type 2 diabetes, used different treatment regimens for different durations and

attended the outpatient clinics at secondary-care units, MOH. Also, the study aimed to recruit HCPs who work in the MOH and were involved in the management of adults with type 2 diabetes. The listed inclusion and exclusion criteria, which were used in this study, reflected this:

Inclusion criteria

The inclusion criteria for patients were:

- A diagnosis of type 2 diabetes
- Age of 18 years or older
- Attending diabetes outpatient clinics at secondary-care units
- Receiving medical treatment (e.g. OHAs and/or insulin injection/pen/pump)
- Signing the consent form

The inclusion criteria for HCPs were:

- Working in the MOH
- Managing adults with type 2 diabetes
- Agreeing to participate

Exclusion criteria

- Patients were excluded in the following cases: a diagnosis of type 1 diabetes or gestational diabetes, as they have different requirements and self-management behaviour that might bias the results. In addition, patients with type 2 diabetes who attended primary care units were excluded. Since primary care units lack the availability of all treatment regimens, such as insulin pens and pumps, they were not considered as recruitment sites.

- HCPs who were excluded were those who did not respond.

3.3.2 Sampling procedures

All patients, except insulin pumps users were identified and approached during their clinical visits to the outpatient clinics of the five hospitals. For patients using insulin pumps, the researcher obtained their names from their consultants and prepared a list of their names, numbers and ages. Diabetes outpatient clinics run at different days of the week in each hospital, a time schedule for each clinic was prepared by the researcher. Accordingly, patients' recruitment was conducted on a daily basis based on working hours of each clinic throughout weekdays.

3.3.3 Sample recruitment

Before commencing data collection, the researcher met with the Heads of the diabetes units in each hospital. The consultants were provided with a leaflet prepared previously, which explained briefly the nature of the study, the aim and objectives and the researcher contact details for any further information **(Appendix 2)**. It was important to undertake this step, in order to ensure the cooperation of the HCPs.

<u>Recruitment of patients</u>

Initially, the researcher prepared a timetable for the clinics' working hours throughout weekdays. The researcher then, visited the diabetes clinics in the hospitals in the mornings between 7 am and 2 pm, as this was the time for diabetes clinic appointments. The sample was chosen at different days of the week, which minimised selection bias and ensured that the study sample was representative and diverse (Bowling, 2009). Patients were approached as they attended their appointments with the consultants. During the pilot period, the researcher was present in the clinic, and after each eligible patient finished his/her consultation, the consultant allowed the researcher to introduce herself to the patient, briefly explain the study, obtain their approval to participate, and agree on when and where to be interviewed. Following such a procedure required the researcher to be present the whole day in the clinic, meeting all patients who were within/outside the eligibility criteria, and obtaining their approvals to participate. This was considered overly time-consuming and inefficient. Thus, a different procedure was adopted, where by the researcher presented in the clinic early in the morning before patients' appointment commenced, and checked the patients' list with the cooperation of the clinic nurse, identifying patients who met the eligibility criteria from their medical notes. Then, the patients were approached as they were waiting in the waiting area.

Upon approaching the patients, the researcher introduced herself as a PhD student and provided them with previously prepared invitation letters **(Appendix 3)** and information leaflets **(Appendix 4)**. The forms were designed to explain the study purpose, the benefit of participating, what the study would involve and how data would be collected, confidentiality procedures and the researcher contact details. All patients responded directly, and those who were unwilling to participate were thanked by the researcher. With those who agreed to participate, the researcher agreed on a time and place for conducting the interview and completing the questionnaires.

Based on information from consultants, patients using insulin pumps were few, and not all of them were regularly visiting their doctors. Therefore, due to the limitation of the data collection period, and to ensure reaching a convenient sample from this group of patients, it was necessary to apply a different recruitment procedure. Accordingly, the researcher obtained contact details of those patients from their doctors/nurses, and contacted them. HCPs were not included in the recruitment process to avoid bias resulting from selection of certain patients, and to give the patients the choice to decide whether to participate and not to be embarrassed or persuaded by their doctors. Also, this reassured patients about the independence of the research and the researcher from the healthcare system, so that they could disclose any negative experiences they have regarding HCPs freely. Thus, upon calling the patients, the researcher introduced herself, explained briefly the aim of the study and what was required from them, and agreed on a time and place for conducting the interview and completing the questionnaires. Recruitment of patients commenced in March 2014 and continued until September 2014.

Recruitment of HCPs

The researcher aimed to meet different HCPs who were involved in the management of adults with type 2 diabetes and worked in different departments of the MOH. Accordingly, a list of the specialities/departments of those HCPs was initially prepared by the researcher based on her experience as a pharmacist in the MOH. Once final stage of data collection commenced, the researcher approached the HCPs by their specialities and departments. One more speciality (psychologist), which was not included in the list, was then added as recommended by a physician. Psychology was not included initially because this speciality has been recently involved in diabetes clinic team. **Table 3.2** shows the final list of the HCPs who were approached and agreed to take part.

Table 3.2: The specialities of the HCPs and their department/working area

HCP	Speciality	Organisation/Area
1	Dietician	Hospital/urban
2	Dietician	Hospital/rural
3	Nurse	Hospital/urban
4	Nurse	Hospital/rural
5	Physician	Hospital/urban
6	Physician	Hospital/rural
7	Psychologist	Hospital/urban
8	Pharmacist	Hospital/urban
9	Pharmacist	Medical Stores/mixed
10	Pharmacist	Management Department /mixed

Seven HCPs were contacted by telephone before conducting the interview with them, and four were approached during working hours in their clinics. The researcher introduced herself as a PhD student, who would like to conduct a final stage of data collection that involved interviewing with HCPs for 10-20 minutes. It was clarified to the HCPs that they were free to choose the type of the interview, e.g. face-to-face or telephone, and the time, according to their convenience. Also, it was explained that the information would be treated confidentially and would be anonymous.

Before commencing this stage of data collection, the researcher prepared an invitation letter **(Appendix 5)**, information leaflet **(Appendix 6)**, and interview topic guide for HCPs. The invitation letter included information about the aim of the interview, what was needed from the HCP, the duration of the interview, and the contact details of the researcher and the academic supervisors. The information leaflet explained briefly the key findings of the study and the main identified issues. It was divided into three parts: part one related to all patients who participated in the study, part two discussed issues particular to patients using syringes/vials and pens for insulin delivery, and part three discussed findings raised from patients using insulin pumps. All those documents were sent by e-mail to the HCPs before interviewing them, except two, who were approached in their clinics, and agreed to be interviewed directly. Recruitment of HCPs commenced in June 2015 and continued until July 2015.

3.4 Data collection methods

Qualitative, semi-structured interviews were undertaken to explore knowledge, beliefs, views and experiences of adults about their disease, medicine and device use to mange type 2 diabetes. In addition, semi-structured interviews were used in this study to investigate the views and experiences of HCPs about the identified issues and address their recommendations to propose service development.

Quantitative measurements were undertaken for the participants' responses to the questionnaires (MMAS-8 and BMQ-S). HbA1c values were collected from medical records of patients; the latest three readings reported in each patient's note were recorded.

3.4.1 Interviews

3.4.1.1 Development of the research instruments (interview schedules)

To achieve the study objectives 1 to 4 **(Section 2.6)**, an interview topic guide for patients was developed. The preliminary fieldwork and the literature review assisted in structuring the schedule and designing some of the questions. The review of the studies helped in highlighting issues that were relevant to the study objectives and the preliminary investigations helped in addressing issues of interest and that were relevant to the area of the study. The topic guide was revised many times by the research team, comments regarding the contents and the structure of the guide were incorporated and the final version of the schedule was agreed by all.

The schedule included closed questions for obtaining demographic data (e.g. what is your residence area? how old are you?). The main part of the schedule comprised open questions, which allowed access to issues that were important to the participants rather than those that the researcher would have expected. This type of question was used for obtaining patients' views and experiences regarding their use of medicines/devices during their daily life (e.g. for your diabetes, what medicines/device are you using currently? how do you use them? tell me in what ways have you found your medicines/device helpful?). In addition, the open questions allowed the researcher to investigate the health behaviour of participants, and the factors that impacted on it, e.g. beliefs, culture, etc. For example, by asking question 9 (Do you remember a time when you have not used your medicines as prescribed, please tell me what you did? why did this happen?), this allowed participants to recall events when they misused their medicines and why they did so. For further obtaining and exploring factors affecting management behaviour this question was followed by asking participants about their medicine use during special occasions, e.g. Ramadan. To minimise bias, the researcher avoided leading questions, which may restrict the discussion of unacceptable attitudes. For example, in question 9, in order to make participants not feel that there is an expected or acceptable answer, the researcher started the question (in order to make life easier, patients sometimes use their medicine in their own ways).

In order to encourage participants to say more and provide rich information, probing techniques were adopted. Prompts and probes were written in italics in the interview schedule to help the researcher obtaining information on particular issues in the areas of interest. For example, under question 14 (can you tell me how do your

family and friends support you in managing your diabetes?), the following probes were used (*collecting medicines from pharmacy, accompanying in appointments, calculating doses, administering doses, checking site of injection, monitoring blood glucose level, eating special food, exercising*).

The interview schedule of patients who were not using an insulin device included questions on: knowledge about diabetes, lifestyle issues (e.g. diet and exercise), current therapy and duration of using it, views and experiences about use of medicines during daily life and in special occasions, SMBG, social support and HCPs and system-related issues. Answers to the questions allowed the researcher to achieve objectives 1 and 2 of the study through investigating the determinants of patients' decision-making, such as health awareness, beliefs and cultural factors in terms of medicine-taking behaviour and other management responsibilities, such as diet, exercise and SMBG. The interview schedule of patients who were using an insulin device included similar questions to those of others in addition to questions on: the ease/difficult of using the device, its acceptance, impact of using the device on daily activities and families, efficacy of using the device in improving glycaemic control and quality of life, training provided for using the device and satisfaction with the device use. Answers to questions related to the use of insulin pens and pumps allowed the researcher to achieve objectives 3 and 4 of the study through interpreting whether the use of such devices introduced benefits to patients in terms of adherence, satisfaction and quality of life (e.g. achieving glycaemic control and avoiding serious complications), or they introduced new problems.

After conducting the first 7 interviews (3 with patients using OHAs only, 2 with patients using OHAs and/or traditional insulin injections and 2 with patients using insulin device), some minor amendments were introduced to the interview schedules **(Section 3.4.1.3)**. A sample of the amended schedule is shown in **Appendix 7**.

Overall, the interview schedules of patients were designed to obtain information about the most important issues to this group of population and to prepare an interview schedule for the final stage of data collection. This involved addressing the key findings to discuss them with different HCPs, in order to propose recommendations and inform policy about the most practical interventions and services (objective 5) that should be applied to improve the management of the disease and the health outcomes. Below is a description for the development of the

interview schedule of the HCPs. A sample of the HCPs' schedule is shown in **Appendix 8**.

As mentioned above, outlining the key findings from the interviews with patients helped in structuring the interview schedule of the HCPs and designing the questions. The interview schedule was developed by the researcher, revised by the academic supervisors and comments regarding the contents and structure were discussed and introduced. In the covering page of the schedule, there was a list of the HCPs' specialities, their working area and the type of the interview. The topic guide included two parts: the first part included 10 statements representing the key findings (the issues identified to impact health behaviour of patients with type 2 diabetes). These included personal factors (e.g. beliefs about the disease and medicines), healthcare provider-related factors (e.g. neglecting patients' social needs) and healthcare system-related factors (e.g. unavailability of certain medicines/items and prescribing issues). In this part, HCPs were asked to rate their responses to each statement on a four-point Likert scale for the agreement (1=Agree, 2=Agree to a certain extent, 3=Disagree, and 4=Uncertain), and for the importance of taking the statement into consideration (1=Most important, 2=Very important, 3=Important, and 4=Least important). Answers to questions of this part helped to evaluate the extent to which the issues raised by patients were correct, and to address the most important issues highlighted and need to be taken into consideration.

The second part of the topic guide included 10 suggestions made by the researcher to meet the patients' identified needs and develop the services provided. This contained the implementation of services, such as educational campaigns, training courses for HCPs, diabetes clinics managed by different HCPs other than doctors and a 24-hours help-line service led by diabetes specialists/educators. In this part, the HCPs were asked to rate their responses for each of these suggestions on a four-point Likert scale, for the importance (1=Most, 2=More, 3=Less, and 4=Least), and for the feasibility (1=Yes, now, 2=Yes, within a year, 3=Yes, within 5-10 years, and 4=No). Answers to this part helped to evaluate the most important and practical service developments that could be considered by policymakers and initiated in the MOH. Then, this was followed with open questions, such as "Do you have any further recommendation that you found helpful to improve patients' awareness, beliefs, medicine-taking behaviour and health outcomes".

Interviews with the HCPs were not limited to answering the questions solely by ticking the appropriate box. Also, the HCPs were allowed to explain their responses, report the barriers and challenges for the management of patients and provide their recommendations in terms of service development. Overall, answers to the questions of the interview schedule of the HCPs enabled the researcher to appraise the existence of the issues identified, address the barriers experienced in terms of disease management and recognise the most feasible interventions that can be applied from the perspectives of the HCPs. After conducting the first 2 interviews (1 with a dietician and one with a nurse), some minor amendments were introduced to the interview schedule **(Section 3.4.1.3)**.

3.4.1.2 Conduct of interviews

<u>Interviews with patients</u>
Patients who agreed to participate in the study were free to choose when and where to be interviewed, allowing them to interact in an appropriate and relaxed manner. In order to ensure patients' privacy and convenience, the researcher suggested the following options: a private room at KDS, a coffee shop, or any other setting that the patient prefer. Most participants preferred to conduct the interview before or after their appointment with the doctor, or while they were waiting for their prescriptions to be dispensed, other patients preferred to be interviewed in their spare times. Regarding the place of the interview, some participants preferred for it to take place outside the clinic, e.g. coffee shops, which they identified. One participant, preferred to conduct the interview at his home, while most preferred to be interviewed in the clinic. When the interview was conducted in the clinic, the researcher was careful to obtain the appropriate place for its conduct, such as the waiting area or a room, which was unoccupied during the clinic working hours.

Before commencing the interview, the researcher explained briefly the nature of the study, gave the participants the chance to ask any question, assured them that their participation was voluntary and that they could withdraw at any time without giving any explanation. Some patients may not disclose certain issues, such as low adherence, if they feel that their doctors might know about it. Therefore, to minimise social desirability bias and ensure that participants would discuss their feelings truly and comfortably, the researcher ensured that participants were relaxed by reminding them about the confidentiality of procedures and the independence of the researcher. In order to obtain rich information, the researcher also clarified to

participants that the aim of the study was to investigate their views and experiences regarding their disease, medicines/devices, and that the main focus of the research was to find out about the problems they experience with HCPs and system and that there were no right or wrong answers. Participants were reassured that their participation would not affect the care services they received because their responses would be anonymous and would not be communicated to HCPs. Then, participants were asked to sign a written consent **(Appendix 9)** for being interviewed and for audio-recording, all the participants agreed to be audio-recorded. The average duration of the interview was anticipated to be 30-45 minutes based on the participants' views and experiences.

Audio-recording was employed to facilitate data analysis. Manual transcription of data during the interview was avoided, as this might jeopardies the comprehensiveness of data and inhibit the interviewer from developing issues raised by the participants. The researcher followed the interview schedule as a guide throughout the interview. To save time during the interview, the researcher highlighted the heading points of the schedule previously and used the probes when necessary to obtain responses from the participants. It should be noted that participants were allowed to talk freely and without following the particular sequence of the questions, by which, topics could be explored according to issues raised by participants. In order to capture all the information that might assist in the analysis, the researcher took into consideration the facial expressions and body language of the participants and took hand-written notes, which were added as memos in the transcripts.

At the end of the interviews, it was very important to conclude the discussion clearly, because some participants may provide rich information towards the end. Thus, the researcher ended with the following question "finally, would you like to add anything about your disease, medicines/device, HCPs or system that we have not discussed". Then, the researcher thanked the participant and asked him/her for permission to obtain data from his/her medical notes. After finishing the interview, the recorder was switched off and the participant was thanked again for participating. However, some participants provided information such as suggestions, comments or statements after switching off the recorder. The researcher was very careful to take hand-written notes of such information as soon as the participant had left and then added them into the transcripts, to incorporate them into the data analysis. Generally, participants were happy to co-operate, being interviewed and

tape recorded. All interviews were conducted, audio-recorded and transcribed precisely in Arabic by the principal researcher only.

Interviews with HCPs

The researcher asked the HCPs to identify the type (face-to-face or telephone) and time of the interview they preferred. Seven HCPs were interviewed face-to-face and three were interviewed via telephone. The researcher followed the interview schedule as a guide throughout the interview. Before commencing the face-to-face interviews, the researcher asked the HCPs whether they would like to read the questions themselves or that the researcher read them loudly. Some HCPs (n=3) preferred that they go through the questions and mark their answers themselves, while others (n=4) preferred that the researcher read the questions loudly and mark their answers. The HCPs were asked during the interviews to provide their views and experiences regarding the issues raised from this study and to highlight recommendations on how to develop healthcare services based on the study findings.

To facilitate the analysis of data, the researcher employed audio-recording for all the conducted interviews. The permission of all HCPs to record the interview was sought at that point. All the interviews were recorded except one, where the HCP declined to be audio-recorded. In that interview, manual transcription of data obtained during the interview was undertaken. At the end of the interviews, the researcher thanked the HCPs for the participation and for their time. Some HCPs provided information after switching off the audio-recording, the researcher took hand-written notes of some reports soon after finishing the interview. All interviews were conducted and transcribed by the principal researcher only.

3.4.1.3 Piloting and amendments of the interviews schedules

Interview schedule of patients

In order to ensure the practicability, comprehensibility and consistency of the interview schedule and the appropriateness of the language from a cultural perspective, a pilot period was considered. Therefore, after conducting the first 7 interviews with participants, the instrument and procedures were revised with the research team. The aim of this piloting was to ensure that the design of the interview schedule was acceptable in terms of format, content and terminology and that it was optimal in obtaining adequate information to meet the study aim and objectives.

Also, the pilot was conducted to address new issues that emerged before completing the rest of the interviews. Therefore, after piloting, a discussion was conducted with the research team and overall, the interview schedule was considered appropriate for obtaining relevant information. However, some minor amendments were considered and applied, in regard to the order of the questions. Thus, those participants included in the piloting period were not excluded from the study sample and the interviews were incorporated into the data analysis.

Based on the initial seven interviews, questions were removed or re-organised. For instance, it was noticed that the patients were spending a lot of time in responding to question 1, which was about recalling the first time they had been diagnosed with type 2 diabetes: (Tell me about when you were first diagnosed with diabetes, how did you feel and what did you do?). The question included some probes for obtaining participants' awareness about the seriousness of the disease such as (*How long ago? What actions you took to manage it?*). Also, it was noticed that there were overlaps, as answers to that question also re-emerged in responses to other questions; therefore, that question was removed. Another question (question 12), which was about participants' beliefs concerning different brands of medicines was re-organised as a probe under question 4, which examined different beliefs about medicines. In addition, the interview schedule was expanded over the course of data collection. The researcher added more probes, as issues emerged. For example, under question 4, which examined beliefs about medicines, the following probe was added for insulin-dependent participants (*How would you describe your life using insulin compared to using tablets only*). Under question 14, which was about social support, the following probes were added: (*Accompanying in appointments, collecting prescriptions*).

Interview schedule of HCPs

After the researcher had tested the interview topic guide with a competent person (B.A; an assistant professor), minor amendments were introduced. The interview was formed to take longer than the indicated time (25-30 minutes). Accordingly, amendments were introduced to make the questions more condensed and the framework more structured. Further minor amendments were introduced after conducting the first two interviews with the HCPs. The design of the guide was re-organised, in order to prevent any confusion when answering some questions. Overall, the interview topic guide was considered convenient for obtaining relevant

information that meet objective 5 **(Section 2.6)** of this study. Therefore, those two interviews were included and incorporated into data analysis.

3.4.2 MMAS and BMQ

The second employed method for collecting data in this project involved the completion of two questionnaires (MMAS and BMQ). MMAS is a valid and reliable tool that showed adequate psychometric properties (Morisky et al., 2002). It is simple, practical and has a sensitivity of 93% in identifying low versus high adherence and a specificity of 53% (Morisky et al., 2008). Researchers in the Middle East have used MMAS, as a translated international scale, among patients with diabetes and reported its benefits in improving clinical pharmacy research (Jamous et al., 2011; AlHewiti, 2014; Bener et al., 2014; Sweileh et al., 2014; Ashur et al., 2015). Using MMAS in this study helped in classifying the adherence of the participants and examining the extent of non-adherence among this group of population. This would be difficult to achieve if other scales, such as (Medication Adherence Rating Scale, MARS), which is more specific for patients with psychiatric disorders, or the Hill-Bone Scale, which is more specific for patients with hypertension were used (Lavsa et al., 2011). A sample of MMAS is provided in **Appendix 10**. BMQ is a valid and reliable scale that can be used among patients with diabetes (Horne et al., 1999). Its validity and reliability have been shown among patients with diabetes in many countries in the Middle East (Kartal and Ozsoy, 2007; AlHewiti, 2014; Sweileh et al., 2014). Using BMQ in this study enabled to gain an overall picture about the participants' beliefs about medicines and to compare the participants' beliefs with their behaviour. A copy of the scale is attached in **Appendix 11**.

After conducting the interviews, the researcher asked the participants to complete the questionnaires (MMAS and BMQ). With regard to the administration of the questionnaires, the researcher adhered to the authors' guidelines, which were e-mailed previously. Therefore, at this point, the researcher explained to participants that there were no right or wrong answers, that they should complete the questions honestly and that the questionnaires were completely confidential. Participants were also informed that the questions were related to diabetes medicines only, as it was the focus of the study. In addition, the researcher explained the aim of each of the questionnaires. For example, for MMAS, the researcher identified that completing this questionnaire would assist in recognising the medicine-taking behaviour of participants, which might assist in targeting appropriate interventions. For BMQ, the

researcher clarified to participants that it would help to find out more about what they think regarding their medicines.

Because the study sample included older people, some of whom could not write and read, and to avoid missing data if participants completed the questionnaires themselves, the researcher gave all participants the option whether to complete the questionnaires themselves, or that the researcher read the questions loudly for them and they give their own answers. However, all participants preferred that the researcher read the questions for them, and they gave their answers orally, except for three participants, who preferred to read and complete the questionnaires themselves. Therefore, the completion of the questionnaires was performed in a face-to-face manner. The researcher administered the questionnaires by reading the questions and the answer choices loudly from the sheet, the participants provided their own answers verbally and the researcher marked the answers. This manner should ensure the validity of the data collected from patients when completing questionnaires (Bowling, 2005).

Although there was no requirement for piloting the questionnaires, as they are validated among Arabic patients with type 2 diabetes, and could not be modified, the researcher administered both of the questionnaires during the pilot period.

3.4.3 Review of patients' records

Reviewing medical records of patients was one of the employed methods in this study to record the participants' HbA1c levels. This measure is the most commonly used to predict blood glucose control over the previous 2-3 months, in patients with diabetes and is an indicator of the disease severity level (Nathan et al., 2007; Herman and Cohen 2012). The aim of obtaining such data was to assess the participants' adherence to medicines and to relate it to qualitative data as a method of triangulation and to put clinical change into the context of participants' experiences. The effective use of medicines is associated with low HbA1c levels (Hill-Briggs, 2005; Cohen et al., 2010). Thus, if a patient has a good adherence, it is more likely that his/her HbA1c level is within normal ranges (53 mmol/mol; 7.0%) (NICE Guideline 28, 2015). Whereas high HbA1c level can be a predictor of medication non-adherence. This also allowed the researcher to examine the disease progression for patients using different treatment options and assisted in identifying the most clinically effective method in managing this population, and recommending suggestions for improving health outcomes.

Accordingly, for all patients who consented to participate in this study, medical records were reviewed and HbA1c levels were obtained. The practice in Kuwait is to measure HbA1c levels for patients with type 2 diabetes every 2-3 months. In this study, the researcher obtained the latest three HbA1c readings recorded in each participant's note. Other clinical information, such as blood glucose level, BMI and smoking status were also collected and recorded along with HbA1c levels in an information sheet prepared by the researcher **(Appendix 12)**. These data were used to compare clinical characteristics of participants with information obtained from interviews regarding the participants' health behaviours, to aid in data analysis. The collection of clinical data was undertaken solely by the researcher. After conducting the interviews, the researcher visited the clinic and obtained participants' medical notes, with the cooperation of the clinic nurse.

3.4.4 Translation of data collection instruments

Since the interview schedules were developed in English to facilitate the discussions with the research team, but would be administered among Arabic-speaking populations, as Arabic is the native language in Kuwait, translation was necessary. However, this did not affect the fluency of the research or the quality of the collected information because Arabic is also the native language of the principal researcher, who was able to collect data herself without the need of a translator. Accordingly, before commencing data collection, the interview schedules were translated into Arabic to ensure the fluency and the interpretation of the interviews by the participants.

Different translation methods may be adopted, but the challenge is to produce a comprehensible translated tool that is as close to the original instrument as possible (Esposito, 2001). In this study, parallel blind technique was applied. This method involves the translating of the instrument to the target language by two translators independently, comparing with each other, looking for any discrepancies and then agreeing on one version (Hambleton and Patsula, 1998). Because the method requires translators to work in parallel, it is practical, fast and has the advantage of acquiring an accurate translation. Therefore, the interview schedules were translated from English to Arabic by the main researcher, who is from Kuwait. The assistance of an academic bilingual professional, who is a Kuwaiti Professor (A.A) in the Public Authority for Applied Education and Training, and competent in the Kuwaiti language and culture as a native speaker, was sought. Then, the two translators met to agree on the translated version. Some discrepancies were noted

and resolved through discussions. This practicality would not have been achieved if other methods of translation, such as back-translation, which is time-consuming and has several limitations, were adopted (Behling and Law, 2000).

For the other used instruments (MMAS and BMQ), the author (Professor Morisky) provided the researcher with an Arabic version for a charge of $210 for MMAS. For BMQ, the researcher used a previously translated version, which was employed within the same culture and was permitted by the author (Professor Rob Horne).

3.5 Data protection and ethics approval

Ethical issues were considered in this study, and the data collected were handled confidentially, coded, anonymised and only the researcher had access during the study period. Hand-notes of the interviews and questionnaires were kept in a folder by the researcher. Data were typed using the researcher computer, which was password protected, and saved on a secure memory stick. The data collected were only shown to the academic supervisors, to facilitate the analysis process and discussions of the study findings. All the collected data have been kept locked at all times in a designated cabinet for this purpose for the whole study period, and will be destroyed once the project is accomplished.

3.5.1 Application for ethics approval

An application was completed and handed to the UCL Research Ethics Committee on 20th December 2013. An ethics approval letter was e-mailed to the researcher on 9th January 2014 **(Appendix 13)**. In addition, the study protocol and all required documents, e.g. the interview topic guide, questionnaires, invitation letter and the consent form were prepared and an application form was completed by the researcher, and handed to the Standing Committee for Coordination of Health and Medical Research, MOH, State of Kuwait on the 29th December 2013. An approval letter for commencing the study was received on the 3rd February 2014 **(Appendix 14)**.

3.5.2 Permission to use the questionnaires

Complying copyright restrictions, permission for using the questionnaires was sought. The researcher sent e-mails to the questionnaires' authors, an agreement form was signed and use of the BMQ was granted free of charge from Professor Rob Horne, Centre of Behavioural Medicine, School of Pharmacy. Permission to the use of MMAS was granted by Professor Donald Morisky, Department of Community

Health Sciences, UCLA Fielding School of Public Health, and an agreement form was signed by the researcher and the author **(Appendix 15)**.

3.6 Data processing and analysis

Prior to commencing the analytical procedures, all the interviews (53 transcripts; 43 for patients, and 10 for HCPs), which were recorded using Olympus Digital Voice Recorder WS-831, were downloaded onto the researcher's computer using the USB memory stick of the recorder and organised in files according to the date of the interview. Due to the need for confidentiality and data protection, the data were anonymised and the files were saved with numbers, indicating the order in which the interviews were conducted, followed by a description of the treatment regimen or the speciality of the HCP. For example, a description of OHAs was related to patients using OHAs only, while patients using insulin, whether alone or with OHAs were described by their insulin delivery method. This allowed the researcher to analyse interviews of patients using insulin devices separately from those who did not use devices and enabled comparisons to be made. Then, the researcher transcribed all the recorded data verbatim in Arabic. Field notes taken including facial expressions, emotions, interruptions, additions outside the interview period and the presence of other individuals and their contribution, were all inserted into the interview transcripts. This was to ensure the inclusion of all the relevant information that might aid in data analysis. In order to ensure the accuracy of data and that all the information were included, the researcher re-listened to the audio-recorded tapes. Then, the transcripts were typed using Microsoft Word.

As recommended by Liamputtong (2009), Computer Assisted Qualitative Data Analysis Software (CAQDAS) is helpful to make data processing and analysis faster. It is particularly helpful for large volumes of data and beneficial for constructing, categorising and storing data in a way that allows it to be managed and accessed easily and rapidly (Burnard et al., 2008; Gale et al., 2013). In this study, the MAXQDA-11 software was chosen because it allowed the researcher to collect, organise and analyse content from interviews in Arabic, in a flexible manner, and is available for students at a reduced price. This software creates easy to read reports and visualisations by: coding segments of text, forming categories and storing data in an organised form, which was easy for searching and retrieval. It also counts the frequencies of words/phrases to enable the researcher to draw up conclusions and search for associations between and within the interviews. In addition, using such software enables the researcher to add memos to the coding

system for clarification. All of the transcripts were imported into MAXQDA-11 and organised in a way that each data unit indicated a case/interview. Interviews were presented in the 'document system' arranged by number, from patient 1 to patient 43 and the treatment regimen, e.g. patient 1 (insulin pen), and from HCP 1 to HCP 10 and the speciality of the HCP, e.g. HCP 1 (physician).

In order to answer the research questions: In what ways did health beliefs impact participants' health behaviour? What were the advantages/problems of using technology in the management of type 2 diabetes? Did insulin pens/pumps have a role in improving participants' management behaviours? What are the barriers to service development and improvement of health outcomes from the perspectives of HCPs? It was essential to adopt a systematic approach. There are different types of data analysis approaches that could be employed, basically, deductive and inductive approaches. Deductive approach depends on using a structure of a pre-determined framework to analyse data, while the inductive approach depends on little or no pre-determined framework, and relies upon the actual data to derive the structure of analysis (Burnard et al., 2008). Although it is labour-intensive and time-consuming, the inductive approach is commonly used in qualitative data analysis and was used in this study.

One of the inductive approaches is the Framework Method or 'thematic framework', which is a matrix-based method that provides an instinctively systematic analysis of summarised data, arising out of grounded theory, and is the most common method of qualitative data analysis (Smith and Firth, 2011; Gale et al., 2013). The Framework Method has become a popular approach in qualitative pharmacy practice research (Harding and Taylor, 2016). The matrix output of this approach provided a structure, which helped the researcher to reduce data and analyse it by codes/themes. Also, it allowed comparison between data across cases as well as within individual ones (Gale et al., 2013). Therefore, the researcher commenced the thematic analytical procedures in three main stages: data management, data description, and data interpretation and explanation **(Figure 3.2)**.

Analysis of <u>research questions</u>:

-What were the common health beliefs among this population?
-How these beliefs affected patients' management behaviours?
-What were the advantages/problems of insulin pens and
 pumps?
-Did insulin pen/pumps improve patients' health behaviour?
-What are the perspectives of HCPs on identified issues?
-What are the barriers to service development and
 improvement of health outcomes?

Explanatory accounts

Descriptive accounts

Data management

Organisation of data

Raw data

Figure 3.2: The steps undertaken for the analysis of the interview data

3.6.1 Data management

Due to the extensive amount of data collected, it was essential to undertake some organisational steps, in order to reduce the data and make it more manageable before describing and explaining it. This stage served as a systematic sifting of data. Therefore, a sample of 8 interviews (interviews with patients using insulin pumps) was selected (by activating the interview files in the 'document system'), to ensure selecting a representative sample and carrying out the required analytical procedures that cover all the study objectives. Then, those transcripts were repeatedly read (from the 'document browser') to define recurring themes, and the interview texts were primary coded (by initiating codes in the 'code system' and relating each code to its relevant texts). An example of a coded transcript is shown in **Appendix 16**. Generation of themes/sub-themes involved labelling textual data, which could be a word, phrase, sentence or paragraph, for the purpose of summarising what is being said in the text, which describes and explains these data. This process facilitated the retrieval and analysis of data, and helped in organising it according to patients' views and experiences within the context of their priorities and concerns.

In this study, coding started during the data collection period. When the pilot study was conducted with the first seven interviews, the researcher did a preliminary analysis, which informed subsequent data collection, by which the interview schedule was modified depending on the findings and the issues that emerged from the interviews. The analysis was continued after conducting all the interviews. As the process of coding throughout the interviews continued, new sub-codes were added. Therefore, by identifying further themes/sub-themes, a conceptual framework was developed and was applied to the whole data set, where relevant. For example, taking the sample of patients using insulin pumps, to achieve objectives 1 to 4 **(Section 2.6)**, the thematic analysis in **Table 3.3** was undertaken.

However, it is worth noting that the process of coding was performed by two analysts; the principal researcher and other competent persons (F.A, an assistant professor and A.A, a diabetologist), discrepancies were then resolved through discussions. In addition, it should be noted that analysis of data was performed in Arabic, the language in which it were collected. Data were analysed in Arabic to avoid limitations, as the participants used culturally bound words, where if translated, the meaning might be affected (van Nes et al., 2010). Then, findings were translated into English to facilitate their discussions with the research team.

Table 3.3: The conceptual thematic framework/codes and sub-codes

No.	Code/sub-code

1	**Impact of beliefs/culture on medicine-taking behaviour**
	-Beliefs about the disease
	   • *Beliefs about seriousness*
	   • *Locus of control*
	-Beliefs about medicines
	   • *Beliefs about benefits*
	   • *Beliefs about brands*
	   • *Beliefs about herbal medicines*
	-Perceived barriers
	   • *Fear of hypoglycaemia*
	   • *Ramadan fasting*
	   • *Adverse reactions (e.g. stomach pain, nausea, dizziness)*
	-Beliefs about ability to control the disease (self-efficacy)

2	**Satisfaction & Quality of life with pump** - The operating of the pump - Practicability and portability - Glycaemic control - SMBG - Awareness of hypoglycaemia - Hospital admissions - Hypo- and hyperglycaemic attacks - Infection/irritation/swelling/bruising at cannula-site - Pain - Weight gain - Mechanical problems
3	**Life activities with pump** - Sleeping - Practising sport - Wearing clothes
4	**Impact of pump on social life** - Initial worries - Independency/help needed - Embarrassment - Confidence

5	**Other management responsibilities**
	-Diet
	   • Nutritional awareness
	   • Perceived benefits
	   • Perceived barriers (e.g. social gatherings, lack of support, food cravings)
	-Exercise
	   • Lack of awareness
	   • Perceived barriers (e.g. lack of time, hot weather, lack of support)

The priority in the construction of the thematic framework was derived by consideration of the original research objectives introduced in the topic guide. From the interviews with patients using insulin pumps, 5 major codes/themes were created. The origins from which the codes were created can be shown in **Table 3.4**. As recommended by Smith (1999), an iterative approach was considered, in which a constant comparison method was used throughout the analysis process. This was achieved by revising data each time a new code/sub-code was added. Therefore, all

the interviews were revisited after primary coding, and inspected for the relevance of these codes, until no additional codes/themes could be developed. This was achieved when no new issues emerged from the data set, e.g. the saturation level had been reached. This means that the analysis was not a linear process, and the researcher kept moving back and forth between the original and synthesised data searching for new issues, and further explaining data.

Table 3.4: The origin of the codes/sub-codes*

No.	Code	Origin
1	Impact of beliefs/culture on medicine-taking behaviour	Study's aims and objectives and Preliminary fieldwork and Literature review
2	Satisfaction & quality of life with pump	Study's aim and objectives
3	Life activities with pump	Interviews
4	Impact of pump on social life	Study's aim and objectives

*Sub-codes were mostly generated from issues raised by participants during the interviews

To achieve objective 5 **(Section 2.6)**, which was related to the perspectives of HCPs, an initial framework was established using the topic guide; this was extended as themes emerged from the interview transcripts. For instance, when analysing the interview transcripts, the following codes were firstly allocated 'facilitator' and 'barrier'. Then, these were subdivided into themes and sub-themes. Themes under 'facilitator' code described the views of the HCPs about the factors that facilitate the implementation of a particular intervention, e.g. 'competent staff'. Themes under the 'barrier' code described the perspectives of HCPs about the barriers of applying such intervention, e.g. 'lack of support', 'lack of staff' and 'lack of time'. The origins from which the themes and sub-themes were created were the study objectives (objective 5) and the interviews with the HCPs. A detailed description for the emergent themes and sub-themes is provided in **Chapter 8**.

3.6.2 Data description

Because the data set collected was relatively large (n=43), further rationalisation was required to present data in a clear manner. In this stage, different groups of participants were organised to facilitate the comparison and association between views and experiences of these groups. For instance, for the selected interviews, the following groups were organised: those who achieved glycaemic control promptly following pump use and those who did not, those who had improved adherence and those who had not, and those who gained weight and those who did

not. At this stage, the researcher examined each theme across all the interviews, and checked for views that were labelled under that theme, to help gain a picture of the issues related to that particular theme across all cases, which was central to meeting the study objectives. This was applied to all the 5 themes created for the selected interviews **(Table 3.3)**. By looking for overlapping, data could be condensed. Condensing data aided in concentrating on the important issues for the next stage of analysis.

3.6.3 Data interpretation and explanation

At this stage, deeper analysis to the descriptive data was undertaken. It involved an interpretation of the data by providing explanations (answering 'why' and 'how' questions) and relating findings to a theoretical framework. As will be shown in the results **(Chapter 5)**, the HBM was used to determine the association between health beliefs and behaviour, and to identify the most influential determinants of behaviour, in order to inform educational interventions that address specific beliefs. This was achieved by looking for associations repeated across the data set or within a particular group of participants.

Using such methods for data analysis enabled the researcher to answer the research questions (what were the beliefs of patients with type 2 diabetes and how those beliefs influenced the management of this disease? what was the role of insulin devices in the management of the disease? and what was recommended by different HCPs to develop services and improve health outcomes?) and making recommendations to improve the disease management and health outcomes. The data obtained reflect the aim and objectives of this study.

3.7 Validity and reliability of the data

To ensure that data processing and analysis are rigorous, it is important to consider validity and reliability issues. This section discusses the validity and reliability of this study in relation to aspects of conduct of interviews and data processing and analysis.

Several steps were undertaken to ensure the validity and reliability of the results. Validity represents the extent to which the study findings truly interpret the issue being examined, while the reliability indicates the extent to which the results are reproducible (Smith, 2002; Smith, 2005). Although the researcher used a semi-structured interview schedule, which allowed participants to explain issues and

views related to medicine/device use without adhering to a definite structure, the schedule served to illuminate the participants' views regarding the relevant issues without influencing their responses. In addition, triangulation was employed in this study by using more than one data source (interviews, questionnaires and HbA1c measures), and findings from qualitative data (interviews) regarding health behaviour and factors affecting on it, were considered in conjunction with the quantitative data (MMAS, BMQ and HbA1c measures).

Steps undertaken to ensure the validity of the findings of this study were:

- Developing the interview schedule after conducting the literature review and the preliminary fieldwork, which ensured that all relevant issues about the investigated phenomena and Kuwait's culture were covered. Also, leading questions, which may influence the participants' responses, were avoided by selecting the appropriate wording.
- Reviewing the interview schedule several times with the research team and modifying it accordingly.
- Attending courses and workshops on conducting qualitative research and improving interviewing skills, and reading books on interviewing techniques.
- Conducting the interviews and obtaining clinical measures alone, which minimised the variability if two researchers were involved in the process.
- Testing the translated instrument in a group of the target language speakers (relatives of the researcher who have type 2 diabetes) to determine their understanding about the translated items, in order to improve the quality of the translation (Behling and Law, 2000), and during the pilot period, in order to ensure its consistency and appropriateness for use within Kuwait's culture.
- Undertaking a pilot period (after conducting the first seven interviews with patients and the first two interviews with HCPs), the researcher revised the interview schedules and introduced some modifications. This step ensured the applicability and reproducibility of the schedule.
- Audio-recording and transcribing data verbatim, to assist in data analysis.
- Reading books and journal articles on qualitative data analysis and undertaking appropriate training on the use of computer software for data analysis.
- Using a Framework Method approach and the latest version of the computer software (MAXQDA-11) in data analysis, which helped in making the process more systematic and comprehensive.
- Analysing data in Arabic, the language in which data were collected. Then,

findings were translated into English to facilitate discussions with the research team.

- The analysis process was undertaken under the supervision of the research supervisors in UCL (F.S and K.T), who have experience in health services research. This peer review process reduces the potential of lone researcher bias.

- Generation of codes/sub-codes was performed by three analysts separately, the principal researcher, a professor assistant (F.A) and a diabetologist (A.A). Then, comparisons and discussions on the generated codes were mad.

- In some cases, where participants couldn't give direct explanations regarding their behaviour, the researcher did some systematic interpretations across all cases.

- Comparing the findings with previous studies (cumulative validity), and explaining conflicting responses (argumentative validity).

- Employing a validated translation method for data collection instruments and during data processing and analysis.

- Explaining in details the procedures followed in data collection and analysis, so that; the reader could critically examine the value of the study.

As described in **Section 3.3.1**, the main five hospitals were chosen as the settings for conducting this study. This enabled the recruitment of participants from different demographic and clinical characteristics (e.g. age, gender, education level, employment status, marital status, duration of the disease, treatment regimen, complications and co-morbidities). In addition, the researcher undertook measures to ensure the reliability of the data obtained, such as:

- Conducting all the data collection alone, which ensured the consistency of the procedures undertaken. For example, the same order was followed for all interviews, starting with briefly explaining the aim of the study, signing the consent form, asking the interview questions and ending with the questionnaires.

- Using a notebook to record all issues encountered during data collection to help in the development of procedures in the subsequent interviews.

- Obtaining the clinical data from medical records alone, which ensured the consistency of data obtained.

- The instruments chosen (MMAS-8 and BMQ-S) had shown good reliability in similar study sample.

Sample characteristics and response rate are described in **(Chapter 4)**.

Chapter 4: Response rate and sample characteristics

This chapter describes the response rate and the characteristics of the participants (patients and HCPs) included in this study. Characteristics of the patients include their demographic and clinical information and characteristics of HCPs include their speciality and working area. The chapter also explains reasons for non-participation and the details of the conducted interviews.

4.1 Response rate and characteristics of the participants

4.1.1 Characteristics of patients

Seventy patients using OHAs and/or insulin injections/pens were approached by the researcher during their clinical visits and invited to take part in the study. All patients responded directly (response rate 100%), from which 35 agreed to participate and were subsequently interviewed (participant rate 50%), while 35 refused to participate (non-participant rate 50%). For patients using insulin pumps, of the 15 patients who were called by the researcher and invited to take part in the study, 12 responded directly (response rate 80%). From those who responded, 8 agreed to participate (participant rate 53%). Patients who did not respond to the researcher's phone call numbered 3 and those who refused to participate were 4 (non-participant rate 47%). As a consequence, the total response rate of all participants in the study was 97%, participation rate was 51% and non-participation rate was 49%. Reasons for non-participation are shown in **Section 4.2, Table 4.4**. The data collection process was terminated when a saturation level of the collected data was achieved; this was reached with 43 patients.

Overall, a mixture of participants using different treatment regimens for the management of type 2 diabetes was achieved **(Table 4.1)**. Demographic and clinical information obtained from medical notes and during the interviews were collected for patients who consented to take part and participated in the study **(Table 4.2)**. Anti-diabetic medications (oral and insulin injection/pen/pump) used in the management of type 2 diabetes by the participants are shown in **(Table 4.3)**.

Table 4.1: Number of patients using each treatment option (n=43)

Treatment option	Number of patients (%)
OHA only	9 (21)
Insulin traditional injection +/- OHA	8 (18.5)
Insulin pen +/- OHA	18 (42)
Insulin pump +/- OHA	8 (18.5)

Table 4.2: Characteristics of the participants (n=43)

Variable	Frequency
Mean age (years)	53
Sex	
Male	11
Female	32
Ethnicity	
White	40
Non white	3
Nationality	
Kuwaiti	36
Non-Kuwaiti	7
Activity	
Employed	12
Retired	14
Housewife	15
Student	2
Education	
Can't read and write	3
Primary school	13
Secondary school	5
Diploma	8
University	12
Postgraduate	2
Area of residence	
Urban	21
Rural	22
Duration of disease	
1-10 years	17
11-20 years	14
>20 years	12
Number of current anti-diabetic and diabetes related medications (e.g. Aspirin, Statin)	
$\leq$ 4 medicines	19
> 4 medicines	24
Smoking	
Smoker	6
Ex-smoker	4
Non-smoker	33
Mean BMI (ranged from 19.9 to 46.9 kg/m^2)	33.5
Mean HbA1c level	**8%**
$\leq$7.5	18
>7.5	24
NA	1

Table 4.3: Details of medicines/devices used in the management of type 2 diabetes by the participants

Route of drug administration	Frequency (number of patients)
Oral anti-diabetic medication	
Metformin	
500 mg	8
850 mg	7
1000 mg	12
Sitagliptin 100 mg	10
Glimepiride	
1 mg	3
2 mg	3
3 mg	1
Gliclazide	
30 mg	2
80 mg	2
Acarbose 50 mg	1
Pioglitazone 15 mg	1
Insulin injection	
Actrapid[R]	1
NovoRapid[R]	2
Lantus[R]	1
Insultard[R]	1
NovoMix[R]30	4
Humalog[R]Mix50	1
Mixtard[R]	1
Insulin pen	
Actrapid[R]	2
NovoRapid[R]	6
Levemir[R]	1
Lantus[R]	16
NovoMix[R]30	2
Humalog[R] Mix25	4
Insulin pump	
NovoRapid[R]	8

4.1.2 Characteristics of the HCPs

All the approached HCPs responded directly and agreed to participate except one who did not reply (n=10; response rate 91%). The speciality of each HCP and their working areas/departments are shown in **Chapter 3, Section 3.3.3, Table 3.2**.

4.2 Characteristics of non-participants

Of the 42 patients who did not participate in the study, 29 were females and 10 were males (the ratio of non-participants females to males is approximately similar to that of participant females to males, 32 females and 11 males). The most common reason for non-participating given verbally by women was pending housework (n=20). 75% of the participants were females; most of them (24/32, three-quarter) were either housewives or retired, and they do housework themselves based on reports from the interviews. The next most common reason given by most non-participation by women was not having a car and not being willing to make a driver or accompanying person wait for a long time while they participated (n=11). However, based on the characteristics of non-participants, there is no evidence of response bias. For those who did not respond (1 female and 2 males) to the researcher's phone calls, despite repeated calls at different times of the day, no information was obtained. Other reasons for non-participating are included in **Table 4.4**.

Table 4.4: Reasons for non-participating

Reason	Frequency (number of patients)
Pending housework	20
Not having a car	11
Other hospital appointments	10
Feels unwell (age, disability, tiredness)	6
Going back to work/university	5
Social circumstances (problems, death)	2
Bringing grand daughter from school	2
Time constraints	2
Travel	1
No reason given	1

4.3 Details of the interviews

4.3.1 Interviews with patients

As preferred by patients, who were approached during their clinical visits, the interviews were conducted in the hospital. For patients who were called by the researcher, the interviews were conducted in coffee shops as planned with the patients, only one interview was conducted in the patient's home. Despite the importance of privacy in interviewing, in some cases the patients were accompanied by one of their family members, e.g. son, daughter, mother or husband. In such cases, no interrupted interactions were recorded; this was because in some cases (n=6), the accompanied persons were waiting outside the interviewing area. However, in cases (n=6) where the family member presented with the patient during the interview, the researcher was very careful to direct all the questions to the patients themselves and keep eye contacts with them only. However, in two cases, when the researcher asked question 19, which was about the needed services/problems, interventions from family members were recorded. This was because those members were accompanying the patients to all their appointments; thus, they felt that they had a valid contribution to answering that question. For example, in one case, a husband raised a problem that they perceived and provided a suggestion; the patient agreed with her husband's suggestion and expressed her concern regarding that issue. In another case, a daughter interrupted at the same question but the patient gave no response. The researcher waited till the daughter finished, took her point of view into consideration and repeated the question to the patient in a way that asked for any additions, (e.g. would you like to add something else?) but the patient did not add anything and agreed with her daughter's opinion.

Being accompanied with other persons was considered helpful to the study, as they provided reminders to the patients, especially when patients had difficulty in remembering an event. Generally, the conduct of the interviews went smoothly, the participants were pleasant to participate and talked about their disease, medicines and problems freely, and the interviews were interactive in most cases. However, in nine cases, the interview was paused briefly because patients were: called to collect their prescriptions from the pharmacy (n=3), called to see the consultant (n=2), and received phone calls during the interview (n=4). In such cases, the researcher switched off the audio-recorder, waited till the patient finished, and then completed the interview with audio-recording.

Overall, data needed to achieve study objectives were obtained from all the interviews with patients. The time required to complete the interviews with patients varied depending on what the patient said (the average time was 32 minutes and 18 seconds). The shortest interview lasted for 20 minutes and 20 seconds, while the longest lasted for 51 minutes and 36 seconds. Patients using insulin device (pen/pump) required more time, as they were asked more questions than patients who were not using such devices. In one interview, the recorder stopped due to dead batteries, and the researcher used her mobile phone as a voice recorder instead.

At the end of each interview, the questionnaires (MMAS-8 and BMQ-Specific) were administered to the patient (response rate 100%). The average time required to complete both of the questionnaires was 8 minutes (range 4 to 12 minutes). The completion rate was 100%, with no missing item in any of these tools in all cases. Overall, there were no difficulties in responding to the items of the questionnaires. Some demographic and clinical data were recorded by the researcher during the interviews, and some were collected from medical notes very soon after ending the interview with each patient.

4.3.2 Interviews with HCPs

The interviews with the HCPs (n=10) were conducted in the HCP's clinic/department, except three, which were conducted by telephone. Generally, HCPs were happy to collaborate, provide their recommendations, and to be interviewed and audio-recorded. The time required to complete the interviews with HCPs varied from 9 minutes 29 seconds to 21 minutes 31 seconds (the average time was 14 minutes and 22 seconds).

The next four chapters include the analysis of the interview transcripts of those who participated in this study, and explain the results obtained from both patients and HCPs. **Chapters 5, 6, and 7** include the results obtained from interviews with patients and **Chapter 8** describes the analysis of the HCPs' interviews.

Chapter 5: Medication adherence, health beliefs and the management of type 2 diabetes

The aim of this chapter is to estimate the level of non-adherence among patients with type 2 diabetes living in Kuwait, using direct self-report methods (e.g. MMAS-8, and semi-structured interviews) and a clinical measure (HbA1c levels). In addition, the chapter describes the health beliefs of the participants and how these beliefs along with cultural factors impacted the management of type 2 diabetes. This is to identify the factors that contributed to poor health outcomes by showing the ways in which health beliefs and culture affected the management behaviour (e.g. medicine-taking behaviour, SMBG and lifestyle) of the participants and consequently to support or disapprove the hypothesis that health awareness, beliefs and culture have an impact on the management behaviour of patients with type 2 diabetes.

5.1 Results of MMAS-8

Assessment of non-adherence using MMAS was based on instructions provided from the author of the instrument. The categorisation of the participants' adherence was based on the total MMAS score, and ranged between low (MMAS score<6), medium (MMAS score 6 to <8) and high (MMAS score=8). The scores were calculated as follows: responses relating to items 1-7 were either (Yes), which denotes (0) score or (No), which denotes (1) score, with the exception of question 5, where a positive response equals 1. Responses to the last item were related to a 5-point Likert scale (never/rarely=4, once in a while=3, sometimes=2, usually=1, and always=0). Item 8 was standardised by dividing the code by 4, in order to result in a scale ranging from 0-8. The participants' responses to individual items of MMAS and their total MMAS scores are shown in **Appendix 17 and 18** respectively. Calculating total MMAS scores for the study participants revealed that 17, 15 and 11 participants achieved a MMAS score of 8, 6 to <8 and <6 respectively. This means that 17 (40%), 15 (35%) and 11 (25%) participants had high, medium and low adherence level respectively **(Figure 5.1)**. Some authors who used MMAS in their studies categorised patients who achieved low and medium adherence levels as low or poor adherents, and only those who achieved a MMAS total score of 8 as adherents (AlHewiti, 2014). Other authors considered participants who achieved a total MMAS score of 6 to 8 as adherents, and those who had a total MMAS score of <6 as non-adherents (Sweileh et al., 2014).
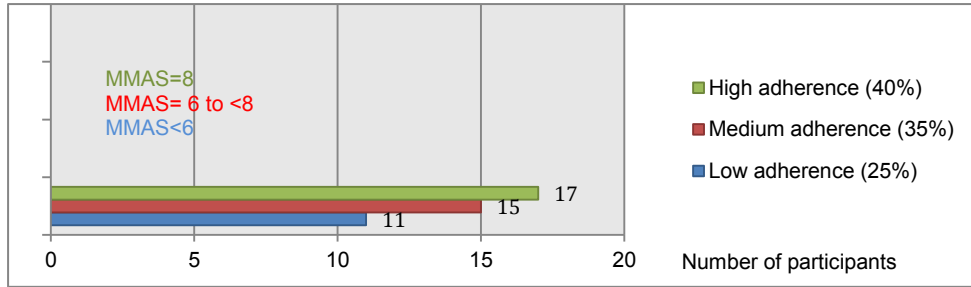
Figure 5.1: Adherence levels of the participants based on their MMAS scores

5.2 Adherence based on HbA1c level

As outlined in **Chapter 3, Section 3.2.4**, HbA1c levels can be used as a means of assessing patients' adherence to their treatments. However, this measure cannot be the sole method for detecting non-adherence due to the possible impact of other factors on the results, such as chronic liver disease, chronic renal failure, rheumatoid arthritis and the administration of some drugs, such as aspirin, iron and vitamin B12 (WHO, 2011). The researcher obtained levels of HbA1c from the participants' medical notes; the HbA1c level recorded in this study was the mean value of the previous three recorded levels. The results revealed that 18 participants (43%) achieved target levels of HbA1c ($\leq$7.5%), 24 participants (57%) were above the target levels (>7.5%), and one participant had no valid result. Therefore, based on the clinical data, 18 participants (43%) had good adherence level, while 24 participants (57%) had poor adherence level **(Figure 5.2)**.

Participant	HbA1c %	Participant	HbA1c %	Participant	HbA1c %
1	7	16	14	31	7.2
2	8	17	8	32	8
3	7	18	8	33	7.7
4	10	19	11	34	8.8
5	7.5	20	7.1	35	8
6	7	21	7.4	36	10.7
7	7.5	22	8	37	6.8
8	6.9	23	9	38	7.5
9	14	24	9	39	7
10	7	25	13	40	7.1
11	8	26	12	41	NA
12	8.3	27	12.8	42	5
13	8	28	7.7	43	5.7
14	4.7	29	9	HbA1c levels of the participants	
15	6.6	30	8.8		
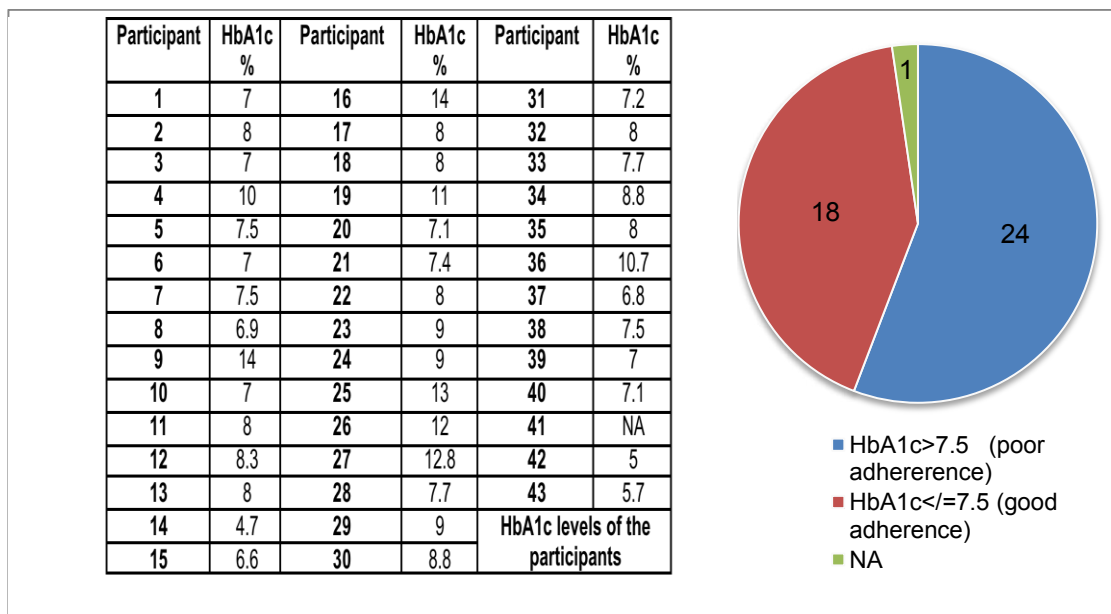
Figure 5.2: The number of participants with poor/good adherence based on HbA1c level

5.3 Results of BMQ-S

Participants' beliefs about anti-diabetic medications were assessed using the BMQ-S. The scale is divided into two sub-scales: BMQ-necessity and BMQ-concern. The results were calculated using a 5-point Likert scale: 1 (strongly disagree), 2 (disagree), 3 (uncertain), 4 (agree), and 5 (strongly agree). The participants' responses to the individual items of the BMQ-subscales, and their frequency are shown in **Appendix 19**.

Then, the scale scores were obtained by summing the individual item scores. The subscales score ranged from 5-25, the necessity-concern differential scores ranged from -20 to 20. Differential scores were obtained by subtracting the concern subscale score from the necessity subscale score, yielding to a positive, neutral, or negative score. The participants' scores of BMQ-S necessity and concern ranged from 5 to 25, and from -20 to 20 for the BMQ differential necessity-concern. **Appendix 20** shows the scores of the participants. Positive score indicates that the participant perceives the benefits (necessity) of taking medicines to outweigh their risks (concern). Conversely, a negative score indicates that the participant perceives the risks (concern) of taking medicines to outweigh their benefits (necessity). In this study, 40 (93%), 2 (5%) and 1 (2%) participant achieved positive, negative and neutral differential score respectively **(Figure 5.3)**. This means that the majority of the participants believed in the necessity of taking their medicines.
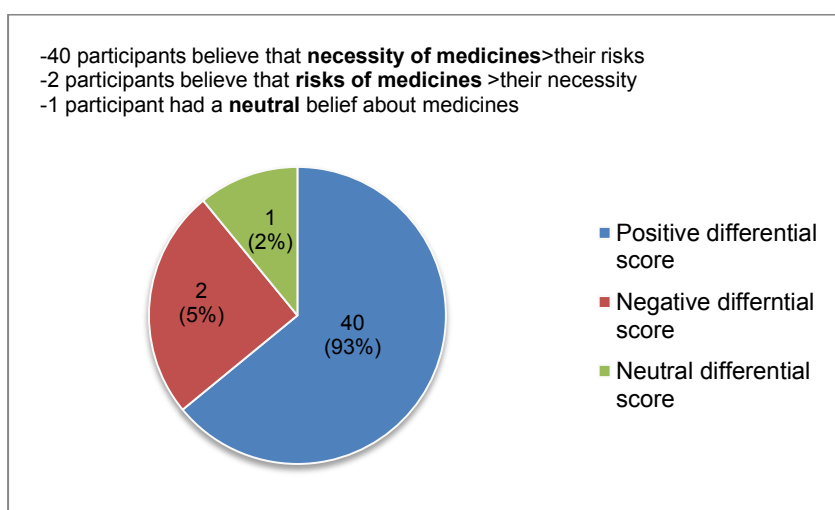
Figure 5.3: The number of participants who achieved positive, negative and neutral BMQ differential necessity-concern scores

5.4 Health beliefs based on semi-structured interviews

The interview transcripts of the 43 participants were analysed using thematic analysis. Because patients used to construct models to interpret their disease and treatment, and this has been found to associate with treatment-related behaviour, such as adherence, it was crucial to explain the psychosocial factors of the participants (Dunning and Martin. 1998). Thus, it was decided to organise the participants' illness and treatment perceptions using an appropriate framework to facilitate the analysis of data and the generation of themes and sub-themes. Several theories have been used to explain the association between patients' behaviour such as medication adherence and their beliefs. Some of the most accepted theories are the self-regulation model, illness perception model, self-efficacy model and health belief model (Myers & Midence, 1998). In this study, the different beliefs that emerged during the semi-structured interviews were organised according to the HBM. The beliefs were about the disease, medicines, perceived barriers and self-efficacy.

5.4.1 Beliefs about the disease

An analysis was undertaken to illustrate the beliefs of the participants about type 2 diabetes. The results revealed different beliefs, such as 'the disease is not serious' and the belief in 'God locus of control'.

5.4.1.1 Beliefs about the seriousness of type 2 diabetes

During the semi-structured interviews, the participants were asked to provide their perceptions about type 2 diabetes. When analysing the interview transcripts, the following terms (mild, moderate and serious) were identified to assist in categorisation of the participants' perceptions about the severity of their disease (Dunning and Martin. 1998). The results revealed that 26 participants were aware about the seriousness of type 2 diabetes and that it could cause other complications such as retinopathy, neuropathy and nephropathy:

> *"Many parts of the body can be affected by diabetes. A patient with diabetes may lose his kidneys and eyes. Also, it* [diabetes] *affects the extremities nerves, in which the risk of infections increases if the patient experiences wounds."*
> [Participant 8, male, age 55 years]

> *"I have to do an operation for my eyes, it* [diabetes] *has affected them. I also know that high blood glucose levels can affect my kidneys."*
> [Participant 39, male, age 28 years]

The remaining participants (n=17) believed that type 2 diabetes could affect their health and cause other complications, but it is not serious:

"Diabetes has become widespread, all Kuwaitis have diabetes, even kids. I don't care that much about having it…I always feel lazy and tired. I have unusual numbness in my legs and hands and I often have headache. I don't think this is because of diabetes."
[Participant 17, female, age 37 years]

"Diabetes is one of our characteristics, all Kuwaitis have it. I always try to forget it…It [diabetes] *may cause nausea or hypoglycaemia."*
[Participant 32, female, age 42 years]

Of the 26 participants who perceived type 2 diabetes as a serious disease, 21 (81%) were using their medicines properly:

"I always take my medicines as prescribed, even when I go outside or travel, I always carry my medicines in my bag. I worry from the progression of the disease if I don't take them [medicines] *regularly."*
[Participant 4, female, age 60 years]

All the 17 participants, except 4 who perceived type 2 diabetes as not a serious disease did not adhere to their medicines:

"The doctor prescribed me tablets [metformin 500 mg]*, but I don't take them regularly. Sometimes, I get them and throw them away or give them to other patients."*
[Participant 17, female, age 37 years]

Reviewing the interview transcripts of the four participants who adhered to their medicines although they did not perceive diabetes as a serious disease revealed that another factor contributed to their adherence. The factor was social support; the participants received help from their family members in the administration of their doses. This may indicate that minimising the seriousness of type 2 diabetes is an important determinant of medicine-taking behaviour. This is because all the participants who perceived diabetes as not a serious disease did not adhere to their medicines except those who had an external factor (e.g. a family member who took the responsibility of doses administration) that might have impact on their decisions-making:

"I take my injection three times a day before meals. My daughter gives it to me."
[Participant 33, female, age 73 years]

5.4.1.2 Locus of control

During the interviews, some participants (n=7) raised some beliefs about type 2 diabetes. For example, some believe that it is caused solely by God and that God has the power to cure them, others believe that stress elevates blood glucose levels even when taking medicines regularly:

"Sometimes when I feel stressed and nervous, my [blood] *glucose* [level] *goes up even if I was taking my medicines as prescribed, and it remains high until I calm down."*
[Participant 32, female, age 42 years]

"Diabetes is from God, it suddenly affects the body without any warning. It has nothing to do with diet; I don't like sweets and eat normally but I have it!"
[Participant 43, female, age 28 years]

Locus of control related to health behaviour describes the belief that one's health is dependent on another power or factors (Norman et al., 1998). Internal locus of control is associated with adherence to diabetic regimens, while external locus of control indicates that the achievement of the goal is related to an external factor outside the individual's control (Norman et al., 1998). In the current study, beliefs about God or stress locus of control were weak determinants of medicine-taking behaviour. All the seven participants except two (71%) who raised such kinds of beliefs were using their medicines properly despite their beliefs that God only has the control of their diabetes and that stress elevates their blood glucose levels even if they adhered to their medicines:

"I feel that stress has an influence on my diabetes. I'm a worrier; I usually think about 60 things at the same time, in which I feel my [blood] *glucose* [level] *increases…I take my medicines according to the doctor's instructions. He knows better about medicines and their actions."*
[Participant 9, female, age 65 years]

Examining the interview transcripts of the two participants who were not using their medicines as prescribed revealed that in addition to locus of control, there were several factors that might impact their adherence, such as minimising the seriousness of type 2 diabetes, disbelief in the benefits of medicines, low self-efficacy and perceived side effects:

"Diabetes comes from God; nothing else can cause it…[What do you think the future holds in terms of your disease?] *I don't know…I don't think that medicines help me; my* [blood] *glucose* [level] *is always high…Glucophage* [metformin 500 mg tablet] *causes stomach pain."*
[Participant 2, female, age 65 years]

5.4.2 Beliefs about medicines

The interview transcripts were analysed to describe the participants' beliefs about their medicines. The emerged themes were beliefs about the benefits, beliefs about brands and beliefs about herbal medicines.

5.4.2.1 Beliefs about the benefits

When participants were asked during the interviews about their beliefs regarding their diabetes medicines, whether they were helpful or not, most of them (n=27) believed that their medicines helped them in controlling their disease and maintaining glycaemic control:

> *"Yes, medicines help me to control my disease."*
> [Participant 4, female, age 60 years]

> *"Yes, medicines are helpful. If I stop taking them, I'll definitely suffer."*
> [Participant 19, female, age 33 years]

> "Yes, thank God, I'm much better, so, they [medicines] definitely help."
> [Participant 43, female, age 28 years]

On the other hand, few participants (n=6) reported that they did not believe in the efficacy of their medicines because they were experiencing uncontrolled blood glucose levels even when they were taking their medicines regularly:

> *"I don't feel that medicines help, or control my* [blood] *glucose* [level]*. It's* [blood glucose level] *often high."*
> [Participant 22, female, age 64 years]

One-fourth of the participants (n=10) were uncertain about the efficacy of their medicines. This was because they did not perceive the benefits of their medicines in reducing their blood glucose levels and maintaining glycaemic control at all times; however, they believed that they should take them for the benefit of their overall health:

> *"I don't feel that medicines are help me or control my* [blood] *glucose* [level]*, yet I have to take them. If I don't take them* [medicines]*, I won't be able to survive."*
> [Participant 16, male, age 47 years]

> *"I don't feel they* [medicines] *work. I always feel tired and the* [blood] *glucose* [level] *is always high although I don't eat much. However, I have to take them* [medicines]*, they are medicines."*
> [Participant 25, female, age 58 years]

Of the 27 participants who believed in the benefits of their medicines, more than half of them (n=17) were using their medicines regularly. This may indicate that beliefs in the benefits of medicines can be a crucial determinant of medicine-taking behaviour:

> *"Yes, medicines help me to control* [blood] *glucose* [level]*. My blood tests* [HbA1c] *are always normal, so they're* [medicines] *helpful…In taking my medicines, I follow the doctor's instructions, even in travelling and holidays, it become my part of daily routine."*
> [Participant 3, female, age 56 years]

Examining the interview transcripts of the 10 remaining participants who were not using their medicines regularly despite their belief in their benefits revealed that the participants had other factors, which might affect their adherence, such as low self-efficacy or other cultural factors such as social gatherings:

> *"Of course medicines help, definitely they have benefits…I can't follow the doctor's instructions all the time, especially when travelling and in weekends. For example, when I go to the chalet with my friends, I don't take the injections* [Lantus and Actrapid; insulin pens]*, even the tablets* [metformin 1000 mg]*. I usually forget to carry them. Also, when I'm invited to a dinner, I don't take my medicines with me because I can't carry them all the time; it's annoying, I just ignore the doses."*
> [Participant 10, male, age 58 years]

On the other hand, of the 16 participants who did not believe in the benefits of medicines or were uncertain about them, 7 were not using their medicines properly. Nine participants adhered to their treatment despite their disbelief in its efficacy due to other factors, such as coping with the disease and the absence of side effects:

> *"I don't feel that medicines are active, it's like drinking water* [taking medicines has no effect on controlling blood glucose level]*, but I have to take them; it's a life-long treatment…I take my medicines according to the doctor's instrucctions. I don't change anything even on holidays…I have no problem with medicines."*
> [Participant 33, female, age 73 years]

> *"Medicines are sometimes helpful, and sometimes not. When I feel stressed, my* [blood] *glucose* [level] *goes up…I'm very careful in taking medicines regularly even in weekends and on holidays…Patients with diabetes have to bear up with their disease; I already control myself to live with diabetes. I bought an ice-bag where I can put my insulin pens and carry them wherever I go so as to take my doses on time."*
> [Participant 36, female, age 51 years]

5.4.2.2 Beliefs about brands

One of the most interesting beliefs that were found in the current study was related to the industrialisation source of the medicine. Eleven participants (about a quarter of the study sample) raised some beliefs regarding the source of the medicine. Some of them perceived Western brands superior, more effective, and safer than local ones:

> *"When I was in Egypt, my* [diabetes] *medicine ran out and I had to buy it there, but I wasn't feeling good and I was always dizzy and tired. When I came back* [to Kuwait]*, and got my Western medicines, I felt well immediately. I believe that local medicines are low quality."*
> [Participant 16, male, age 47 years]

> *"Once, they* [pharmacists] *dispensed me a medicine from Saudi company. When I took it, it caused me a stomach pain and hypoglycaemia. That's why I prefer medicines from Western sources."*
> [Participant 28, female, age 66 years]

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Few participants (n=3) reported that they preferred to use the medicine from the same origin, which they were initiated on, regardless whether it was local or foreign:

> *"Since my last administration to the hospital, they* [pharmacists] *dispensed me new tablets* [metformin tablet 1000 mg]*. Every time I told them this is not my medicine, they said: yes, it's but it is from another company. Since then, I'm not feeling well and I'm always tired. I prefer to use my old tablets."*
> [Participant 18, female, age 65 years]

Although it has not been adequately discussed in the literature, other researchers have also reported some perceptions among patients with type 2 diabetes regarding the belief about the efficacy and safety of Western brands (Lawton et al., 2005). However, examining such beliefs among the participants in the current study revealed no impact on their medicine-taking behaviour. Although there were some participants who preferred using medicines from specific origin, e.g. Western, no one reported poor adherence as a consequence of not providing them with their preferred option:

> *"I prefer to take medicines from Western companies, but if they* [pharmacists] *dispense a different brand to me, no problem, I'll take it as long as it gives the same result."*
> [Participant 8, male, age 55 years]

5.4.2.3 Beliefs about herbal medicines

There was a proportion of the study participants (n=22) who believed in the safety and/or efficacy of alternative medicines, e.g. herbals in treating type 2 diabetes and achieving glycaemic control. The participants perceived them safer than conventional (chemical) medicines, as they cause no adverse effects:

> *"If herbals* [medicines] *didn't work* [reduce blood glucose level]*, they wouldn't cause any harm because they're natural."*
> [Participant 7, male, age 85]

Of those 22 participants, 17 reported that they used herbal medicines in the management of their disease without consulting their doctors:

> *"I feel that herbals are effective in treating diabetes, and safer than* [chemical] *medicines. I use a mixture of herbals; I don't know their names. I feel that they reduce my* [blood] *glucose* [level]*."*
> [Participant 1, female, age 40 years]

> *"I use 'myrrh', it's effective in reducing* [blood] *glucose* [levels]*, and doesn't cause any harm to my stomach as Glucophage* [metformin 500 mg tablet] *doses."*
> [Participant 2, female, age 65 years]

Of the 17 participants, 14 reported some barriers to continue using herbal medicines such as lack of perceived efficacy (n=10), complexity of preparation (n=3), unpleasant taste (n=3) and perceived side effects (n=2):

"I used a mixture of herbals, I don't know their names, but I used them for a month only. I couldn't continue because of their complex preparation. I had to soak them [the raw herbs] *for two hours; there were too many bags with similar contents, which was confusing. Besides, the herbals had a bitter taste."*
[Participant 36, female, age 51 years]

However, examining the impact of the belief in the safety and efficacy of herbal medicines on medicine-taking behaviour revealed that the participants' adherence to conventional medicines was affected at different times, e.g. at the beginning of the diagnosis or during the period of medical treatment. Some participants (n=11) started managing their disease with herbals, and after the failure in achieving glycaemic control, they decided to visit the doctor to commence the medical treatment:

"I was diagnosed with diabetes, I've been to the Islamic Centre and they [pharmacists] *dispensed me a herbal mixture, I don't know its name. I used it for about years but I stopped it, because I didn't notice any benefit. Then, I went to the doctor and he told me that I have to commence* [medical] *treatment."*
[Participant 24, male, age 58 years]

Other participants (n=6) abstained from their medical treatment and used herbal medicines for a period of time. Again, when the herbal treatment failed to achieve glycaemic control, they returned to their medical treatment. From the above statements, it can be concluded that beliefs in herbal medicines led to poor management behaviours. Both behaviours were unacceptable and could lead to serious complications. Delaying the medical treatment or discontinuing it causes poor glycaemic control. Poor glycaemic control accelerates the progression of diabetes-related complications, and reduces the life expectancy and life quality of the patient (Goodall et al., 2009). Two participants reported that they complained from short-term complications, such as blurred vision because they stopped their medical treatment and used herbal medicines:

"I have started using herbals 5 years after being diagnosed with diabetes. I've been to the herb shop and the seller told me that I can use 'olive leaves extract', and cancel all my [chemical] *medicines. You can't imagine, during only one week, I suffered from blurred vision, and felt as if there was fog in my eyes all the time. I couldn't go out or drive. Then, I threw the bottle* [herbal preparation] *and returned to the* [insulin] *injections. I then felt OK."*
[Participant 32, female, age 42 years]

5.4.3 Perceived barriers and self-efficacy

An analysis was undertaken to identify the barriers that were experienced by the participants, such as side effects and other general barriers, such as social gatherings and social stigma. An analysis was also undertaken to identify the

participants who had high and low self-efficacy about their ability to manage their disease.

5.4.3.1 Fear of hypoglycaemia

Hypoglycaemia occurs when blood glucose levels fall below 4 mmol/L. In this study, there was a common belief among some participants (n=14; one-third of the sample) regarding hypoglycaemia. The participants believed that if they missed their meal/snack or even had a light fat and sugar meal, such as portions of fruit, yogurt and salad, they would definitely get hypoglycaemia, without checking their blood glucose levels or experiencing any symptom. This kind of belief had an impact on the participants' medicine-taking behaviour. The participants reported omitting doses of insulin and/or OHAs as a consequence of this belief:

> *"The doctor prescribed me Glucophage* [metformin 500 mg tablet] *three times a day but I take it once only. This is because I usually have coffee and biscuits in the morning and go to the gym. Also, at night I just have a light dinner, and have the Lantus* [long-acting insulin] *at bedtime. So, if I take it* [metformin tablet] *three times, I'm afraid that my* [blood] *glucose* [level] *will fall down very much."*
> [Participant 5, male, age 67 years]

> *"As for the Glucophage* [metformin 500 mg tablet]*, I take it only twice instead of three times a day because I don't eat much for lunch. I sometimes cancel the Lantus* [long-acting insulin]*, especially if I miss my dinner or just have an apple because I worry from getting hypoglycaemia while sleeping."*
> [Participant 23, female, age 72 years]

> *"I take the rapid one* [insulin; Novomix 30] *at morning and afternoon, and the slow one* [insulin; Lantus] *at night. Sometimes, when I wake-up late and miss breakfast, I just cancel the morning dose."*
> [Participant 31, female, age 40 years]

Hypoglycaemia is a common problem to patients using insulin, or some types of OHAs such as sulphonylureas, e.g. chlorpropamide and prandial glucose regulators, e.g. repaglinide. Patients using these treatments should monitor their blood glucose levels regularly to help adjust their doses. As for insulin-dependent patients, the appropriate dose and time for insulin administration depends on the individual response, food intake and physical activity. Omitting an insulin dose because of missing a meal without monitoring blood glucose level could lead to hyperglycaemia and uncontrolled blood glucose levels. Sometimes, blood glucose levels rise even when the patient has not eaten. For example, blood glucose levels can be high in the morning because of taking little insulin in the previous evening or due to Dawn Phenomenon, a state of increased blood glucose level in the morning due to secretion of specific hormones, such as cortisol, glucagon and epinephrine. Therefore, patients should use insulin in a way that suits their daily routine and is in

line with their doctor's guidelines (ADA, 2015). In addition to the participants' fear of hypoglycaemia, they lacked the awareness about how their medicines work, where they had specific practices and behaviours that were inconsistent with their doctors' recommendations. For instance, the participants neglected their long-acting insulin dose because they did not know that it should be taken to regulate their blood glucose levels for the next 24 hours, and that it was not related to food intake (ADA, 2015). In addition, the participants did not take their metformin doses when they missed their meal or had light meals to avoid hypoglycaemia because they lacked the awareness that metformin does not cause hypoglycaemia, unless it was combined with insulin or another hypo-causing OHA (BNF, 2015). As a result, the participants were complaining from uncontrolled blood glucose levels:

> *"I didn't take the Lantus* [long-acting insulin] *yesterday because I slept without eating dinner, I woke-up this morning and it* [blood glucose level] *was high. When I took my breakfast, it increased."*
> [Participant 23, female, age 72 years]

5.4.3.2 Ramadan fasting

Twenty three participants (nearly half of the sample) reported that fasting during the day and reducing the number of meals from three to two daily, would expose them to hypoglycaemia regardless of the amount and type of food they had in their meals and snacks. The fear of hypoglycaemia during Ramadan fasting affected the participants' medicine-taking behaviour. Of the 43 participants, some (n=11) followed their doctors' recommendations based on Islamic instructions, which allow patients with chronic diseases, such as diabetes, not to fast in Ramadan and thus can take their doses as usual:

> *"I use my medicines as usual in Ramadan because I can't fast as I have to take insulin 5 times a day. The doctor insists that I should not fast since I am on insulin 3 times a day."*
> [Participant 9, female, age 65 years]

The remaining 32 participants fast in Ramadan, from which 12 ignored their doctors' advice about not fasting. The participants added that they had religious beliefs in the benefits of fasting in Ramadan on their overall health, since it is one of the five fundamental pillars of Islam. In Ramadan, people refrain from food and drinks from dawn to sunset, and the duration of fasting may range from 12 to 18 hours, which makes taking medicines challenging, especially for patients who require three doses or more per day (Meo and Hassan, 2015). Also, if doses of OHAs or insulin were not changed during Ramadan, severe hypoglycaemia could occur (Salti et al., 2004).

Therefore, patients with diabetes should consult their doctors about their medicine use in Ramadan. In this study, the results revealed that of the 32 participants who fast Ramadan, some (n=19) used their medicines according to their doctors' recommendations. Those participants either re-scheduled their doses by taking them during the free access hours at night or omitted doses based on their doctors' advice. For instance, the participants explained that they took their morning doses immediately after *Iftar (sunset time)*, afternoon doses between *Iftar* and *Suhoor (before dawn)*, and the evening doses at *Suhoor*:

> *"In Ramadan, I take Amaryl* [glimepiride 1 mg table] *after Iftar, and Glucophage* [metformin 500 mg tablet] *twice (after Iftar and after Suhoor) instead of three times. I do this because I don't eat a snack between Iftar and Suhoor, and if I take it* [metfromin 500 mg tablet] *without a meal it causes a stomach pain. The doctor knows about it* [metformin dose omission]."
> [Participant 3, female, age 56 years]

> *"In Ramadan, I re-schedule my doses. I take Glucophage* [metformin 500 mg tablet] *three times a day: one after Iftar* [the morning dose], *one after a snack* [the afternoon dose] *and one after Suhoor* [the night dose]. *Januvia* [sitagliptin 100 mg tablet], *I take it once after Iftar* [the morning dose].*"*
> [Participant 4, female, age 60 years]

The other participants (n=13; one-third of the sample) changed their medicine-taking behaviour without consulting their doctors. Reviewing the interview transcripts of those participants revealed that fear of hypoglycaemia and the belief in becoming hypoglycaemic due to eating fewer meals per day without monitoring blood glucose levels to confirm hypoglycaemia, led to omitting doses of their OHAs and/or insulin:

> *"In Ramadan, I take all my medicines* [Lantus, Actrapid, and metformin 1000 mg tablet] *together at Iftar time. Because at Suhoor I don't eat too much, I just have yogurt and fruit. So, if I took my doses* [second doses of Actrapid and metformin]. *with this meal I would get hypoglycaemia."*
> [Participant 10, male, age 58 years]

> *"In Ramadan, I take Lantus* [long-acting insulin] *before I go to bed, and I stop taking the rapid one* [Humalog; rapid-acting insulin], *because I don't eat much food during Ramadan, and if I take it* [3 doses of Humalog], *it may cause hypoglycaemia."*
> [Participant 13, female, age 61 years]

> *"In Ramadan, I take Glucophage* [metformin 1000 mg tablet] *after Iftar and Suhoor, Actos* [15 mg tablet] *after Iftar, and Lantus* [long-acting insulin] *after Suhoor. I stop taking Januvia* [sitagliptin 100 mg tablet] *in Ramadan because I worry about hypoglycaemia."*
> [Participant 24, male, age 58 years]

> *"In Ramadan, I take Glucophage* [metformin 1000 mg tablet] *twice a day, after Iftar and Suhoor instead of three times because I only eat two meals. I stop taking Januvia* [sitagliptin 100 mg tablet] *because I eat a light Suhoor, and I think Glucophage* [metformin 1000 mg tablet] *is enough to maintain* [glycaemic] *control."*
> [Participant 27, female, age 56 years]

In addition to fear of hypoglycaemia because of Ramadan fasting, it was noticed that the participants had poor nutritional awareness. They believed that fasting and eating fewer meals would expose them to hypoglycaemia, without taking into consideration the amount and nutritional contents of the meals, e.g. carbohydrates, fat and sugar. Carbohydrates have the greatest effect on blood glucose levels (Warshaw, 2005). This lack in nutritional awareness makes the participants convinced that they eat less in Ramadan, are more exposed to hypoglycaemia and that they do not require taking their doses as usual.

All the behaviours reported by the participants during Ramadan, e.g. ignoring the doctor's advice about not fasting, fear of hypoglycaemia and omitting doses of OHAs or insulin without checking blood glucose levels and consulting doctors could be serious and may lead to serious complications. Alteration of doses without consulting doctors was associated with severe glycaemic complications, such as hypo- or hyperglycaemia (Salti et al., 2004). During Ramadan fasting, many hormonal changes occur including insulin hormone. As glucose levels tend to fall, the secretion of insulin decreases, and glucagon increases leading to breakdown of glycogen and augmentation of gluconeogenesis. In the case of patients with diabetes, the secretion of insulin is disrupted by the underlying pathophysiology and the pharmacological agents that enhance insulin secretion. In the case of patients with severe insulin deficiency, extended fasting hours with the absence of adequate insulin results in excessive breakdown of glycogen and enhanced gluconeogenesis and ketogenesis, in which hyperglycaemia and ketoacidosis can occur (Meo and Hassan, 2015). Rapid-acting insulin is the mealtime insulin and its action curve mimics the human normal insulin secretion at mealtimes; it acts within 5-15 minutes with overall duration of about 3-4 hours. Glucose levels start to rise in the blood within minutes of starting to eat and peak within 1-2 hours from eating the meal (BNF, 2015). Omitting rapid-acting insulin dose or stopping to take it could lead to sharp increase in blood glucose levels and hyperglycaemia. Patients should take their insulin dose that matches the type and amount of carbohydrates they eat (Warshaw, 2005).

To identify the impact of the participants' behaviour during Ramadan on health outcomes, further examination of the interview transcripts was undertaken. It was found that of the 13 participants who do not use their medicines properly in Ramadan, ten had high HbA1c levels (>7.5%). Information about hospital admissions were also obtained during the interviews. Of the 13 participants, three reported that they had needed emergency hospital admissions due to diabetes complications, in which they were managed and discharged at the same day. In addition, records on hospital admissions due to hypoglycaemia or ketoacidosis were observed. According to the latest statistics, no cases of hospital admissions were recorded during Ramadan (Amiri Hospital Statistics, 2013). Overall, in addition to the impact of poor awareness about medicines actions and about nutrition and the fear of hypoglycaemia on medicine-taking behaviour, the lack of immediate clinical effect and harm on patients' health could also motivate the participants to continue their poor medicine-taking behaviour during Ramadan. Feeling normal despite of poor medicine-taking behaviour was likely to allow the participants to downplay the severity of such behaviour or perceiving it as a good behaviour.

5.4.3.3 Side effects: stomach pain, nausea and dizziness

The entire sample except 11 participants reported that they had experienced side effects. Part from side effects of insulin, which are discussed in next chapters, the participants reported stomach pain and nausea from metformin tablet and dizziness from other OHAs, such as sitagliptin:

> *"I couldn't withstand Glucophage* [metformin 850 mg tablet]*, it caused me a stomach pain even when I took it after meals, and I felt nauseas all the time."*
> [Participant 1, female, age 40 years]

> *"Glucophage* [metformin 1000 mg tablet] *causes bloating and stomach pain. Januvia* [sitagliptin 100 mg tablet] *makes me dizzy all the day."*
> [Participant 27, female, age years]

Experiencing side effects had an impact on the participants' medicine-taking behaviour. Of the 14 participants who reported side effects, such as stomach pain and dizziness, 8 were not taking their medicines properly. Some participants (n=4) reported omitting doses of their OHAs to become less exposed to their side effects, while others (n=4) reported stopping taking the medicine without consulting their doctors:

> *"I was taking Glucophage* [metformin 500 mg tablet]*, but I stopped it for a while. I felt tired when I was taking it because it caused me stomach pain."*
> [Participant 2, female. Age years]

> *"I sometimes take Glucophage* [metformin 1000 mg tablet] *once a day instead of twice, and sometimes I don't take it for some days. It causes a stomach pain."*
> [Participant 26, female, age years]

5.4.3.4 Irregular daily routine, forgetfulness and social stigma

General barriers to adherence that were reported by some participants (n=14) were forgetfulness, change of daily routine, social gatherings and social stigma. Experiencing those barriers had an impact on the participants' medicine-taking behaviour and led to misuse of their medicines:

> *"When I'm at home, there is no problem* [in taking medicines]*, but if I'm outside with my friends, I don't prefer to take my medicines* [doses]*. Also, sometimes I forget to carry my medicines with me, so I wait till I arrived home and take them, and sometimes I forget to do so."*
> [Participant 15, male, age 35 years]

Experiencing barriers, such as change of daily routine and social stigma was an important determinant of medicine-taking behaviour in this study. Examining the interview transcripts of the participants who did not perceive such kind of barriers revealed that 21/29 participants were using their medicines properly, while nine participants of the 14 who reported such barriers had poor medicine-taking behaviour:

> *"I feel embarrassed taking my injection in the presence of people…when I'm invited to a dinner or a wedding party, I don't carry it* [the injection] *with me, and I wait until I get back home and take the rapid one* [NovoRapid; rapid-acting insulin]*. I usually cancel the Lantus* [long-acting insulin] *that night because I take the rapid dose very late."*
> [Participant 22, female, age 64 years]

5.4.3.5 Lack of belief in the ability to manage diabetes

Of the 43 participants, 11 (one-fourth of the sample) were not confident of their ability to manage their diabetes:

> *"I feel very tired; my* [blood] *glucose* [level] *is always high although I don't eat much! When I take the tablets* [metformin 850 mg]*, I have nausea and stomach pain. The doctor's increased the Actrapid* [rapid-acting insulin] *dose for me. It was 15* [units] *then 30, now it's 60, and the* [blood] *glucose* [level] *is still high. I feel under stress; the* [insulin] *injections are three times a day! It's too much."*
> [Participant 25, female, age 58 years]

Self-efficacy was an important determinant of medicine-taking behaviour among the study participants. All the participants, with the exception of three, who disbelieved in their ability to manage their diabetes, did not use their medicines regularly:

"I feel that my diabetes is uncontrolled; it [blood glucose level] swings up and down. I don't know how to control it…Sometimes I take the injection [NovoMix 30; rapid-acting insulin], and when it's [blood glucose level] low, I take from my wife's pills [metformin tablet 500 mg]."
[Participant 7, male, age 85 years]

Examining the interview transcripts of the three participants who were using their medicines regularly despite their low self-efficacy revealed that other factors, such as social support helped them manage their diabetes:

"When I was on tablets only [metformin 500 mg and gliclazide 80 mg], I didn't have any problem, everything was OK. But the injections [Novorapid; rapid-acting insulin] are annoying. I can't take them myself; they're difficult to carry and are painful…My daughter helps me administering my doses, and sometimes my husband."
[Participant 20, female, age 50]

On the other hand, participants who had high self-efficacy beliefs showed better medicine-taking behaviour than others with low self-efficacy. Of the 32 participants who had high self-efficacy managing their diabetes, the majority (n=21) were using their medicines regularly:

"I can fit my medicines within my daily routine; I have already balanced my life with my treatment…I take my medicines as prescribed by my doctor. If I change my doses, I'll worry about the effects of these changes…When travelling, the first thing I remember is my medicines; they're the first thing I put in my bag. On holidays, when I sometimes wake-up late, I re-schedule my doses and take them accordingly."
[Participant 24, male, age 58 years]

5.5 Health beliefs and other management behaviours

5.5.1 Health beliefs and SMBG

Self-monitoring of blood glucose is an integral component of diabetes self-management behaviour; it is recommended for all patients with diabetes to achieve target levels of glycaemic control and prevent hypoglycaemia. It provides information about the blood glucose levels at different times allowing to identify the more precise regimen that maintain a more constant blood glucose level and delay complications (Kirk & Stegner, 2010). Patients, particularly insulin-dependent, should use SMBG to help adjusting their dietary intake, physical activity and insulin doses to improve their daily glycaemic control, as they experience day-to-day inconsistency in blood glucose levels (Silva & Bosco, 2015). Regular SMBG may not indicate that patients are well adhered to their treatment, but it gives an indication about the commitment of patients to the management of their disease (Shams and Barakat, 2010). As for patients with type 2 diabetes, the frequency

varies depending on the therapeutic regimen and whether they are in the adjustment or target phase for glycaemic control. For example, for controlled patients using OHAs only, infrequent SMBG is appropriate, while insulin-dependent patients with type 2 diabetes should use SMBG at least 4 times per week (Farmer et al., 2008).

The interview transcripts were reviewed to assess the adherence of the participants to SMBG and examine the barriers for non-adherence. Of the 43 participants, 17 did not regularly monitor their blood glucose levels. To examine the factors that contributed to non-adherence, the interview transcripts were further analysed, and themes such as 'benefits' and 'barriers' emerged. The benefits theme was allocated to the participants who were aware about the importance of performing this behaviour, e.g. to identify cases of hyper- and hypoglycaemia and take appropriate responses towards them. Barriers theme was given to those who provided barriers to non-adherence, such as pain and fear of a high result.

5.5.1.1 Awareness about the benefits of SMBG

Of the 43 participants, 25 reported their awareness about normal blood glucose levels, what makes them hyper-/hypoglycaemic and how to take appropriate actions towards each case. For example, the participants reported reducing food intake, increasing physical activity, drinking plenty of water and adjusting insulin or taking correction doses in response to hyperglycaemia, while having some sweet, honey or juice in response to hypoglycaemia. However, it was noted that awareness about the benefits of SMBG was an important determinant to adherence to this management behaviour. Of the 25 participants who had good awareness, 15 (more than half) did regularly monitor their blood glucose levels:

> *"I monitor my* [blood] *glucose* [level] *once on a daily basis, but when I feel tired, I worry and monitor it 3-4 times a day. I hope to see it* [reading] *between 5-6* [mmom/L] *but I often see it 7* [mmol/L]. *When it's high, I watch my diet, and care more about taking medicines."*
> [Participant 3, female, age 56, OHAs only]

> *"I monitor the* [blood] *glucose* [level] *1-2 times a day………I noted when I eat too much, especially sweets, it becomes 8-9* [mmol/L], *but when I reduce the amount of food, it becomes normal…I usually get hypoglycaemia at the early morning; it falls to 4* [mmol/L]*………I feel shivering and sweating…I drink juice until it goes up…I told my doctor about this and he reduced the dose* [basal insulin dose].*"*
> [Participant 37, male, age 67 years, insulin pump]

> *"I monitor the* [blood] *glucose* [level] *8 times a day…I hope to see it between 5 and 6* [mmol/L]*…I often achieve this reading. Sometimes when it increases it just reaches 7-8* [mmol/L]*…Yes, I know why, it's when I have my dinner very late…If it becomes high in the morning, I take my dose as usual and keep monitoring, if this happens at night, I take a correction dose."*
> [Participant 38, female, age 49 years, insulin pump]

5.5.1.2 Perceived barriers to regular SMBG

Of the 43 participants, 31 reported barriers to regular SMBG **(Table 5.1)**. The most common barriers reported by the participants (n=15) were unavailability of test strips in the MOH, need of help, getting error readings, pain, and fear of high blood glucose level:

> *"My daughter bought the* [monitoring] *device for me but I gave it to another patient. I didn't know how to use it and I felt nervous about the needle. Also, I didn't use it because I didn't want to be shocked by the reading* [high blood glucose level]*."*
> [Participant 11, female, age 60 years, OHAs only]

> *"It's* [finger pricks] *annoying and painful. Sometimes I bleed."*
> [Participant 15, male, age 35, OHAs only]

In addition, some participants (n=7) reported that their non-adherence to SMBG was because of becoming aware about hyper- and hypoglycaemic events:

> *"I only monitor it* [blood glucose level] *when I feel it's high or low. When I feel that my* [blood] *glucose* [level] *is low, I eat something and then monitor it…I am aware when it's* [blood glucose level] *high or low. Also, I do the blood* [HbA1c] *test every 3 months, so I think this is enough."*
> [Participant 39, male, age 28 years, insulin pump]

However, although they reported similar barriers, such as pain and unavailability of test stripes in the MOH, 16 participants were regularly performing SMBG:

> *"I monitor the* [blood] *glucose* [level] *every day before and after meals…It's* [finger pricks] *painful and annoying, and causes stiffness to my fingers. Besides, I have to buy the* [test] *strips from private pharmacies, they're unavailable in the* [Ministry of] *Health, and they cost me 10* [Kuwaiti] *Dinars."*
> [Participant 1, female, age 40 years, OHAs + insulin pen]

> *"I monitor it* [blood glucose level] *3-4 time daily…it's* [finger pricks] *annoying, painful and leaves scars on my fingers.*
> [Participant 43, female, age 28 years, insulin pump]

Table 5.1: Barriers to regular SMBG as reported by the participants and their frequency

Barrier	Frequency
Pain	14
Finger stiffness	3
Stress from the result	3
Error readings	6
Fear of needle	1
Too much finger pricks	3
Bleeding	1
Complex	1
Unavailability of test strips in the MOH	4
Need of help	4
Awareness about hyper-and hypoglycaemia	7
HbA1c is enough	2
Forgetfulness	1

Perceiving barriers can be a strong determinant to non-adherence to regular SMBG. In this study, the majority of the participants (10/12) who reported no barriers regularly monitored their blood glucose levels. Examining the interview transcripts of the two participants who did not perform SMBG regularly although they had no barriers, revealed that they had poor awareness about good blood glucose levels or how to respond to hyper- and hypoglycaemia:

> *"I don't monitor it* [blood glucose level] *regularly.........I know that 6-6.5 is good; I usually achieve it...*[what do you do if you have not achieved your target?] *I do nothing...I don't feel upset because I take my medicine, and have my injection in the morning, I can do nothing."*
> [Participant 24, male, age 58 years, OHAs + insulin pen]

5.5.2 Health beliefs and lifestyle

Healthy diet helps to achieve glycaemic control, and regular physical activity helps the body to use the insulin efficiently (Colberg, 2008). According to the Clinical Practice Guidelines of Kuwait for diabetes, the diet of patients with type 2 diabetes should contain the minimum number of calories, which the normal person requires under similar conditions. As for patients who have to lose weight, a moderate reduction in calories of approximately 250-500 Kcal per day less than the average daily intake is recommended to lose 2-4 kg per month. Also, it is recommended in the guidelines to distribute the calories intake between carbohydrates (50-60%), Protein (10-20%) and fat (25-35%). Regarding the physical activity, the guidelines recommend that patients with type 2 diabetes should perform moderate-intensity aerobic physical activity (50-70% of maximum heart rate) at least 150 minutes per week (Al-Wotayan, 2011).

5.5.2.1 Diet

Most of the participants (n=35) except those who were using insulin pumps not follow the guidelines' recommendations for diet, e.g. counting calories/carbohydrates due to their poor nutritional awareness. Therefore, the analysis of the interview transcripts to examine the adherence to diet was performed according to the following classification:

- The participants who introduced changes in their diet, such as reducing fat and sugar in their food because of their disease and maintained this behaviour had good management behaviour (adherence to diet).

- The participants who reported that they ate as before they were diagnosed with type 2 diabetes had poor management behaviour (non-adherence to diet).

Of the 43 participants, 25 had good management behaviour, while 18 had poor management behaviour. To identify the factors that contributed to adherence to diet, the interview transcripts of the 25 participants were reviewed. The results revealed that awareness about the role of bad dietary habits in causing and increasing the prevalence of diabetes impacted the participants' behaviour (n=20) and led to introduce changes in their diet:

> "*It's the lifestyle* [which causes type 2diabetes]. *Nowadays, there is a chocolate shop between any two shops. We have an easy access to unhealthy food…Since I was diagnosed with diabetes, I have reduced the carbohydrates and sugar intake. I wish I could stop sugar at all.*"
> [Participant 3, female, age 56 years]

In addition to awareness about the importance of diet, perceiving benefits of adherence to diet also emerged as a contributing factor to good management behaviour. All the participants except four, reported that adherence to diet helped them to reduce their blood glucose levels and maintain glycaemic control, whether they maintained changes in their diet or not:

> "*At the beginning of the disease, it* [efficacy of medicines] *was ok, but now I feel that without diet, it* [blood glucose level] *doesn't go down even when I take my tablets regularly.*"
> [Participant 12, female, age 34 years]

Perceiving barriers to adherence to diet, such as food cravings, social gatherings and lack of social support were reported by 26 participants, from which 19 (about three-quarters) had poor management behaviour:

> "*If I eat at home, it's ok. I have told my wife to prepare specific food for me, but when I eat out with friends in the restaurants, or when we go to the chalet, I can't control my desire, so I eat whatever I like.*"
> [Participant 10, male, age 58 years]

Few participants (n=4) reported that they believed that their eating habits are enough for achieving and maintaining glycaemic control:

> *"I didn't change my diet; I love Kit Kat* [chocolate]; *it's always on me. Generally, I eat little, but I don't like to eat specified food or fat-free food, I like to eat whatever I want."*
> [Participant 21, female, age 65 years]

Overall, it was noted in this study that the participants lacked the nutritional awareness and perceived personal and social barriers to adherence to diet. Barriers were mostly mentioned in Ramadan, when people fast during the day, and eat *Iftar* with their family. At *Iftar*, the participants drink juices, which are high in sugar contents, and have dates and *Laban (yogurt drink)*. After that, they visit their relatives, where different kinds of desserts and savouries are usually offered. The late meal in Ramadan is *Suhoor*, which is eaten very soon before the start of fasting the next day. Some participants reported that they had light fat and sugar food, such as yogurt, fruit and salad for their *Suhoor*, while others reported that they ate food similar to their *Iftar*, which is rich in fat and carbohydrate count.

5.5.2.2 Exercise

In this study, 16 participants were performing the recommended level of exercise (150 minutes/week). The remaining 27 participants reported barriers to adherence to exercise. The most common reported barrier was co-morbidity followed by beliefs in the sufficiency of housework, lack of time and hot weather:

> *"I can't walk; I have had heart attack many times. When I walk, I easily get tired and start coughing."*
> [Participant 22, female, age 64 years]

> *"There are many things* [barriers] *in addition to the hot weather and laziness, I have many responsibilities-my house, family, and children…. They restrict me."*
> [Participant 24, male age 58 years]

Because it is common in Kuwaiti culture that women perform all the house chore, and that men are not expected to take part, some female participants (n=5) believed that house chore is sufficient for maintaining glycaemic control, and that they do not have to do any exercise:

> *"At the beginning* [of diagnosis], *I started walking but I stopped because I felt bored. I do the entire house chore myself, which I think is enough."*
> [Participant 13, female, age 61 years]

Few participants (n=4) reported social factors as a contributor to their non-adherence to exercise, such as lack of social support and social stigma:

"I feel that exercise is the most difficult part; our weather doesn't help. If I'd like to go to the gym, but I feel embarrassed. Nowadays, most of people who go to gyms are fit, and because of my weight I'll look different. Besides, most gyms are far from my house and with traffic is terrible, so I feel lazy to go."
[Participant 10, male, age 58 years]

"I feel that my life is disorganised, I'm divorced; my wife couldn't withstand my disease [diabetes]. *I am responsible for three daughters. I tried to walk but couldn't, because I can't leave my daughters alone. Sometimes, I told them to go and walk with me but they have homework, and I don't have any friends."*
[Participant 16, male, age years 47]

In addition to the mentioned barriers, there were other psychological factors that contributed to non-adherence to exercise. The participants were asked during the interviews about their beliefs in exercise, e.g. their perceptions about the role of sedentary lifestyle in increasing prevalence of type 2 diabetes, whether they perceived the severity of not exercising on their disease or whether they perceived the benefits of exercising on maintaining glycaemic control. Of the 43 participants, ten did not perceive sedentary lifestyle as a contributor to type 2 diabetes, and that it is caused solely by other factors, such as hereditary and stress. Most of the ten participants (n=6) who did not perceive sedentary lifestyle, as a risk factor for type 2 diabetes did not adhere to exercise:

"I don't know why diabetes increases, maybe from eating much sweet. Nowadays, in Kuwait we have lots of sweet shops. I have it [diabetes] *because of experiencing problems, sadness, fear and shock. I have had it since Saddam Husain* [the Ex-President of Iraq] *invaded us* [Kuwait] *twenty years ago...The doctor and my family advised me to walk but I always feel tired. I just do the house chore; I don't have time for walking."*
[Participant 28, female, age 66 years]

The belief about the benefits of exercise in maintaining glycaemic control was mentioned by most participants (n=38). However, this belief was not a strong determinant of the participants' behaviour, as the majority of them (n=27) did not exercise due to experiencing barriers:

"The changes [diet and exercise] *are much helpful; I felt much better when I joined the gym, but now I can't move. I have pain in my back and legs, hypertension and diabetes."*
[Participant 11, female, age 60 years]

5.6 Main findings

- When participants' adherence and beliefs about medicines were assessed using MMAS-8, BMQ-S and semi-structured interviews, there were some inconsistencies in data obtained from each method. However, using semi-structured interviews allowed to obtain a comprehensive data that meet the study objectives, as they included open questions, e.g. tell me what you did? why did this happen? what changes do you apply to your treatment during weekends and travelling? do you think your medicines are helpful?, where the participants were able to provide rich information about their views and experiences with medicine use. Unlike MMAS-8 and BMQ-S, where the responses are rigid, e.g. yes, no or categorised into a Likert scale. This also enabled the researcher to gain a complete picture about factors that impacted health behaviour and to identify different practices and behaviours, while with questionnaires, reasons behind particular behaviour were difficult to explore **(Section 5.1)**.

- Several factors that impacted the participant's management behaviours (medicine-taking behaviour, SMBG and lifestyle) were identified in this study. In addition, it was identified which factors were more significant predictors of participants' health behaviour. For example, the most influential determinants of medicine-taking behaviour were lack of awareness about diabetes complications and minimising its seriousness followed by beliefs in efficacy/safety of herbal medicines, self-efficacy, lack of awareness about how medicines work, perceiving barriers, such as, fear of hypoglycaemia, side effects (e.g. stomach pain) and social stigma and beliefs about necessity/efficacy of medicines **(Section 5.4)**.

- Lack of awareness and beliefs of the participants affected the management of type 2 diabetes and the health outcomes as a consequence to poor participants' management behaviours. For instance, lack of awareness about how medicines work and fear of hypoglycaemia led to omitting doses without consulting doctors, beliefs in efficacy and safety of herbal medicines led to abstaining from medical treatment, lack of nutritional awareness (e.g. carb counting) led to following poor diet and beliefs in the sufficiency of housework in maintaining glycaemic control led to abstaining from exercise **(Section 5.4, 5.5)**.

- In addition to the participants' specific beliefs, there were cultural factors that contributed to poor adherence to medicines, diet and exercise, such as social gatherings and social stigma. For instance, some participants, especially who were socially active and did not prefer to take medicines in front of others, were omitting their doses if they were not at home at the time of the doses **(Section 5.4, 5.5)**.

5.6.1 Contribution of this chapter to this study

- This chapter enabled the researcher to identify the key issues regarding the participants' non-adherence, designing a list of these issues and assessing their importance from the perspectives of HCPs **(Chapter 8, Figure 8.1)**.
- By identifying gaps in participants' knowledge and health awareness, this chapter helped in constructing a list of recommendations **(Chapter 8, Section 8.1.1-8.1.7; 8.1.9-8.1.10)** that are crucial for improving health behaviour of patients with type 2 diabetes.
- Examining the practicality of these recommendations from the perspectives of HCPs helped to inform evidence-based policy **(Chapter 8, Section 8.2)**.

5.6.2 Contribution of this chapter to the literature

- In the context of the management of type 2 diabetes in the Middle East, this chapter helped in identifying the most influential determinants of patients' management behaviour as perceived by patients. Also, this chapter describes the most significant predictors of patients' health behaviour using the HBM as a conceptual framework through qualitative methods (semi-structured interviews) **(Chapter 9, Section 9.2.1)**. This is crucial in order to design targeted educational interventions based on a chronic disease care model and to identify valuable ways for healthcare provision and resources utilisation **(Chapter 8)**.

Chapter 6: Management of type 2 diabetes with insulin injections (syringe/vial and pens)

As this study aims to inform policy and healthcare provision, in order to improve management of type 2 diabetes and health outcomes, this chapter and the next one **(Chapter 7)** identify whether the use of insulin devices (pens and pumps), had a supplemental role in improving patients' medicine-taking behaviour and the disease management, in order to inform recommendations and guidelines modifications. This was performed by exploring the participants' experiences and perceptions about these devices.

Of the 43 participants, 34 were managing their disease with insulin with/without OHAs. Eight participants were using insulin pumps **(Chapter 7)**, and 26 were on insulin injections **(Figure 6.1)**. This chapter discusses the views and experiences of the participants (n=26) regarding the management of their disease with insulin injections, with particular consideration to insulin pen devices, as an option available for all patients with type 2 diabetes receiving treatment in secondary-care units in Kuwait. The chapter describes the participants' perspectives about the use of these devices compared to the traditional method of insulin delivery (syringe and vial), in terms of benefits, advantages, disadvantages, convenience, and the overall preference. Examining patients' views and experiences will assist in identifying whether insulin pens were an effective method for the management of type 2 diabetes in the context of patients' daily life. Results of this chapter will inform decisions for achieving better disease management and health outcomes.
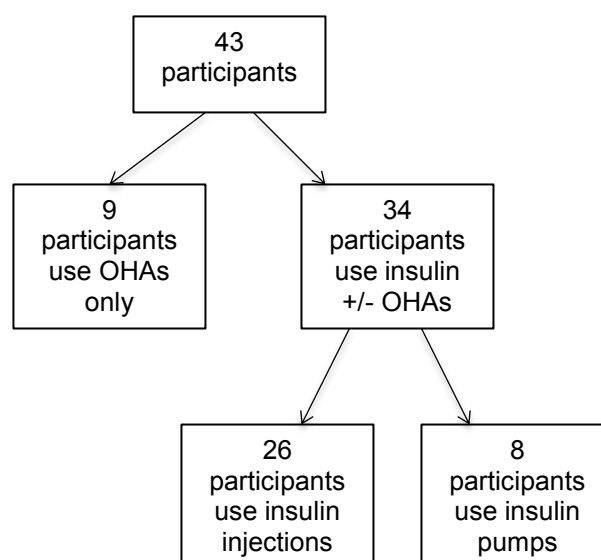
Figure 6.1: The number of participants using each treatment regimen

Participants using insulin injections in this study were classified into two groups: one group used both delivery methods of insulin (syringe and vial and the pen device); the other group had an experience in one delivery method only (either syringe and vial or the pen device). Participants who used both delivery methods were either converted from syringe and vial to the pen or vice versa. Participants who used one delivery method were initiated on that method and continued on it. **Table 6.1** shows the current and previous insulin delivery method used by the participants, and the duration of using the pen device.

Table 6.1: Current and previous insulin delivery method used by the participants

Participant	Mean HbA1c %	Previous insulin delivery method	Current insulin delivery method	Duration of using insulin pen (years)
1	7	S/V	Pen	1
5	7.5	S/V	Pen	3
6	7	Pen	S/V	-
7	7.5	S/V	S/V	-
9	14	S/V	Pen	10
10	7	S/V	Pen	3
13	8	Pen	Pen	4
14	4.7	Pen	S/V	-
16	14	S/V	S/V	-
19	11	Pen	Pen	1
20	7.1	S/V	S/V	-
21	7.4	S/V	Pen	8
22	8	S/V	Pen	3
23	9	S/V	Pen	3
24	9	S/V	Pen	4
25	13	Pen	Pen	3
27	12.8	Pen	Pen	8
28	7.7	Pen	Pen	1
29	9	S/V	S/V	-
30	8.8	Pen	Pen	15
31	7.2	Pen	S/V	-
32	8	S/V	Pen	1
33	7.7	S/V	S/V	-
34	8.8	Pen	Pen	3
35	8	S/V	Pen	2
36	10.7	S/V	Pen	3

*S/V= Syringe and vial, Pen= insulin pen

6.1 Reports of participants on overall glycaemic control and quality of life

6.1.1 Glycaemic control

To explore the benefits of insulin pens in achieving glycaemic control, the participants were asked during the interviews to describe their experiences concerning the overall glucose control and quality of life once they used insulin

pens. Of the 18 participants, 14 provided positive comments in terms of improving glycaemic control with insulin pens. This was manifested by an overall improvement in blood glucose levels compared to levels on their previous treatment regimen. Participants (n=11) who switched from the syringe and vial method, described their experiences about glycaemic control by comparing the two delivery methods (insulin pen versus syringe and vial), while some believed that other factors along with using insulin pens had contributed to their improvement in overall glycaemic control, such as adherence to diet and OHAs:

> *"When I started adhering to Glucophage* [metformin 850 mg tablets] *this month, I noticed that my* [blood] *glucose* [level] *became more controlled. Also, using the Lantus* [pen], *I feel that I can control my diabetes more."*
> [Participant 1, female, age 40]

> *"Before using* [insulin] *pens, I didn't adhere to my diet and I ate lots of chocolate and ice cream. Now I avoid all such sweets; I think that's why it's more controlled now with the* [insulin] *pen."*
> [Participant 9, female, age 65 years]

> *"Using* [insulin] *pens improved my life more than the traditional injections did; all problems which I used to face have been terminated. It* [insulin pen] *helped me to control my* [blood] *glucose* [level] *more, particularly, the Lantus* [pen]; *it has decreased my* [blood] *glucose* [level] *significantly."*
> [Participant 10, male, age 58]

6.1.2 Hypoglycaemic events

The participants were asked during the interviews to describe whether the use of an insulin pen had a role in reducing hypoglycaemic events. Some participants provided information about hyperglycaemic events as well. However, the participants reported conflicting results. Of the participants who were converted from the syringe and vial method (n=11), some (n=5) reported the same frequency of hypoglycaemia with both delivery methods; others (n=4) reported fewer events, while few (n=2) reported more hypoglycaemia on insulin pens **(Table 6.2)**. Regarding hyperglycaemia, the participants (n=5) reported less hyperglycaemic events with insulin pen, while some (n=4) reported the same frequency of hyperglycaemia with both delivery methods:

> *"Hypoglycaemic and hyperglycaemic episodes have significantly been reduced since I started using* [insulin] *pens. Approximately, I experience one episode in two months, but when I was using the traditional injections* [syringe and vial], *I experienced hypoglycaemia and hyperglycaemia. Now, with the* [insulin] *pens, it's* [blood glucose level] *more accurate."*
> [Participant 10, male, age 58]

"Before using the [insulin] *pens, I experienced hypoglycaemia a lot; I felt weak and shivered. As I was monitoring my* [blood] *glucose* [level], *I found it 70* [mg/dL]. *Now, it's* [frequency of hypoglycaemia] *reduced. Also, I experienced hyperglycaemia several times when I was using the* [traditional] *injections* [syringe and vial]. *After using the* [insulin] *pens, it's* [blood glucose level] *much better."*
[Participant 23, female, age 72]

Table 6.2: Frequency of experiencing hypo-/hyperglycaemic events on insulin pens by the participants, compared to syringe and vial

Frequency / Event	Less	More	Same
	No. participants		
Hypoglycaemia	4	2	5
Hyperglycaemia	5	-	4

From the participants' reports, it can be concluded that using insulin pen had a role in reducing hypo- and hyperglycaemic events in some cases compared to syringe and vial. In few cases, the frequency of hypoglycaemia increased on insulin pen compared to syringe and vial.

Of the 7 participants who initiated on insulin pens, some (n=4) reported experiencing hypoglycaemia sometimes, and two rarely, while one participant reported no hypoglycaemic event, on the insulin pen period **(Table 6.3)**:

"I sometimes experience hypoglycaemia, especially when I miss a meal or go for a walk. I rarely have [blood] *high glucose* [level].*"*
[Participant 19, female, age 33 years]

"With the [insulin] *pen, I have never experienced hypoglycaemia. I always have hyperglycaemia even when I fast; I wake-up and find it* [blood glucose level] *12-15* [mmol/L].*"*
[Participant 34, female, age 68 years]

Table 6.3: Frequency of experiencing hypo-/hyperglycaemic events on insulin pen period

Frequency / Event	Sometimes	Rarely	Never
	No. participants		
Hypoglycaemia	4	2	1
Frequency / Event	**Always**	**Sometimes**	**Rarely**
	No. participants		
Hyperglycaemia	2	3	2

This indicates that the use of an insulin pen did not prevent hypo- and hyperglycaemia, as some participants who initiated on insulin pen were experiencing these events sometimes.

6.1.3 Awareness of hypoglycaemia

In addition, the participants were asked during the interviews to report whether the use of insulin pen helped them to be aware, or improved their awareness of hypoglycaemic events. Therefore, the researcher revisited the interview transcripts of all participants using insulin pens. From the 11 participants who were converted from the syringe and vial, some (n=6) reported an improved awareness about hypoglycaemia, while others (n=5) responded that they had not felt any difference in the awareness of hypoglycaemia between the two delivery methods. Reviewing the other participants' transcripts (n=7), who were initiated on insulin pens revealed that most participants (n=5) mentioned that whenever they experienced hypoglycaemia, they were aware about it **(Figure 6.2)**.

The 'awareness of hyperglycaemia' theme emerged in some interview transcripts. Of the 18 participants, 4 reported that using insulin pens improved their awareness of hyperglycaemia as well:

> *"When I started using the* [insulin] *pen, I monitored my* [blood] *glucose* [level] *frequently during the day, but now I'm aware when it's high or low. Many times when it is high, I feel dizzy, weak and I want to sleep. I also know when it's* [blood glucose level] *low although I feel dizzy as well, but I can differentiate between hypoglycaemia and hyperglycaemia."*
> [Participant 19, female, age 33 years]

> *"Since I started using the* [insulin] *pen, I have become aware of it is* [blood glucose level] *ups and downs. When I feel tired and nervous, I know it's low, whereas if I have headache and dizziness, I realise it high."*
> [Participant 22, female, age 64]
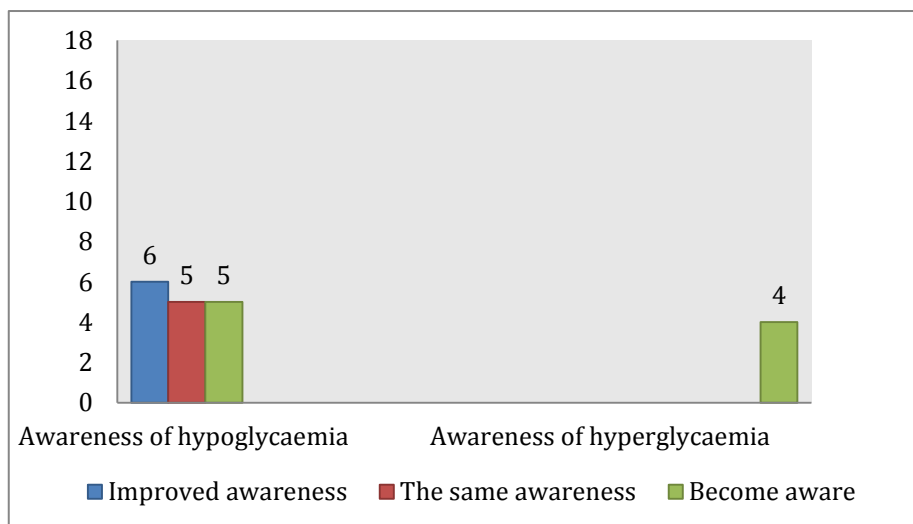
Figure 6.2: Number of participants and their awareness of hypo-/hyperglycaemia on insulin pens

6.1.4 Hospital admissions

To investigate the benefits of using insulin pens in terms of improving general health, the researcher asked the participants during the interviews whether they needed hospital admissions or urgent medical interventions due to diabetes complications. Reports on hospital admissions were also reviewed by the researcher, and correlated with data recorded in the participants' medical notes and obtained during the interviews. Of the 11 participants who were converted from syringe and vial to insulin pen, six did not perceive any difference in hospital admissions between the two delivery methods. The participants provided that they neither had been admitted to hospital before using insulin pen nor after using it. The remaining five participants reported that they required hospital admissions due to diabetes complications during the insulin pen period. Regarding the frequency of hospital admissions, three participants said that they required hospital admissions sometimes, while two participants reported one hospital admission only. This indicates that the use of insulin pen instead of traditional injections helped some cases (n=6) to avoid diabetes complications that require hospital admissions, while in other cases (n=5), the hospital admissions increased:

> *"I sometimes experience headache and dizziness, and when I go to the hospital they* [the doctors] *keep me in the observation room to give me* [intravenous] *a drip to reduce the* [blood] *glucose* [level]; *they discharge me the same day"*
> [Participant 35, male, age 28 years]

Regarding the participants (n=7) who initiated on insulin pen, all of them reported no hospital admissions. Two participants added that they had been admitted to the hospital due to severe hyperglycaemia and nephropathy before using insulin pen, when they were on OHAs only. This indicates that using insulin pen helped most participants (n=5) to avoid hospital admissions, and reduced it in few cases (n=2):

> *"Once I experienced severe hyperglycaemia, and I was admitted to hospital. This was before using insulin pen; when I was using tablets* only [metformin 850 mg and sitagliptin 100 mg]*."*
> [Participant 25, female, age 58 years]

Overall, although most participants (14/18) reported improved glycaemic control with insulin pens, episodes of hypo and/or hyperglycaemia were reported by all of them. Correlating data obtained from the interviews with HbA1c levels **(Table 6.1)** revealed that not all participants achieved the target goals. Data were consistent in 4 cases only; where the participant reported improved glycaemic control and had a normal HbA1c level (e.g. $\leq$7.5%). This could be because that the participants were comparing between their overall glycaemic control on insulin pens and their status

while they were using the syringe and vial, or before they were initiated on insulin, regardless of achieving target levels of HbA1c. Also, it could be that the participants were considering improved glycaemic control as a general improvement in their blood glucose levels, as manifested to them in SMBG, general health, or in their quality of life. To explore factors that affected the maintaining of good glycaemic control on insulin pens, the interview transcripts were reviewed, factors were identified, and are described in **Section 6.2**.

6.2 Factors affecting the achievement of glycaemic control on insulin pens

Analysing the information obtained from the interviews revealed that reasons for experiencing hyperglycaemia among the study participants ranged from lifestyle to inappropriate treatment regimen **(Table 6.4)**. Non-adherence to diet and exercise was the predominant cause of hyperglycaemia identified by most participants. Most participants mentioned that eating sweet, fat and rice particularly, raised their blood glucose levels; others found that even having few portions of fruits increased their blood glucose levels, while some participants noticed that eating a large meal very late at night caused hyperglycaemia to them. However, some participants added that culture and traditional norms, which impose them to eat with family and to be engaged in lots of social gatherings, were responsible for non-adherence to diet, and eating as normal persons who do not have diabetes. Other participants found that the bad weather most of the year hindered them from practising exercise and walking:

> *"I always try to change my dietary habits, but it changes according to circumstances. For instance, if at home, I ask my wife to cook a special meal for me, which is low in fat and sugar. However, if I eat outside, where lots of temptations are available, it's difficult to control my appetite. I noticed that starchy food, sugar and fat increase my* [blood] *glucose* [level]…*I usually spend my holidays in Europe, when I go there I walk a lot, from day to night. The weather is good and many people usually walk there, which encourages me to walk. I noticed that my average* [blood] *glucose level decreases during holidays, although I used to eat a heavy breakfast in the hotel."*
> [Participant 10, male, age 58]

In cases where stress was identified as the contributing factor for hyperglycaemic events, the participants clarified that although they had adhered to diet and treatment, their blood glucose levels increased in particular situations, such as sadness, anger, or worrying:

"I found that sometimes, when I was tired, my [blood] glucose [level] increased even if I was taking my treatment, and it stayed high until I cool down. Nowadays, because I'm experiencing a bad mood due to my son's death, I always feel tired, dizzy, and numbed. I also experience headache, and blurred vision most of the time and when I monitor it [blood glucose level], I find it high. Once it is controlled, all these symptoms disappear."
[Participant 32, female, age 42]

"Psychological factors play an important role in increasing my [blood] glucose [level]. I'm this kind of person who usually worries, and gets angry easily. Sometimes, my [blood] glucose [level] goes up even if I eat nothing, and take my doses as prescribed; that happens when I am angry or worryied about something."
[Participant 36, female, age 51]

Hyperglycaemia was also common among participants who did not adhere to their treatment regimens as prescribed, such as taking insulin only and missing OHAs.

Also, in this study, some participants were experiencing hyperglycaemia due to an inappropriate treatment dosage/regimen:

"Yesterday, I didn't take my injection at night because I only had an apple for dinner. When I woke up this morning and it [blood glucose level] was high. It even got higher when I had my breakfast."
[Participant 23, female, age 72]

"Medicines [OHAs and insulin] were effective, but for some time, it [blood glucose level] it has become always high, the doctor therefore prescribed an extra injection for me to take before lunch."
[Participant 28, female, age 66]

"I was on Glucophage [tablets] only, and my [blood] glucose [level] was good, the best ever. Once I had been admitted to the hospital, they [doctors] gave me insulin and discontinued Glucophage [tablets]. Also, when I had been discharged, they [pharmacists] dispensed insulin [pen] only to me, without Glucophage [metformin 850 mg tablets]. Then, my [blood] glucose [level] started to increase and became high. I told my doctor during my clinical visit, and he added it [metformin tablets] to me again. Now, 'thank God', my [blood] glucose [level] is good and my diabetes is better controlled."
[Participant 34, female, age 68]

Table 6.4: Reasons for experiencing hyperglycaemia on insulin pens, and their frequency

Reason	Frequency
Non-adherence to diet	14
Inadequate physical activity	5
Stress	4
Infections	2
Non-adherence to treatment (OHA or insulin)	3
Inappropriate dosage/treatment	5

However, there were other factors, which could contribute to hyperglycaemic events among the study participants, such as thyroid diseases (n=4), pregnancy (n=2), acute asthmatic attacks (n=2), and postmenopausal period (n=1).

In addition to hyperglycaemic events, some participants mentioned that they experienced hypoglycaemia as well. Reviewing the interview transcripts, especially to identify reasons for experiencing hypoglycaemic events was undertaken. The participants raised a variety of reasons **(Figure 6.3)**, such as missing snacks or a meal (n=4), avoid eating sweet (n=1), performing hard work (n=2), sport, e.g. spending long time in the gym (n=2), insomnia (n=1), and experiencing an accident, e.g. son's death (n=1). Interestingly, one participant mentioned that she was experiencing hypoglycaemia since she started to eat large portions of *Jujube* fruit:

"I have been experiencing hypoglycaemia for two months. I noticed that now I'm eating 'jujube' [fruit] *a lot, I like it. Maybe it's the reason behind the reduction in my* [blood] *glucose* [level]. *I also noticed that even when I had a fatty dinner and sweet at night, I woke up in the morning and it* [blood glucose level] *was below 4* [mmol/L]. *I once woke up and was shivering and sweating, and when I checked it* [blood glucose level], *I found it below 4* [mmol/L]. *Even my average blood glucose level* [HbA1c], *started to decrease to 8* [%]*."*
[Participant 13, female, age 61]

"I usually experience hypoglycaemia, especially when I take my morning [insulin] *dose, and work hard after that. For example, I once, while travelling by car, I took the insulin* [dose] *in the morning; I felt tired, cold, and sweaty. When I checked it,* [blood glucose level] *it was low."*
[Participant 24, male, age 58]

"It [blood glucose level] *5-7* [mmol/L] *in the morning. I experience hypoglycaemia if I take my morning* [insulin] *dose, and have some work to do outside, or an appointment, especially if I miss breakfast. I also experience hypoglycaemia in the afternoon if I avoid eating for a long time."*
[Participant 30, female, 63]
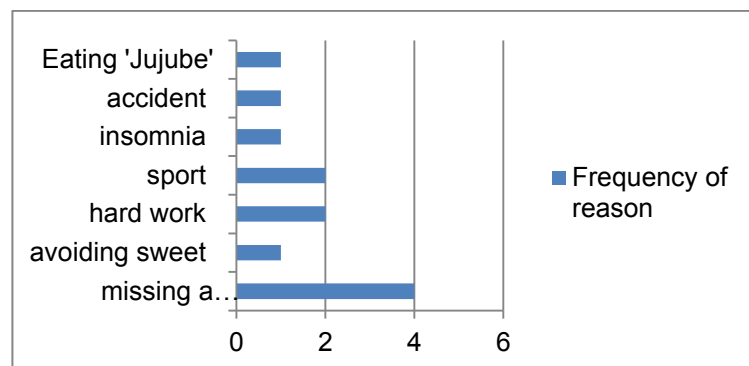
Figure 6.3: Reasons for experiencing hypoglycaemia on insulin pens, and frequency of reporting them

Although most participants in this study commented positively, during the interviews on the benefits of using insulin pens in terms of glycaemic control and awareness of hypoglycaemia, there were difficulties in maintaining good metabolic control at all times, and episodes of hypo-/and hyperglycaemia were common. Factors contributing to hyperglycaemic events on insulin pens ranged from lifestyle factors to inappropriate dosage or treatment regimen, while cases of hypoglycaemia were common when the participants were missing a snack or a meal, and when they were performing works that consumed their energy. The next section **(Section 6.3)** describes the participants' views and experiences about the benefits of using insulin pens in terms of usage, transporting, problems, and preference.

6.3 The impact of using insulin pen on patient's life

6.3.1 Ease of use, portability, and convenience of the pen

<u>Ease of use</u>

From the 18 participants who were using insulin pen in this study, 12 reported that it was easy to learn how to use the pen device. The participants identified that once they were prescribed the pen, they were taught how to use it by the doctor, pharmacist or the nurse, and then, when they tried it alone, they experienced no difficulties. For the remaining participants, there were some difficulties at the beginning of using the pen. One participant added that he needed to visit the nurses several times until he learned the correct pen use. However, to investigate what difficulties did the participants experience and why, the researcher reviewed the interview transcripts particularly for that reason. It was found that the most frequent difficulty experienced by the participants (n=5) was 'bent needle'. The participants explained that when they placed the needle into their skin to inject their dose, it bent, and the insulin dose could not be delivered and remained in the reservoir. The participants added that they solved the problem by changing the pen needle. Experiencing such problem could be due to an inaccurate injection technique, as it is recommended to hold the pen perpendicular to the skin, at 90-degree angle, and to gently press the needle into skin:

> *"When I started using the* [insulin] *pen, every time I wanted to take my dose, it* [the pen] *didn't work properly, and I didn't get the dose. Firstly, I thought that there was something wrong with the* [insulin] *pens. I therefore threw them after each unsuccessful try. Then, I tried to check it. I noticed that it didn't work because the needle was bended. So, I became more careful to place it* [the needle] *straight into my skin; it worked then. My sister had the same problem as well, and I taught her how to do it."*
> [Participant 9, female, age 65 years]

Although there were some difficulties at the beginning of using the pen, eventually, all the participants (n=11), who were converted form the syringe and vial agreed that using insulin pens was more comfortable, much easier, and better. To investigate factors that contributed to the pen's ease of use, the interview transcripts were reviewed, and the factors were identified **(Table 6.5)**.

Table 6.5: Factors that contributed to the pen's ease of use, and their frequency

Factor	Frequency
Involves less steps (e.g. save time, less complex)	**12**
No need to remove air bubbles	**5**
No need to prepare the dose (mixing two types of insulin)	**2**
Dose could be administered easily (e.g. no need to visit the polyclinic)	**2**

Generally, the participants found the use of insulin pen easier because it involves less and simple steps. The participants explained that using the syringe and vial required removing the cap from the needle, withdrawing the dose from the insulin vial, paying attention for the correct dose in the unit marking of the syringe, removing air bubbles, and injecting the dose into skin. On the other hand, the use of pens required uncapping the pen, fitting the needle into the top of it, dialling up the dose, and injecting it. Many participants (n=5) mentioned discarding air bubbles as the most difficult step in using the syringe and vial, and that they found the pen easier because it helped them to avoid this step. However, although pen devices do not develop air bubbles, it is recommended to do an air shot (safety shot) by holding the pen with the needle pointing upwards, and pressing the injection button until a drop of insulin appeared (Luijf and DeVries, 2010). In this regard, only one participant mentioned that she was discarding air bubbles from her *NovoRapid* pen only, while she was using the *Lantus* pen without removing air bubbles. Two participants added that using the syringe and vial was more complex because they needed to mix two types of insulin (cloudy + clear) to prepare their doses, while with the pen, the dose was already prepared, and ready to inject. Although it was not a good practice, one participant added that he found the pen use easier because he was using the same needle for 3-4 days. Keeping the needle fitted into the pen between uses, and not changing it after each use could lead to the generation of air bubbles, and increases risk of contamination:

"Learning how to use the [insulin] *pen was very easy. It's* [pen use] *more comfortable than* [traditional] *taking injections* [syringe and vial]. *It doesn't need to remove air bubbles. Besides, I don't need to change the needle every day, I use it for 3-4 days."*
[Participant 5, male, age 67 years]

"It was easy to learn how to use the [insulin] *pen. It's easier than* [traditional] *injections* [syringe and vial]. *Using the* [traditional] *injections was horrible and annoying. I have to draw the drug* [insulin], *and get rid of air bubbles. Also, when I used the injections, I felt sloppy all the time, but with the* [insulin] *pen, I feel tidier."*
[Participant 21, female, age 65 years]

To some participants (n=2), the pen was easier and more comfortable because they could administer their doses themselves, while on the syringe and vial; they were visiting their local primary care unit each time they needed to take their doses, to get the help of a nurse:

"Since I started using the pen, I have realised that many times the insulin didn't go through. I used to throw the pens and use new ones each time, and I had to get extra pens. Now it is [using insulin pen] *became so easy; it's easier than using the traditional injections* [syringe and vial]. *It was tiring and time consuming; I had to go to the polyclinic to get it* [the dose]. *The* [insulin] *pen is better; I can use it myself. It's more convenient; I just need to place it* [the needle] *into my skin, wait for 10 seconds, and that's it."*
[Participant 23, female, age 72 years]

Of the three participants who were converted from the pen to the syringe and vial, two mentioned that using the pen device was much easier, due to involving less steps, and that they were annoyed for being converted to the traditional injections. Also, there was one participant who initiated on insulin pen and continued on it, but was able to compare between it and the syringe and vial, because she was taking care of her mother by administering her doses:

"The [insulin] *pen is much easier to use than the* [traditional] *injections* [syringe and vial]. *When I was first prescribed the pen, the nurse taught me how to use it, and it was OK. I found the use of* [insulin] *pen so easy as I gave my mother her doses by* [traditional] *injection, which was difficult. I learned how to use them* [traditional injections] *by the assistance of the nurse, who advised me to try it on an orange several times. So, I learned it very well. It's* [the use of syringe and vial] *time-consuming. I have to draw the drug* [insulin], *check the correct dose, eliminate air bubbles, and inject it* [dose] *carefully. But using the* [insulin] *pen, I only need to adjust the dose* [using the dosage knob], *and gently press the needle into my skin. It's simple."*
[Participant 27, female, age 56 years]

However, although one participant mentioned that the use of the pen device was much easier than using the syringe and vial, and that she learned how to use it from the nurse, she was not administering her doses alone, and she was seeking the

assistance of her daughter or the housekeeper. It was not identified why the participant was not administering her doses alone, but this could be because the participant was very obese, and experiencing pain due to spinal disc problems. Being very obese and having pain on movements could result in difficulties in reaching the body injection sites. Although that participant had ever used the syringe and vial, she had friends using that delivery method, thus, she was able to make the comparison:

> *"The nurse taught me how to use the* [insulin] *pen; it's easy. I taught my daughter and the housekeeper how to do it. If I had to use* [traditional] *injections, I think that no one at home would know how to use them, and give me my doses. It's* [using traditional injections] *difficult; my friends use them."*
> [Participant 34, female, age 68 years]

However, because it was not in the objective of this study, and was not discussed during the interviews, to compare between different types of insulin pens, only some participants (n=5) mentioned that using the disposable (prefilled) pens was much easier, in terms of adjusting and injecting the dose, and more comfortable, in terms of discarding the whole pen once it is finished instead of replacing the empty insulin cartridge with a new one.

Portability and convenience

To examine the participants' perspectives regarding the portability and convenience of the pen, and to investigate factors that contributed to these characteristics **(Figure 6.4)**, the researcher reviewed the interview transcripts. Regarding transporting the pen, most participants (n=11) found the pen suitable for transportation and travelling, while others (n=7) reported their annoyance from transporting insulin pens with them everywhere. However, although transporting insulin pens was troublesome to some participants, all of them were consistent in that carrying insulin pens was more comfortable and easier than transporting syringe and vial, in terms of carrying less items, and the simplicity of the administration of the dose. One participant mentioned that she was annoyed from carrying syringe and vial during travelling to the extent that she was avoiding taking insulin during that period, and was taking OHAs instead. Replacing insulin with OHAs could negatively impact on glycaemic control, and result in hyperglycaemia. However, the use of insulin pens improved the adherence of that participant to her insulin doses during travelling:

> *"It annoys me to carry the* [insulin] *pens in my bag everywhere, but it's OK compared to [traditional] injections. Carrying traditional injections* [syringe and vial] *was inconvenient, especially when travelling. When I used them, I avoided taking insulin and took* [anti-diabetic] *tablets during the travel period. "*
> [Participant 1, female, age 40 years]

In addition to carrying them, some participants mentioned storing of insulin pens, and the theme 'storage of insulin pens' was emerged in some interview transcripts. In this regard, most participants managed to store insulin pens in an icebox or a cooler bag/mug to keep them in a suitable temperature, while they were travelling or going outside. Only one participant reported that he had difficulties in storing insulin pens outside home, and keeping them in an appropriate temperature all the time:

> *"The* [insulin] *pen is difficult to store and transport. If I leave it in the car, it* [insulin] *lose its effect because of the hot weather. When I wanted to go to the chalet with my family or friends I put it in my pocket, but it became hot because the chalet is far away. Carrying* [traditional] *injections* [syringe and vial] *is inconvenient as I have to carry many items."*
> [Participant 10, male, age 58 years]

All the above mentioned characteristics, such as simplicity, ease of use, ready to use, and portability rendered administering doses outside home via the pen device to be more convenient than administering them using the syringe and vial. In this regard, most participants (n=13) mentioned that with insulin pens, they became able to administer their doses outside, while it was difficult with the syringe and vial, where they were either taking their doses earlier before going out, or delaying their doses until they arrived to the home:

> *"Using* [traditional] *injections* [syringe and vial] *was inconvenient. It* [using traditional injections] *involves many steps to prepare the dose (withdraw the dose, check the accuracy, discard air bubbles, and take more care with injecting). In the case of the* [insulin] *pen, the dose is already prepared, and it's easy to administer. I can even use it* [the pen] *outside. For example, today I came for my* [clinical] *appointment and I missed my morning* [insulin] *dose. Now I have to go to the 'Toilets' to take it* [the dose], *and then eat a sandwich."*
> [Participant 22, female, age 64 years]

In addition, some participants (n=3) identified that using the syringe and vial in public areas stigmatised them, as it could withdraw peoples' attention, and give the impression of a 'drug-user' or a 'dependant', while with the insulin pen, they were able to take their doses without attracting attention:

> *"The* [traditional] *injection* [syringe and vial] *is improper to use in public areas; you need to carry many items, in addition to the complex preparation of the dose. It involves many steps (removing the cap of the needle, drawing the dose from the vial, removing air bubbles, injecting the dose, and disposing of the syringe). It's time consuming. Also, you need to look for a proper place because you have to inject it very carefully. In addition, if you take it* [the dose via the syringe and vial] *outside, people could notice and think that you're a 'drug-user'. Using the* [insulin] *pen, I can inject myself even when I'm in a meeting without withdrawing peoples' attention. I administer my dose through the small aperture between my shirt buttons, as simple as that."*
> [Participant 9, female, age 65 years]

> *"Using the pen* [insulin] *is easier than using traditional injections* [syringe and vial]. *I can even take my doses while I'm waiting in the car. When I used traditional injections* [syringe and vial], *I couldn't take my doses outside; it attracted peoples' attention and I felt like taking 'drugs'."*
> [Participant 30, female, age 63 years]

Two participants mentioned that administering doses outside, via the pen was more convenient because it was safer, and that the chance for the needle contamination was greater with the syringe and vial:

> *"In the case of traditional injections, I never administered my doses outside, because the needle could easily be contaminated. Once you remove the cap of the needle, it takes time to draw the insulin* [from the vial]. *Besides, it needs to be disposed in a special container. Using the* [insulin] *pen, the dose is ready to inject; I just need to remove the cap of the needle and inject it directly."*
> [Participant 35. Male, age 28 years]

To one participant, the pen was more convenient for administering doses outside because it is 'unbreakable'. The participant explained that when he was using the syringe and vial, he experienced many times, where the vial fell off from his hands and smashed into pieces, in which he missed the lost dose:

> *"When I used the* [traditional] *injections* [syringe and vial], *and wanted to take my dose outside, I usually looked for a proper place, such as 'Toilets'. Many times, the vial fell off from my hands and broke into pieces, where I waited until I went back home to take my lost dose. The* [insulin] *pen is unbreakable and more convenient."*
> [Participant 10, male, age 58 years]
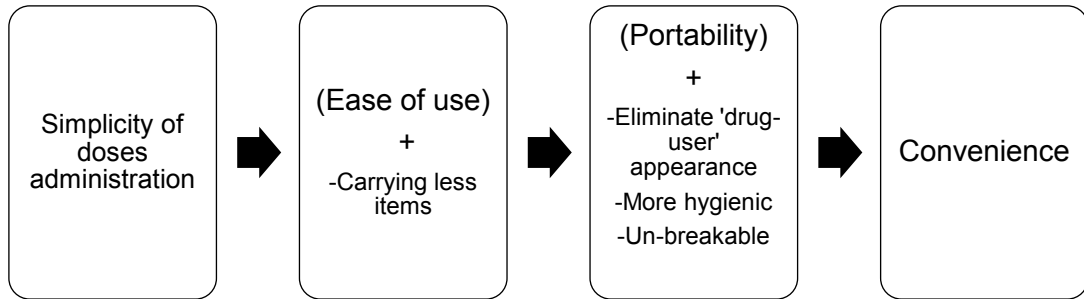
Figure 6.4: Factors contributing to the portability and convenience of insulin pens, as perceived by the participant

Therefore, the ease of use, and portability of the insulin pen made it more convenient for administering doses outside than using the syringe and vial. The convenience of using the insulin pen outside improved the participants' adherence to treatment, in which they were able to take their doses within the accurate time (Korytkowski et al., 2005).

6.3.2 Dosing accuracy and confidence

From the 18 participants in this study, 15 identified that they were confident about the accuracy of dosing with the insulin pen. Comparing with the syringe and vial method, some participants (n=10) found the pen device more accurate in delivering the required dose, and they were less confident in setting up their doses with the syringe and vial. This was because of the injection technique; some participants found that withdrawing their insulin dose using the syringe could not be completed without any error, and that it was difficult to withdraw the exact dose they required. Some participants (n=4) added that the size of the numbers listed in the syringe (which related to the units) was too small, so that, they had to take more attention for reading the accurate number. On the other hand, with the insulin pen, the numbers appear large and clear in the dose window, and all what the participants needed was to dial up their dose using the dosage knob:

> *"Using* [insulin] *pen, I don't have to worry much about how to take my dose. All what I need to do is to dial up the pen* [dosage knob] *on the* [required] *dose, and inject it."*
> [Participant 1, female, age 40 years]

"I have a visual impairment, and with the [traditional] *injections* [syringe and vial], *I suffered from reading the correct numbers* [dose units] *because they were very small. In the case of the* [insulin] *pen, numbers are big and clear."*
[Participant 24, male, age 58 years]

However, one participant reported conflicting response; she found that the syringe was more accurate in delivering the required dose than the pen:

"I doubt that the [insulin] *pen gives me the whole dose. When I used* [traditional] *injections* [the syringe and vial], *I noticed that all the insulin* [solution] *transfer from the injection* [syringe]. *In the case of the* [insulin] *pen, when I shake it after injecting my dose, I notice that a little* [insulin solution] *remains* [in the insulin reservoir], *and doesn't transfer into my body."*
[Participant 22, female, age 64 years]

Also, few participants (n=2) mentioned that sometimes the insulin pen included more than the dose that they required, but it was difficult to administer that dose using the same technique. One of these participants reported that he was obliged to throw the pen even if it had some insulin solution remaining, while the other participant mentioned that she used a syringe to withdraw the remaining insulin solution from the reservoir, and used it for her next dose:

"It is easy to dial up the dose with the [insulin] *pen, but sometimes I only need 20 units while the pen includes extra 5-10 units; they're difficult to administer. So, I throw the pen, lose the remaining dose* [insulin solution], *and use a new one. Many times I asked the pharmacists to dispense me extra pens because of that problem but they refused."*
[Participant 10, male, age 58 years]

6.3.3 Problems of insulin injections

6.3.3.1 Problems of pen devices

Although the MOH in Kuwait works toward providing patients with type 2 diabetes with the most advanced pharmaceutical products, such as insulin pens, data on their efficacy and safety is lacking. Therefore, it was important in this study to examine whether these devices are advantageous over traditional methods of insulin delivery, e.g. syringe and vial, and that they cause less problems. To this purpose, the researcher asked the participants during the interviews to report all the problems they experienced during the pen use period. The participants provided two main problems, e.g. pain and injection-site reactions. Participants who were converted from the syringe and vial method reported problems of insulin pens in comparison with problems they experienced previously, before using the pen. In addition, this section includes information from participants who were using syringe and vial method. This is because few of them were converted from the pen device,

so they had the experience of both insulin delivery methods. Also, to report problems of syringe and vial method, as perceived by the participants, in order to consider all the problems caused by both insulin delivery methods.

Needle anxiety and pain perception

Of the 18 participants in this study, 10 reported pain at the administration site after injecting their doses using the pen. The participants provided different perceptions ranged from a mild sting to a moderate pain, which was leading sometimes to a muscle cramps. Some participants added that they could withstand the pain and did nothing for it, others identified that they changed the injection site every time to avoid the pain, and used different body sites, such as thigh, belly, or the triceps. Some participants added that they felt pain only when they used large needles (6 mm), and that using short ones such as 2 mm needles did not cause any pain. Others noticed that injecting their dose in the belly caused less pain than other body sites. This could be because the belly is richer in fatty tissue especially in overweight or obese people. One participant commented that she was experiencing pain only at the beginning of using the insulin pen, and over time, she knew how to inject herself without causing any pain. The speed of injecting the dose could contribute to feeling pain at the administration site; the quicker the needle penetrates the skin, the less pain results:

> *"When I started using the* [insulin] *pen, I didn't like it because of the pain. Over the time, I knew how to take it* [the dose]. *I even feel no pain, and I accept it* [the insulin pen].*"*
> [Participant 19, female, age 33 years]

> *"The* [insulin] *pen sometimes causes pain, especially when they* [the pharmacists] *give me large needle (6 mm), but the small one (2 mm), I doesn't make me feel pain at all."*
> [Participant 27, female, age 56 years]

However, when comparing with the syringe and vial method, some participants provided that because the pen needle was shorter and smoother than the needle of the syringe, the pen device caused less (n=6) or no pain (n=8). As a result, some participants (n=5) added that the pen allowed them to use different body sites to inject their doses without feeling any pain, while they were injecting their doses only in the belly, when they were using syringe and vial:

> *"Using the* [insulin] *pen, I only feel a mild sting when I take it* [the dose]. *It usually* [the pain] *disappears when I stretch my skin. The* [traditional] *injection* [syringe and vial] *caused more pain; I only took it* [the dose] *in my tummy. In the case of the* [insulin] *pen, I can even take it [the dose] in my shoulders."*
> [Participant 32, female, age 42 years]

Overall, it was found that the factor, which contributed to less pain, or no pain on insulin pens was the short size of the pen needle. That characteristic of the pen device provided an advantage over the traditional injections by allowing some participants to use different injection body sites, which they were avoided due to fear of pain. However, factors contributed to experiencing pain on insulin pens in this study could be the injection technique, the injection site, and the diameter of the needle.

Injection-site reactions

From the 18 participants who were using the pen device in this study, 9 reported injection-site reactions, such as bruising. The participants added that their skin coloured red to blue at the administration site. Some participants mentioned that the problem occurred only sometimes, and that the bruising was disappeared spontaneously, by changing the administration site, or by using alcohol wipes. Some participants provided different complications, such as bleeding (n=3), and itching (n=1). From participants who experienced bleeding, two reported that the problem occurred sometimes, while one experienced the problem at the beginning of using the pen only. In addition, experiencing that problem affected negatively on the injection technique of one of the participants. Because of the compressible feature of insulin cartridge of the pen, insulin is delivered slowly.

Thus, it is recommended that the patient hold the needle for 10 seconds after injecting the insulin dose to prevent leakage of insulin, and to get the optimum delivery of insulin (Luijf and DeVries, 2010). However, that participant stated that he was avoiding this step, in order to avoid injecting contaminated insulin dose:

> *"They* [the nurses] *told me that I have to keep the needle in my skin for 10 seconds after injecting the* [insulin] *dose, but I pull it out it rapidly after injecting. This is because I always experience bleeding, and when I keep it* [the needle] inside [the skin] *for seconds, the blood get mixed with the* [remaining] *insulin solution* [in the insulin reservoir]*. In this case, I need to throw the pen and use a new one…Compared to the* [traditional] *injection* [syringe and vial], *the* [syringe] *needle is thicker and caused more bleeding."*
> [Participant 10, male, age 58 years]

Where itching was experienced, the participant added that he experienced this problem as a result of using the same administration site several times, and that he used *Vaseline Jelly* to solve the problem. However, it is worthy to note that the same participant who was experiencing difficulties in using the insulin pen, and had difficulties in transporting and storing it, was experiencing all the problems that

related to the pen use, e.g. pain, bruising, bleeding and itching. Patients' dissatisfaction in their treatment regimen could impact on their abilities to accommodate to that regimen, acceptance, and adherence, and result in experiencing problems. Although it is mechanically more complex than the syringe and vial, and is prone to malfunction over time, there were no reports of mechanical malfunctions in the current study. Depending on the experiences of the 21 participants who were using the pen device during the data collection period, or had used it before, no one reported mechanical malfunctions during the pen use period.

6.3.3.2 Problems of syringe and vial

In order to include all the problems caused by the different insulin delivery methods, the researcher reviewed the interview transcripts of the participants who were using syringe and vial. Problems caused by the syringe and vial method were manifested as pain, bleeding, bruising, hypoglycaemia, and complexity of doses administration **(Table 6.6)**. In addition to causing the previous problems, it was noticed that using the syringe and vial method annoyed some participants in terms of relying on others to help them in administering their doses. In this study, some participants (n=4) reported that they could not administer their doses themselves, and they had to wait for their sons/daughters to help them. One participant mentioned that she used to go to the local primary care unit to obtain help from nurses in administering her doses:

> *"I don't have any problem with the tablets but with the* [insulin] *injections; they're annoying, painful, and sometimes they cause bleeding and bruising. In addition, they're difficult to use in transportation when I want to be away from home. They have to be kept in a cold place, but the tablets can be taken everywhere. Also,* [insulin] *injections are really annoying; they're linked with the food. Every time I want to eat, I have to wait for my husband or daughter t get back so as to give me the injection. I can't take it* [the dose] *alone; it's difficult. Every time they* [patients' husband or daughter] *give me the injection* [dose], *I turn my face to the opposite side."*
> [Participant 20, female, age 50 years]

Table 6.6: Problems caused by using the syringe and vial method and their frequency

Number	Problem	Frequency
1	Hypoglycaemia	1
2	Pain	6
3	Bruising	3
4	Bleeding	2
5	Time-consuming/complex	4
6	Inconvenience for transporting	5
7	Dosing inaccuracy	2

Overall, insulin pens were not free from problems and side effects (problems 1-4; **Table 6.6**), such as pain and bruising but depending on reports from participants, the effects were much less in frequency and severity compared to those cause by the syringe and vial method. Furthermore, insulin pens helped to eliminate other problems caused by the syringe and vial (problems 5-7; **Table 6.6**), such as complexity of doses administration and difficulty in transporting. Although it is mechanically more complex than the syringe and vial, insulin pen was not susceptible to mechanical malfunctions, and there were no reports of malfunctions in the current study.

6.3.4 Overall preference and acceptance

In order to investigate the preferred insulin delivery method, the participants were asked during the interviews, whether they accepted the pen device and continue on it. All the 18 participants reported that the pen was comfortable, and they were happy using it. The 11 participants who were converted from the syringe and vial method added that they never thought about returning to that method. In regard to recommending the pen device to other patients, all the participants reported that they recommend the pen to other patients; some of them (n=2) had already recommended it to their families or friends, who were using traditional injections. Two participants added that the pen would be easy to use for old and young people, while one commented that old people might find it difficult, especially if they cannot read, as they would have difficulties in dialling up their doses using the dosage knob, while with the syringe, they could count the number of lines, which related to the units:

> *"I feel comfortable using the* [insulin] *pen. No, no, no, I won't change it. If I knew another patient using insulin, I would advise him to ask his doctor to prescribe the* [insulin] *pen to him. It* [insulin pen] *can be used effectively, and easily; it's really something good, good, good."*
> [Participant 24, male, age 58 years]

> *"I'm happy with the* [insulin] *pen; it's easy, and I can inject my dose easily. It is much better than traditional injections. I didn't use them* [traditional injections] *but I helped my mother with her doses. It's* [insulin pen] *really a good invention for everybody, old and young. I would recommend it, but there are some people who are more familiar with the traditional injections and like them. For me, I'm used to the* [insulin] *pen."*
> [Participant 27, female, age 56 years]

Of the participants who were using syringe and vial in this study, two switched from the pen to the syringe and vial. One participant stated that he was prescribed the insulin pen in a period of time but he returned it to the pharmacy, and dispensed the

traditional injections instead. The participant reported that he had a difficulty in using the pen, and felt uncomfortable with it. It was not clear why that participant did not like the pen use, although he was educated and could read the unit marking in the dose window, and dial up his dose using the dosage knob easily. Impaired vision and/or dexterity could be a reason but are excluded, because the participant preferred the use of traditional injections.

Administering doses using the syringe and vial required good vision to read the small numbers listed in the syringe, and proper dexterity to withdraw the insulin using the syringe and injecting the dose. However, reasons that made that participant disliking the pen could be that he was more familiar with the syringe and vial, as he used them since he diagnosed with type 2 diabetes (e.g. approximately for 10 years), so, when he was prescribed the pen at the middle of his diabetes, he did not like to change his treatment regimen, or to learn a new method. In addition, this participant was 77 years old; some old people might find it difficult to use technical devices, and preferred traditional methods, although there were many old participants in this study who adapted the use of technology of the pen. The other participant who switched to the syringe and vial provided that she preferred the pen, but this was because she required a higher insulin dose, which could not be delivered via the pen, and that she had to inject herself twice, if she want to keep using the pen. With the syringe and vial, the participant could withdraw the required dose and inject herself at one time:

> *"I used to have the* [insulin] *pen, but now I'm using the traditional injections* [syringe and vial]. *This is because the doctor increased my* [insulin] *dose, but the* [insulin] *pen includes a limited dose, less than what I need. Therefore, instead of using the* [insulin] *pen twice, I chose to use the* [traditional] *injection* [syringe and vial] *because it provides with me the dose I need at one time."*
> [Participant 6, female, age 56 years]

Overall, insulin pen was considered the preferred insulin delivery method among the study participants. To identify the factors that contributed to its preference, a comprehensive analysis to the interview transcripts has been undertaken, which provided the broad picture of the characteristics of insulin pens. The dominant factors that contributed to the preference of insulin pen in this study, as reported by the participants are outlined in **Figure 6.5**.
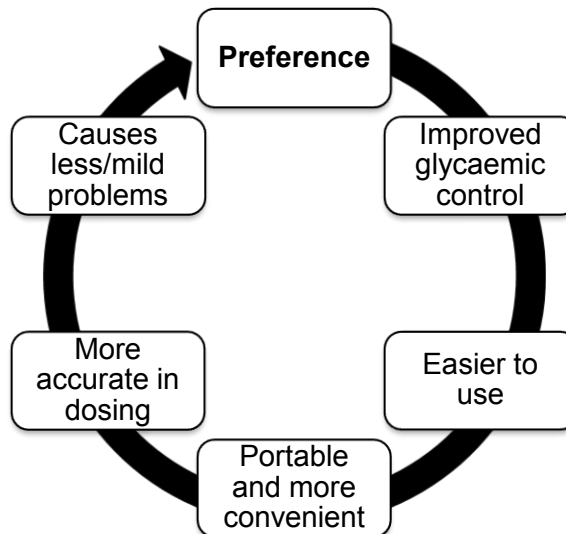
Figure 6.5: Factors that contributed to the preference of the insulin pen

Results of the current study revealed that using insulin pen had many advantages in terms of improved glycaemic control, improved patients' quality of lives, ease of use and transporting, convenience, dosing accuracy, with less problems than those caused by the syringe and vial. However, it is worth to note that reports on improved glycaemic control were not supported with clinical data, e.g. HbA1c levels. Most participants, who reported improved glycaemic control on insulin pen, had poor blood glucose levels (e.g. HbA1c> 7.5%).

However, some participants (n=3) clarified that they had been offered the pen device but they needed to switch to syringe and vial due to different reasons, such as the requirement for higher insulin dose that could not be delivered via the pen, or due to having difficulties in using the pen. To one participant, it was not clear why she had been converted from the pen to syringe and vial, and she reported her annoyance during the interview for being transferred to the traditional injections. Other participants (n=5) did not use the pen device at all; reasons for not being dispensed the pen device were neither raised during the interviews nor identified by the participants.

6.4 Main findings

- Findings of this chapter revealed that using the pen device was more acceptable and preferred among the participants than traditional injections. Of the 21 participants who were prescribed and used insulin pens for a period of time, or at the time of data collection, only two switched to syringe and vial deliberately **(Section 6.2.4)**. Overall, reports of participants who used insulin pens and continued revealed that the pen was more advantageous in terms of ease of use, portability, convenience, accuracy of dosing, and caused less pain and injection-site reactions. As a consequence, most participants reported improved adherence with the insulin pen.

6.4.1 Contribution of this chapter to this study

- Describing the participants' views and experiences about the use of insulin pens and comparing their use with traditional injections enabled the researcher to:

  -Inform policy to consider insulin pens as a part of a comprehensive diabetes management approach.

  -Highlight a key information gap for physicians regarding the benefits of insulin pens, in order to extend their prescribing.

  -Discuss a recommendation of (informing patients about the availability of an insulin pen and involve them in decision-making) and obtain its importance and practicality from the perspectives of HCPs **(Chapter 8, Section 8.1.8)**.

6.4.2 Contribution of this chapter to the literature

- Although there were many international published studies revealing consistent results with this study regarding patients' preferences, convenience and acceptability to insulin pens, patients' preferences and barriers to appropriate injection have not been adequately reported in the Middle East (only two studies). This study provides an update data among Eastern Mediterranean patients with type 2 diabetes that may add a benefit to the local literature **(Chapter 9, Section 9.2.2)**.

Chapter 7: Management of type 2 diabetes with insulin pumps

This chapter investigates views and experiences of adults with type 2 diabetes (n=8), about the use of insulin pumps, in terms of glycaemic control and problems associated with their use. Also, it describes the impact of using such devices on patients' life, adherence to treatment, and on other family members. Describing the participants' experiences in this study will help in understanding whether insulin pumps are effective options for this group of patients, and making recommendations for better management of this disease and improved health outcomes.

7.1 Glycaemic control with insulin pumps

7.1.1 HbA1c levels from medical records

To evaluate the benefits of using insulin pumps in terms of achieving glycaemic control, HbA1c levels of the participants during the insulin pump period were reviewed. **Table 7.1** shows the HbA1c and blood glucose levels of the participants, in addition to other characteristics, such as gender, age, education level, BMI, and other co-morbidities.

Table 7.1: HbA1c readings, blood glucose level and other patient's characteristics

Patient	Gender	Age (years)	Education level	Mean HbA1c (%)	Blood glucose level (before meal) (mmol/l)	BMI (kg/m^2)	Co-morbidity
26	F	47	Secondary school	12*	5	30.1	Nil
37	M	67	University	6.8	4	38	CVD
38	F	49	Diploma	7.5	6.3	46.9	CVD
39	M	28	University	7	6	35.1	Nil
40	F	34	Diploma	7.1	6.5	26.7	Nil
41	F	25	Primary school	NA^	7	24.9	Nil
42	F	28	University	5	4.2	28.1	Nil
43	F	28	Postgraduate	5.7	7	25.7	Nil

* Old data, collected two months ago
^ No reading during the pump period was available

All participants were on intensified insulin regimen, either injections and/or pens before switching to insulin pump. The duration of using insulin pump and the previous insulin regimen of each participant, as reported during the interviews are provided in **Table 7.2**.

Table 7.2: The duration of using insulin pump and the previous insulin regimen as reported by the participants

Patient	Previous insulin regimen	Duration on insulin pump (year)
26	Injection → pen	2
37	Pen	0.5
38	Injection	6
39	Injection → pen	6
40	Pen	1
41	Pen	1 (month)
42	Pen	1.5
43	Injection → pen	2

In patients with type 2 diabetes, it is ideal to aim for an HbA1c of 6.5-7.5% or less (BNF, 2015). From **Table 7.1**, it seems that of the 8 participants, 6 achieved target levels of HbA1c ($\leq$7.5%). For the two remaining patients, one still above the target levels (patient 26; HbA1c=12%), and for the other patient (patient 41), there were no valid HbA1c level during the data collection period. Therefore, according to HbA1c levels, all participants except one (excluding patient 41 to avoid bias of the results) had achieved glycaemic control on insulin pump. Data of blood glucose levels, as monitored in the clinic were also collected. Blood glucose targets for patients with type 2 diabetes before meals are 4-7 mmol/l (Peragallo-Dittko, 2006). Thus, it seems that all participants had achieved normal blood glucose levels. However, some participants were using the insulin pump for a long period (e.g. more than a year) rendering their data collected before the pump period very old and difficult to obtain from medical notes. Therefore, relying on clinical data only does not help in answering the 'why' and 'how' questions, and understanding the efficacy of insulin pump in achieving glycaemic control. Thus, in order to understand the role of insulin pump in achieving glycaemic control compared to MDI, and to identify why not all the participants achieved target HbA1c levels, it was important to revise data obtained from the interviews. Information revealed from analysing the interview transcripts are provided in **Section 7.1.2**.

7.1.2 Reports of participants on overall glycaemic control

7.1.2.1 Achieving glycaemic control

To investigate the benefits of using insulin pump, compared to other insulin delivery methods, in improving and maintaining good blood glucose levels, the participants were asked during the interviews to describe their experiences regarding the effectiveness of the pump in achieving glycaemic control. Because all participants

were transitioned from insulin injections and/or pens **(Table 7.2)**, they were able to compare between insulin pump and the other insulin delivery methods. Exploring participants' views and experiences revealed that the entire sample (n=8) reported improved blood glucose levels on insulin pumps compared to previous insulin therapy:

> *"Compared to insulin pens, my average blood glucose level has become good since I used the pump."*
> [Male, age 67 years, 6 months of pump use; interview no. 37]

> *"When I was on* [insulin] *pens, my blood glucose level always fluctuated, ups and downs, but now it's much better. The pump gives me the accurate dose according to the carbohydrate counting."*
> [Female, age 28 years, 18 month of pump use; interview no. 42]

Two participants added that the pump helped them to achieve glycaemic control to the extent that they felt became uncontrolled and their health deteriorated when they replaced the pump with insulin pens temporarily:

> *"I tried to stop using it* [the pump] *for a week and use* [insulin] *pens instead, but my health deteriorated; I couldn't control my blood glucose levels. It went up and down."*
> [Female, age 47 years, 12 months of pump use; interview no. 26]

> *"I once stopped using it* [the pump] *for one day, and returned to* [insulin] *pens. You can't imagine how my health deteriorated and my blood glucose level fluctuated between ups and downs. It was only for one day!"*
> [Female, age 34 years, 12 months of pump use; interview no. 40]

7.1.2.2 Reducing hospital admission

Reports from interviews with the participants and clinical data suggested that insulin pumps improved the participants' (n=6) general health compared to previous insulin therapy, and they did not need hospital admissions due to hypo-/hyperglycaemia or any other diabetes complications. In some cases (n=3), the use of insulin pump even reduced hospital admission rate **(Table 7.3)**.

The participants reported several hospital admissions due to experiencing diabetes complications on previous insulin therapy:

> *"Before using the pump, you wouldn't believe how many times I had been admitted to the hospital, but now 'thank God' I don't need it* [hospital admission]*."*
> [Female, age 34 years, 12 months of pump use; interview no.40]

> *"When I was on* [insulin] *pens, I had been admitted to the hospital many times. I had acidity in the blood* [ketoacidosis]*."*
> [Female, age 25 years, 1 month of pump use; interview no. 41]

Table 7.3: Reported hospital admission rate, due to diabetes complications, on insulin pump compared to previous insulin therapy

Patient	Hospital admission rate
26	Increased
37	Did not change
38	Increased
39	Did not change
40	Reduced
41	Reduced
42	Reduced
43	Did not change

7.1.2.3 Onset of glycaemic control

Regarding the onset of glycaemic control, most participants (n=6) noticed the improvement in their blood glucose levels promptly, at the start of using the pump therapy **(Table 7.4)**. The remaining two participants reported experiencing hypo-/hyperglycaemic episodes at the onset of commencing treatment with insulin pump, in which their hospital admission rate increased **(Table 7.3)**:

"At the beginning, it [the pump] *didn't help me, and my blood glucose level was always high. I've been admitted to the hospital 4 times to reduce the acetone and blood sugar level. After two months achieved good glycaemic control."*
[Female, age 47 years, 24 months of pump use; interview no. 26]

"When I started using the pump, I suffered from low blood glucose levels to the extent that I lost my consciousness, in which I needed to be admitted to the hospital. It [achievement of glycaemic control] *took a long time (about one year), but now everything is OK."*
[Female, age 49 years, 72 months of pump use; interview no. 38]

Table 7.4: The onset of glycaemic control after using insulin pump, as reported by patients

Patient	Onset of glycaemic control	Evidence of the control
26	Worsened (for 22 months), then improved	SMBG/Interview
37	Promptly improved	SMBG/HbA1c/Interview
38	Worsened (for 12 months), then improved	SMBG/HbA1c/Interview
39	Promptly improved	SMBG/HbA1c/Interview
40	Promptly improved	SMBG/HbA1c/Interview
41	Promptly improved	SMBG/Interview
42	Promptly improved	SMBG/HbA1c/Interview
43	Promptly improved	SMBG/HbA1c/Interview

7.1.2.4 Maintaining glycaemic control

The aim of using insulin in type 2 diabetes is to achieve and maintain glycaemic control in poorly controlled patients. However, not all patients with type 2 diabetes, who are insulin-dependent, could maintain normal blood glucose levels at all times.

In addition, intensifying insulin regimen in patients who did not meet target levels is associated with increased risk of hypoglycaemia (Reznic et al., 2014). Therefore, in this study, it was crucial to assess whether the use of insulin pumps had a role in maintaining glycaemic control at all times, and avoiding hypoglycaemia. In this study, cases of hypo-/hyperglycaemic episodes at particular times of the day, or at special occasions were reported:

> *"With* [insulin] *pens, I always got hypoglycaemia, it* [blood glucose level] *reached less than 1* [mmol/l]. *Now it's OK. Using the pump, I sometimes have hyperglycaemia; it* [blood glucose level] *goes up to 8-9* [mmol/l]*."*
> [Female, age 34 years, 12 months of pump use; interview no. 40]

Overall, all participants reported an overall improvement in their glycaemic control after using insulin pump. In most cases (n=6), the control was achieved promptly, at the onset of commencing insulin pump therapy, and the improvement in HbA1c readings was instantaneous. In two cases, where no valid HbA1c levels were available, the improvement was manifested by normal blood glucose levels as monitored by the participants and in the clinic. The participants who achieved a prompt glycaemic control added that they had not been admitted to the hospital due to diabetes complications, and compared to previous insulin therapy; the hospital admission rate was reduced in some cases (n=3). The remaining two participants who had delayed achievement of glycaemic control reported worsened glycaemic status during the transition period, the period when they switched from insulin injections/pens to insulin pump therapy. The participants reported that they experienced a period of erratic blood glucose levels, with hypo-/hyperglycaemic episodes, and increased hospital admission rate. The period required to gain glycaemic control was different between the two patients, and ranged from 12-22 months. Despite achieving an overall good glycaemic control, hypo-/hyperglycaemic episodes were reported through all the cases.

Correlating clinical data and data obtained from the interviews revealed that insulin pumps were effective in achieving glycaemic control (target HbA1c levels and/or normal blood glucose readings). Although the control with insulin pump had been achieved since a short period in two cases (patients 26 and 41), both patients reported stable glycaemic status at the time of the interview. Data obtained from the interviews were consistent with HbA1c levels in the majority of cases (n=6). In the remaining two cases, valid data on HbA1c level were not available due to not performing the HbA1c test during the control period (patient 26), or at the pump treatment period (patient 41). Patient 26 reported that she had just achieved

glycaemic control, two months before her interview date, and that her last HbA1c test was performed before that period. Patient 41 used the insulin pump a month before conducting the interview, and her last HbA1c level was collected before she started using insulin pump. Participants who needed time to achieve glycaemic control were within the same age range, and both were female and obese. However, to explore factors that hindered achievement of glycaemic control on insulin pumps, and reasons for not maintaining the control at all times throughout the day, the interview transcripts were reviewed through all the cases, factors were identified and are described in **Section 7.1.3**.

7.1.3 Factors affecting the achievement of glycaemic control with insulin pumps

This section is divided into two parts; the first part describes reasons that impeded achievement of glycaemic control in the two cases. The second part describes factors contributed to irregular blood levels, and hypo-/hyperglycaemic episodes across all cases.

7.1.3.1 Reasons for not achieving glycaemic control at the onset of insulin pump therapy

The justification for not achieving good blood glucose levels, at the transition period **(Table 7.5)** could be due to experiencing difficulties in working out how the pump works, inadequate awareness about the tasks required with the pump therapy, such as carbohydrate counting, doses calculation (bolus and correction doses), and depending solely on the doctor in adjusting doses (basal insulin):

> *"When I received the training from the company, it was OK, but when I tried it* [the pump] *myself, I felt nervous, and didn't know how to deal manage it. Every time I experienced hyperglycaemia I went to my doctor to adjust my doses* [basal insulin], *but now I am used to it."*
> [Female, age 47 years, 24 months of pump use; interview no. 26]

> *"At the beginning, it* [the pump] *didn't help me, but after I had learned how to count carbohydrate and take correct doses, it became much better."*
> [Female, age 49 years, 72 months of pump use; interview no. 38]

The use of the pump technology requires the patient to learn all the tasks that are linked to its use. Lack of awareness of these tasks contributed to a failure in achievement of glycaemic control. Furthermore, the timing of the transition to the pump therapy is important. One participant reported that she started on the pump when she was pregnant. Pregnancy causes hormonal and metabolic changes followed by insulin resistance, in which insulin requirements increased:

"When I switched to the pump, it didn't help me much. I had to see my doctor many times to adjust the doses [basal insulin] *for me. It* [blood glucose level] *became OK for 1-2 weeks, but then it returned to high levels. I was admitted 4 times to the hospital to reduce acetone and blood glucose levels as I was pregnant. I should get my blood glucose level reduced for the sake of my baby."*
[Female, age 47 years, 24 months of pump use; interview no. 26]

Table 7.5: Reasons for delayed achievement of glycaemic control on insulin pumps

Reason	Frequency
Inadequate awareness of all tasks	**2**
Difficulties in working the pump	**1**
Timing of the transition	**1**

7.1.3.2 Reasons for not maintaining good blood glucose levels at all times throughout the day

The participants identified several reasons for experiencing hypo-/hyperglycaemic episodes on insulin pump. Reasons for experiencing hyperglycaemia ranged from lifestyle to pump-related factors **(Table 7.6)**. Non-adherence to diet was reported by the majority of participants, as the contributing factor for high blood glucose levels. Non-adherence to diet was manifested by eating large portions of food during social gatherings, consuming more sweets or having a very late dinner:

"When I eat large meals, especially sweets, my blood glucose level goes up."
[Male, age 67 years, 6 months of pump use; interview no. 37]

"My blood glucose level is usually fine, but I noticed that if I have my dinner very late at night, I experience hyperglycaemia."
[Female, age 49 years, 72 months of pump use; interview no. 38]

In some cases, where non-adherence to diet was mentioned, it was accompanied with other factors, such as forgetting to administer the bolus dose or not counting carbohydrates:

"When I am invited to weddings, I usually eat lots of fats and sweets. Sometimes, I forgot to press the button [take the bolus dose], *at such occasions; I lose control on my blood glucose level and it becomes high."*
[Male, age 28 years, 72 months of pump use; interview no. 39]

"When I eat a lot and don't count carbohydrate, it [blood glucose level] *goes up, but if I adhere to my diet, eat wisely and count the carbohydrate, everything is OK."*
[Female, age 25 years, 1 month of pump use; interview no. 41]

Other factors, which were related to the female gender, were irregular menstruation and childbirth:

"I feel that because my period is irregular, my blood glucose level is not good all the time. Also, every time I have an exam, my blood glucose level becomes high, even if I don't eat anything."
[Female, age 28 years, 18 months of pump use; interview no. 42]

"Sometimes, I get shocked by the readings [blood glucose monitoring]; *I feel that because I have recently had a new baby. My hormones changed; I think I need to adjust it* [basal insulin rate].*"*
[Female, age 28 years, 24 months of pump use; interview no. 43]

Other factors influenced glycaemic control could be the presence of other co-morbidities, such as hypothyroidism (n=1), where the body's requirements of insulin changed. However, in some cases, participants could not identify specific reasons for not achieving good glucose control.

Table 7.6: Reasons for experiencing hyperglycaemic episodes, and their frequency

Reason	Frequency
Non-adherence to diet	**6**
Non-adherence to therapeutic regimen:	
• Forgetting to take bolus doses	**1**
• Not counting carbohydrates	**4**
Need of dose adjustment (basal insulin)	**2**
Stress due to exams	**1**
Recent child birth	**1**
Irregular menstruation	**1**
Unknown reason	**2**

In this study, cases of hypoglycaemia, where blood glucose level dropped below 4 mmol/l were also identified. Hypoglycaemia is the dominant complication of intensive insulin therapy (Herman et al., 2005). However, the majority of participants (n=6) reported less hypoglycaemic episodes on insulin pump compared to their previous insulin therapy **(Table 7.7)**. Insulin pump not only reduced hypoglycaemia, but also lessened the severity of the episode in some patients (n=3). In addition, three participants added that insulin pump helped to eliminate these episodes at all:

"I didn't experience hypoglycaemia when I was on the pump, but when I was on [insulin] *injections and pens, I experienced many times of hypoglycaemia."*
[Male, age 28 years, 72 months of pump use; interview no.39]

"Hypoglycaemia had been greatly decreased using the pump. When I was on [insulin] *pens, I always had hypoglycaemia, and sometimes I lost consciousness, and was admitted to the hospital many times."*
[Female, age 28 years, 18 months of pump use; interview no. 42]

Table 7.7: Frequency and severity of hypoglycaemia on insulin pumps compared to previous insulin therapy

Patient	Frequency of hypoglycaemia	Severity of hypoglycaemia
26	Less	Same
37	More	Same
38	More To Less	Same
39	Less To Nil	Same
40	Less To Nil	Less
41	Less To Nil	Less
42	Less	Less
43	Less	Same

On the other hand, cases of more frequent hypoglycaemic episodes on insulin pump were reported. Participants who experienced more hypoglycaemia on insulin pump identified 'overdosing' as the cause of the episodes. One participant mentioned that she was administering her doses (bolus doses) without counting carbohydrate in her meals, and she was on diet, in which insulin could exceed her body's requirement and act as an overdose. The other participant thought that the way in which the pump works, secreting insulin continuously, and during sleeping, made him vulnerable to overdosing and experiencing hypoglycaemia early at morning:

> *"I feel that hypoglycaemia increases when I use the pump. I usually have it early in the morning when I wake-up to pray. It goes down to 3-4* [blood glucose level in mmol/l], *and it lasts about 15 minutes, but after I drink a juice, I feel OK. This is because the pump gives me insulin continuously…I talked to my doctor and he said that the dose* [basal insulin rate] *should be reduced".*
> [Male, age 67 years, 6 months of pump use; interview no. 37]

To consider all the reasons that contributed to hypoglycaemic episodes on insulin pumps, all the interview transcripts were revisited, even for patients who experienced less hypoglycaemic episodes. Reasons why participants experienced hypoglycaemia on the pump therapy are summarised in **Table 7.8**. In participants who were uncertain about the cause of their hypoglycaemia, the reason was considered 'unknown'.

Table 7.8: Causes of hypoglycaemic episodes on insulin pumps and frequency of reporting them

Reason	Frequency
Overdosing	2
Forgetting to adjust the pump when exercising	1
Not eating for a long time before sleep	1
Unknown reason	3

In addition to exploring the effect on hypoglycaemic episodes, participants were asked to report whether insulin pumps improved their awareness of hypoglycaemia.

Of the 8 participants in this study, five reported better awareness of hypoglycaemia on insulin pump, while three stated that their awareness about hypoglycaemia remained the same, and they sometimes had low blood glucose levels without recognising it **(Table 7.9)**. Moreover, one participant commented that she observed a remarkable improvement in recognising hypoglycaemia at all times throughout the day, as she was experiencing different symptoms in the morning than in the night:

> *"Yes, now I can feel the symptoms of hypoglycaemia. It's different* [the symptoms] *in the morning than at night. In the morning, I have a headache and nauseas, while at night, I feel ill."*
> [Female, age 47 years, 24 months of pump use; interview no. 26]

Because it was not included in the study objectives, participants were not asked during the interviews about their awareness of hyperglycaemia. Thus, not all participants discussed it; only one participant added that his awareness of hyperglycaemia was improved on the pump:

> *"Being on the pump, I can tell whether my blood glucose level is high or low. When I need to urinate more frequently, it's* [blood glucose level] *high but when I feel fatigued and tired, it's low."*
> [Male, age 28 years, 72 months of pump use; interview no. 39]

Table 7.9: Awareness of participants about hypoglycaemic episodes on insulin pumps compared to previous insulin therapy

Patient	Awareness of hypoglycaemia
26	Improved
37	Improved
38	Did not change
39	Improved
40	Did not change
41	Improved
42	Improved
43	Did not change

7.2 Problems of insulin pumps

It was crucial to determine safety of insulin pumps in this study, due to the lack of data and published studies around the efficacy and safety of this technology among adults with type 2 diabetes in similar population. Therefore, during the interviews, the researcher asked the participants to report the problems they experienced during the pump therapy. Various problems were obtained and identified from the interviews; these were classified into clinical, such as inflammation, weight gain/loss, and mechanical.

7.2.1 Carb counting and weight gain

Insulin pumps are devices that provide insulin, and could cause side effects, such as those occurred with other forms of insulin. In this study, using insulin pumps was associated with some clinical problems, such as weight gain/loss, and mechanical problems, as emerged from the interviews.

One of the prevalent clinical problems of using insulin pumps in this study was the change in participant's body weight. Participants were divided into two groups, one group gained weight and the other maintained or lost weight. The majority of participants (n=5) reported a considerable weight gain after the initiation of insulin pump therapy, and some added that they even tried to lose weight many times but they failed. From the remaining participants, two noticed no changes in their body weight, while one reported loss of weight. Because it was evident among this study sample, it was crucial to identify factors contributed to weight gain on insulin pumps. Therefore, the interview transcripts of participants who reported weight gain were reviewed. Likewise, transcripts of other participants who's their bodyweight remained the same or reduced were examined to explore the reasons behind not putting some weight as others. The main reason behind weight gain on insulin pumps was non-adherence to diet as a consequence of pump-related factors. Two participants mentioned that the effectiveness of the pump in reducing blood glucose level, even if they eat large portions and variety of food at anytime, made them feel more flexible with eating without blaming themselves. Two other participants stated that the simplicity in the pump use was the reason for eating more comfortably, having more dietary freedom, and consequently, putting on some weight. Those participants explained that the pump helped them in avoiding complex doses calculation (bolus and correction doses), which were required with insulin injections/pens, and that all what they needed was to press few buttons to administer their doses:

> *"I have started eating a lot since I put the pump. It's* [the pump] *so simple, one only needs to enter one's blood glucose level and the calories, and it* [the pump] *gives one the correct dose. When I was on* [insulin] *pens, I needed to calculate the dose that matched my blood glucose level and the calories; this is rather difficult as one has to try several times until gets it* [insulin dose] *right! I avoided eating enough because of this reason."*
> [Female, age 34 years, 12 months of pump use; interview no. 40]

Other reasons for gaining weight, as raised by the participants could be the reduced level of movement deliberately or due to an accident, and to some participants, the reason was unknown **(Table 7.10)**. On the other hand, participants who maintained

or lost weight on insulin pumps emphasised their adherence to appropriate regimens of diet and exercise:

> *"I don't eat sweets; I don't like them. I don't like soft drinks such as 'Pepsi' or artificial juices either. They contain too much sugar. I only drink natural juices…I had practised walking 3 days a week before I used the pump, and I'm keeping on exercising."*
> [Female, age 28 years, 24 months of pump use; interview no. 43]

7.2.2 Skin reactions at cannula-insertion site

Other clinical problems identified by the participants were related to inflammation and bruising resulting from administration procedures. In this study, from the entire sample, one participant mentioned that she experienced inflammation at the cannula-insertion site, where her skin became red, swollen and painful. This participant reported that she was not complying with the manufacturer's instructions regarding changing the site frequently, every 2-3 days. However, it is worth noting that this participant had not achieved glycaemic control for a period of time. Therefore, other justification for not achieving good control, in addition to factors mentioned in **Section 7.1.3** could be due to an occlusion. An occlusion is a common problem with insulin pumps, in which a blockage preventing the proper delivery of insulin is occurred, and this is usually resolved by changing the infusion site (Ross et al., 2015). Three participants in this study reported that they experienced bruising at the cannula-insertion site. No reason was identified from the interview transcripts, but the participants mentioned resolving this problem by rotating the site regularly. One participant added that massaging the coloured skin with ice relieved his bruising:

> *"It* [the pump] *colours my skin; it changes it to red, then green, but it* [skin marks] *gets back to normal when I put some ice on. I keep injecting myself in different places."*
> [Male, age 28 years, 72 months of pump use; interview no. 39]

A summary of the experienced clinical problems, frequency of reporting them, and the reasons for gaining weight in this study are provided in **Table 7.10**.

Table 7.10: Clinical problems of insulin pumps and their frequency

Problem	Frequency
Bruising	3
Inflammation and redness	1
Weight gain	5
Reasons of weight gain	
Non-adherence to diet	4
Reduced level of movement	3
Unknown	2

7.2.3 Mechanical problems

Some participants (n=4) reported mechanical malfunctions, from which three required replacing their pumps with new ones. The main problem reported by those participants was technical, affecting the pump functions, in which the pump stopped working completely. One participant added that her problems started with experiencing bolus-delivery problems (the pump was recording bolus doses incorrectly), giving false alarms (the pump gave alarms about the need to fill-in the insulin reservoir while it was already filled). Then, it ended up with 'frozen' buttons, then the pump stopped working. It is worth noting that this participant reported not achieving glycaemic control for a long period on insulin pump. Therefore, in addition to factors mentioned in **Section 7.1.3** and **Section 7.2.1**, the participant thought that the mechanical problem she experienced had also contributed to her blood glucose deterioration at that period, as she was using her pump for duration of time before it had been stopped working completely and replaced:

> *"Yes, I feel that my blood glucose level is getting better, although I went through times of high* [glucose] *levels. Perhaps this was because of the malfunction of the first pump; I might have been taking inaccurate doses* [bolus doses]*."*
> [Female, age 47 years, 24 months of pump use; interview no.26]

Another participant added that his pump gave him 'error' readings and ended with 'frozen' buttons as well. In all cases where the pump stopped working, the participants replaced them with new ones from the MOH. In one case, a spare pump was provided to the participant temporarily until she received the new one, while in another case the participant needed to use insulin injections, as she was abroad, until she returned to the country and got a new pump:

> *"It once stopped working when I was abroad. I called my doctor and he advised me to use injections instead. I did that until I came back to Kuwait and replaced it* [the pump] *with a new one."*
> [Female, age 49 years, 72 months of pump use; interview no.38]

One participant reported a different problem from the others, the participant explained that her pump stopped working temporarily each time she took it off, to swim or take a shower, and re-connect it. This was manifested to the participant when she monitored her blood glucose level and found it high. The participant reported that she changed the infusion site to resolve this problem. However, it was not clear to the participant why this was happening, but the justification could be due to a failure or deficiency in delivering insulin into her blood, as a result of an occlusion, which is usually resolved by changing the infusion site:

> *"When I want to take a shower or swim, I remove it* [the pump] *for 1-2 hours, and then re-fit it. I have noticed that it* [the pump] *doesn't work properly during these times. If you asked me how I knew that, I would say that I detected it when I monitored my blood glucose level that day and found it high. It dropped down when I took it* [the pump] *off and re-connected it."*
> [Female, age 34 years, 12 months of pump use; interview no. 40]

Insulin pumps are new devices that deliver insulin in a continuous manner, which is different than any other traditional method. Using such technology requires the patient to gain some technical skills, in order to run the device and mange the disease during the daily life. Accordingly, patients might need to introduce some changes into their daily routines or require assistance from other family members. The next two sections **Section 7.3** and **Section 7.4** describe the experiences of the participants in using insulin pumps during their daily life, and whether it had an impact on their family members.

7.3 The impact of using insulin pumps on patient's life

7.3.1 Psychological wellbeing

The participants were asked during the interviews to describe whether the use of insulin pump had an impact on their social lives. Particularly, participants were asked to express their feelings about 'using the pump' in front of people. However, some participants raised another issue 'the look of the pump'. Themes, such as 'self-confidence' and 'self-consciousness' were also emerged.

All the participants (n=8) reported their feelings of normalcy in living with the pump. Two participants mentioned that at the start of using the pump, they were bothered from it being attached all the time, but then they get used to it:

> *"At the beginning, I felt bothered wearing it* [the pump] *all the time, but then I used to it. Sometimes, I don't even feel it."*
> [Male, age 67 years, 6 months of pump use; interview no. 37]

In most cases (n=7), the pump had no impact on participants' self-confidence. Participants reported feeling confident and not ashamed with administering their doses via the pump in front of people. From which, two participants added that they were embarrassed from using the pump or showing it to others, at the beginning of pump use but this feeling was relieved over time:

"At the beginning, I tried to hide it [the pump] *so as not to be bothered by the questions (Why? How? What is this?) of those who see it. But now, I don't mind showing or using; I don't feel embarrassed at all."*
[Female, age 28 years, 24 months of pump use; interview no.43]

Factors that contributed to participants' confidence in using their pumps were the wide prevalence of diabetes in the country, and the expansion in using insulin pumps among patients. Having a peer group, persons in the same age range, suffering from the same disease, and using similar therapy, positively affected 'self-confidence':

"Sometimes, the tube of the pump comes out of my cloths, but I don't bother. Nobody says anything or comments. I feel that diabetes is common nowadays; I've just read in the newspaper that it's widely spread among Kuwaitis. Also, I know many patients using the pump in the presence of people."
[Female, age 28 years, 18 months of pump use; interview no.42]

Insulin pumps were also found to have psychosocial benefits over insulin injection and pens. In this regard, one participant reported feeling embarrassed from administering her doses in public settings when she was on insulin injections, while with the pump it was fine. On the other hand, one participant reported that he had not got the confidence to administer his doses even in front of his close family and friends, and neither via insulin injections, pens, nor with the pump.

'Look of the pump' and its visibility to others contributed to participants' stigmatisation and feeling self-consciousness. Some participants (n=3) reported that people were staring on them. However, one participant added that this happened long time ago, when she was feeling over looked by others, and this feeling relieved over time. The other participants revealed that the pump looks unacceptable, particularly, in weddings and parties, when they liked to wear tight dress or jeans and t-shirt:

"The pump is annoying, especially if I want to go to a party and wear a night dress, or jeans and T-shirt, it's visible and looks unacceptable. One can easily recognise that there is something wrong."
[Female, age 34 years, 12 months of pump use; interview no.40]

7.3.2 Daily activities
In this study, insulin pumps affected the participants' daily activities in various ways. Some of the activities were listed in the interview schedule, and discussed with the participants, such as 'sleeping', 'practising sport', and 'wearing clothes', while others were emerged during the interviews, such as 'travelling'. Experiences of participants about sleeping with their insulin pumps were obtained, and it was found that only

two participants were still not used to it. The cause of the inconvenience was related to the tubing of the pump, where the participants wake-up with their tubing wrapped around them:

> *"For the whole day, the pump is perfect, but during sleeping it's annoying. I always find myself tangled up in the pump tube."*
> [Male, age 28 years, 72 months of pump use; interview no.39]

Although sleeping with insulin pump was initially bothersome, some participants found that they get used to it immediately, or they created positions in which they sleep with their pumps comfortably. One participant explained that she rolls a lot during sleeping, and the pump tubing was bothering her. Interestingly, this participant added that over time; her body tended to adjust to the position of the pump, and naturally turned in response to discomfort:

> *"At the beginning, it was very annoying, especially because I move a lot in bed. I find myself wrapped with the tube every day. But now, I got used to it; I spontaneously turn right and left. Also, I tend to move the pump according to my position; all this happens while I'm sleeping, hahaha* [patient laughed]*."*
> [Female, age 34 years, 12 months of pump use; interview no.40]

> *"I heard that I have to put it* [the pump] *under my pillow, but I felt I would be tied to it and uncomfortable. Then, I started clipping it to my pyjamas bottom; this position is much better."*
> [Female, age 28 years, 24 months of pump use; interview no.43]

Surprisingly, participants (26 and 39) who were still annoyed from sleeping with their pumps were not recent pump users, as they were using it long time ago (2-6 years), **Table 7.2**. Thus, sleeping comfortably with the pump is not related to the duration of using it rather than being adapted to it, and finding the most convenient position for it. For example, wearing the pump belt, to keep it in a fixed position (fastened around the waist) or clipping the pump in the pyjama pant (as practised by some girls). All these are suitable options, especially for participants who roll a lot. Other options, such as putting the pump in the bedside table or under the pillow, as practised by some participants could be suitable options for patients with a little movement.

Participants' experiences about the impact of insulin pump on practising sport were obtained, and from the 8 participants in this study, six mentioned that they were exercising happily. Activities mentioned by the participants were walking, going to the gym or swimming. Participants were either disconnecting their pumps during the exercise and then reconnecting them, or suspending the delivery of insulin for one hour. However, the most activity affected by the use of insulin pump mentioned by

participants was swimming. Two participants reported that they still feeling upset because they have to disconnect the pump and reconnect it afterwards, and pay attention not to stay long in the water. From those participants' point of view, the pump was disadvantageous for practising water-based activities and swimming, and that insulin pens were more convenient in these contexts. One participant added during the interview that she even thought about turning to insulin pens on the days of the sport:

> *"My favourite sport is swimming. When I became on* [insulin] *pens, I swam as much as I liked. There were no worries, but with the pump, I have to take care not to stay in water more than one hour, it's annoying. I've even been thinking of switching to* [insulin] *pens in order to be able to go swimming."*
> [Female, age 28 years, 24 months of pump use; interview no.43]

Findings of this study suggest that exercising with insulin pumps among the study participants was safe, and no problems were raised by any of them. However, one participant explained that she was experiencing hypoglycaemia while she was walking and keeping her insulin pump attached. From that patient's perspective, no factor was identified to contribute to her blood glucose level going too low, thus, the reason was unknown. This participant added that she resolved that problem by suspending insulin delivery during her exercise and it went well. However, reasons that contributed to that participant's problem could be exercising for a long time, not reducing the basal insulin delivery rate, or not taking carbohydrate before exercise.

Regarding wearing clothes with insulin pumps, the participants in this study were divided into two groups. One group (n=4) neither had complaints, nor were they annoyed from wearing the pump. The participants mentioned that they could wear whatever they want, as before using the pump. They put the pump inside their pockets, fastened it around their waist using its belt, or clipping it in their trouser/skirt and cover it. The other group of participants (n=4) expressed their dissatisfaction from wearing the pump because it limited them to wear particular types of clothes. For example, one participant reported that wearing the pump obliged her to wear either a trouser or a skirt, to clip her pump in, because she felt uncomfortable when she wore *Abaya*, a traditional women dress, and fixed the pump around her waist under the dress. On the other hand, other participants found that wearing traditional clothes, e.g. *Dishdasha*, a traditional men dress, and *Abaya*, was more suitable for the pump, as these dresses are long and wide enough to cover it, in which they would be avoided from overlooking.

However, only one participant in this study reported a problem with wearing the pump. The participant mentioned that at the start, he used to clip his pump to a thigh garter, but this option was inconvenient because he suffered from a swollen thigh. It was unclear why the participant suffered from such problem. The justification could be that the garter was too small and affected the blood flow to his thigh. Interestingly, this participant used his sewing skills and modified all his clothes (*Dishdashas*) to a style that allowed him to pass the pump from his pocket, to facilitate the administration of his doses (bolus doses):

> *"Since I used the pump, I have been wearing it around my thigh, using a garter to fix it in. But it was annoying at the beginning, and over time, my thigh became larger. Then, I tore-up all the pockets of my Disdashas so as to I can clip it* [the pump] *in my underwear. I passed it* [the pump] *through the torn pocket easily."*
> [Male, age 67 years, 6 months of pump use; interview no.37]

Some participants (n=4) provided information about travelling with the pump, while others did not discuss about it. This could be because the activity was not mentioned in the interview schedule, or that the participant had not travelled since she/he used the pump. However, there were different viewpoints, some participants provided positive comments, while it was bothersome to others. The most common reasons for 'liking' the pump during travelling were the portability of the device, availability of the required insulin *(Actrapid^R)* in pharmacies abroad, and the maintained metabolic control:

> *"I travelled 16 times since I used the pump. I've been to the Gulf, Europe and Iran. I liked it* [the pump]; *it's much easier for travelling than* [insulin] *pens. I don't need to carry too many items anymore, only the pump, which is attached, and the insulin ampoule* [Actrapid^R], *which is small. Also, with* [insulin] *pens, I was always worried about how to store them. When I was carrying them in my pocket, I worried if they became hot, so, they would lose their activity…I usually forget my medicines at home, when I was on* [insulin pens]; *I tried my best to get them abroad, but they were not available in all countries. On the other hand, the insulin used in the pump is available everywhere."*
> [Male, age 67 years, 6 months of pump use; interview no.37]

> *"I travelled several times with the pump, and everything was ok 'Thanks God'. I've been to an Island as well and swam a lot; I hadn't experience any problem."*
> [Female, age 34 years, 12 months of pump use; interview no. 40]

'Disliking' the pump was attributed to the annoyance that the participants experienced from the security in some airports, and the unsuitability of the pump in wearing particular types of clothes:

> *"It's* [the pump] *annoying with travelling. At some airports they don't let me pass before being examined* [scanned with the machine] *several times, and they keep questioning me about the device? I've been to Iran; they don't know what it is."*
> [Female, age 47 years, 24 months of pump use; interview no. 26]

"I didn't like the pump in travelling, because it made me liable to investigation a lot at the security points; they [security] *always keep asking 'what is this device?' Also, in travelling, I like to wear jeans and t-shirts but with it* [the pump], *I couldn't; it would be visible and looks unacceptable."*
[Male, age 28 years, 72 months of pump use; interview no. 39]

7.4 The impact of using insulin pumps on family

7.4.1 Worrying about the patient's status

Since the technology of pump therapy was different from other traditional methods, the use of such devices prompted family members to worry about their patients. In this study, families responded variously regarding the use of insulin pumps. In two cases, families were anxious about using a new device. On the other hand, two participants mentioned that their families were happy for them being improved and satisfied on the pump. One participant reported that her family was ambitious to find the solution, which is good glycaemic control with the pump. In two cases, families had no response, while in one case, the family had mixed feelings, as they were satisfied at the beginning but worried at special occasions. Analysing the interview transcripts helped in identifying the factors that affected families' reactions towards using insulin pumps **(Table 7.11)**.

Table 7.11: Families' perceptions towards using insulin pumps, reasons behind their feelings, and their frequency

Family's perception	Reason	Frequency
Satisfied for pump use	Participant was uncontrolled on insulin injections and pens	1
	Participant achieved glycaemic control on pump	2
	Participant's satisfaction improved on insulin pump	1
Worried about pump use	A new device	3
	Participant experienced irregular blood glucose levels for a period of time	2
	The pump is complicated	1
	Changes in the participant's status, e.g. pregnancy	1

One participant explained that being uncontrolled for a long time even under intensive insulin regimen with injections and pens, prompted her family to encourage her using insulin pump. The participant added that her family were yearning for reaching normal blood glucose levels with the pump. However, having a period of erratic blood glucose levels disappointed the family. Surprisingly, there were conflicting views about the use of pump within this participant's family. The participant's mother, brothers and sisters were still worrying about her being on such

device, while her husband, sons and daughters are encouraging her to continue on the pump:

> *"My husband and family encouraged me to use the pump. I feared from using it at the beginning but they supported me. At the same time, they were disappointed because they were looking for reaching good blood glucose levels, but I didn't achieve it for a long period. My mother and siblings still feel upset for my situation: changing the needle* [infusion site], *disconnecting and reconnecting the pump, and they keep asking me when I discontinue using it?"*
> [Female, age 47 years, 24 months of pump use; interview no. 26]

In cases (n=2) where families were worrying about using a new device, the participants explained that this was because they were insulin injections/pens users for a while, and so, families were uncertain about the results they would get from the pump. One of those participants added that her family disagreed with her to use the pump, and were insisting on discontinuing it, particularly, when the participant experienced severe hypoglycaemic episodes at the transition period:

> *"When I thought about using the pump, they* [her family] *said to me 'it's a new device; it's better not to use it'. Especially, when I was experiencing hypoglycaemia and needed hospital admissions, they said 'it's all because of it'* [the pump]*!"*
> [Female, age 49 years, 72 months of pump use; interview no.38]

In one case, the source of family's worrying was the change in the participant's situation. The participant reported that her family was not worrying at the start of using the pump, but when she became pregnant, she and her family started worrying:

> *"At the beginning, everything was ok, but when I became pregnant, me and my family began to worry. There were lots of question marks because I needed caesarean operation. We were worried about how it* [the pump] *would go during the operation? Would I disconnect it? What about after the operation? How I would adjust it* [basal rate]*?"*
> [Female, age 28 years, 24 months of pump use; interview no. 43]

On the other hand, families of two participants were satisfied with using insulin pumps because the participants themselves were more satisfied and controlled compared to insulin injections and pens:

> *"Nobody worried about me; I explained to them that it was* [the pump] *more convenient for transport, I don't need to carry many items, and it would relive me from several injections, so they felt happy."*
> [Male, age 28 years, 72 months of pump use; interview no. 39]

> *"It has no effect on my family; they only ask me from time to time: how it's* [the pump] *going with you? But when I was on* [insulin] *pens, they were always worried, because I looked tired and fatigued."*
> [Female, age 34 years, 12 months of pump use; interview no. 40]

However, two participants reported no response from their families regarding the use of insulin pumps. One participant added that the concern of his family was related to diabetes more than to the pump, especially, if he experienced irregular blood glucose levels.

7.4.2 Involvement in the management responsibilities

Participants were asked during the interviews whether they could manage all the tasks associated with insulin pump use, such as doses calculation, carbohydrate counting, operation of the pump, changing the infusion set and checking the needle site, or that a family member needed to be involved in any of these tasks. A new item was emerged during the interviews, which was 'support and reminding'. In this study, all participants (n=8) were able to perform all the tasks (e.g. doses calculation, carbohydrate counting, operation of the pump, and changing the infusion-set and checking the needle site) independently:

> *"I was able to do all the pump-related work alone, from A to Z; I needed no help. I tried to teach my husband but it was difficult to him"*
> [Female, age 34 years, 12 months of pump use; interview no. 40]

For doses calculation, such as insulin boluses and correction doses, almost all participants (n=6) explained that they used the Bolus Wizard; a system by which the required insulin dose is calculated automatically after typing the blood glucose level and the amount of carbohydrate in the meal and snack. However, two participants mentioned nothing about carbohydrate counting, and presumably they were taking their bolus insulin doses manually by pressing the button after each meal/snack:

> *"I know how to make correction doses; I only needed them sometimes, particularly, if I was invited to a wedding and had a fatty dinner, where my blood glucose level went high. So, I press the button to administer the correction dose."*
> [Male, age 28 years, 72 months of pump use; interview no. 39]

With regard to the pump operation, including setting and re-setting basal insulin according to activities, no participant reported intervention from family members. However, it is worth noting that in most cases (n=5), participants were still dependent on their doctors in adjusting their basal insulin rates. Participants were uncertain about their ability to set/re-set their basal doses due to different reasons, such as being new to the pump technology, experiencing hormonal changes due to recent childbirth, or preferring to double-check doses with the doctor at special occasions, e.g. travelling:

> *"Before I travel, I visit my doctor to show him my readings* [SMBG], *and let him check my pump and adjust the doses* [basal rates] *if this was necessary."*
> [Female, age 28 years, 18 months of pump use; interview no. 42]

Carbohydrate counting is an important step for patients using insulin pumps, where the patient needs to evaluate the amount of carbohydrate in the food; accordingly insulin bolus dose is calculated and administered. In this study, all the participants mentioned that they did not receive any assistance in performing such task. However, it should be noted that not all the participants were completely aware about how to calculate carbohydrate. From the 8 participants, three were confident in performing such step, and they knew the basic information about it. The remaining participants were either knowing nothing about it or misunderstanding it. One participant mentioned counting the amount of calories instead of carbohydrate, while another mentioned 'calories' in one occasion and 'carbohydrate' in another during the interview:

> *"During the appointment, the doctor takes my blood glucose reading, and if it's not normal, he checks the blood glucose monitoring card* [SMBG] *with me. Also, he* [the doctor] *asks me about how I'm taking my doses. No one has taught me carbohydrate counting."*
> [Male, age 28 years, 72 months of pump use; interview no. 39]

> *"Although I'm still not counting calories very well, it's* [the pump] *so simple. One only needs to calculate the calories in one's meal, and it* [the pump] *calculates the dose."*
> [Female, age 34 years, 12 months of pump use; interview no. 40]

Apparently, there was a relation between carbohydrate counting and weight gain **(Section 7.2.1)**. All participants who lacked the awareness about 'carbohydrate counting' or misunderstood it (e.g. counting calories instead) had gained weight. So, they presumed that they were counting carbohydrate but they were not. On the other hand, participants who maintained or lost weight were certain about their information and demonstrated their adherence to counting carbohydrate contents of their meals and snacks. Lack of awareness of carbohydrate counting or not counting carbohydrate at all could contribute to excessive consumption of carbohydrate, and consequently weight gain (Johnson, 2000).

Using insulin pumps requires that patients change the infusion set regularly (every 2-3 days), in order to avoid side effects, such as infection, allergy or irritation. Infusion-set is a tubing system that connects the insulin pump to the patient's body, and attaches to a cannula that should be inserted subcutaneously in fatty-rich tissues, such as the abdomen. In this context, all participants revealed that they could change the infusion set, and checked the cannula-insertion site themselves. However, as emerged from the interviews, the family role was centred on providing support to participants and reminding. Support provided by most families (families of

5 patients) was related to the management of the disease more than to the pump tasks, as it was around encouraging and motivating patients towards adherence to healthy diet and exercise.

In addition, some participants (n=5) revealed that their family members were accompanying them during exercise or were eating like them. Also, the participants revealed on other kinds of support, such as taking care of them when experiencing hypoglycaemic episodes (n=3), or accompanying them to the doctor appointments or to the pharmacy to collect their prescriptions (n=5). Interestingly, one participant stated that she and her sisters, as all were patients with type 2 diabetes, usually talk and advise each other regarding their blood glucose readings and other management responsibilities. Moreover, the closest family member to the participant was undertaking the 'reminding role'. The most frequently appeared 'reminded task' was checking blood glucose levels (n=3), followed by administration of bolus doses (n=2), and changing the infusion set (n=1). Three participants reported not receiving any reminding messages from their families.

7.4.3 Factors that helped patients to perform all pump-related tasks

To perform all the pump-related tasks, the patient requires technical skills for administration of doses, changing and checking the infusion site, and cognitive thinking for calculation of doses and carbohydrate counting. As it is obvious from **Table 7.1**, the participants' ages ranged from 25-67 years old. All the participants reported their ability to carry out all the pump-related tasks alone without the need of any assistance regardless of their age. The competency of the study participants and their ability to use electronic devices might be related to their education level, as most of them (n=6) had Diploma and Bachelor degrees.

Regarding the ease/difficulty of learning how to use the insulin pump, the participants reported that tasks were considered easy to learn. Although there were some difficulties from the viewpoint of some participants (n=4), these were at the start of using the pump only. Tasks that were considered difficult were doses calculation (bolus/basal insulin), and carbohydrate counting:

> "It was easy to learn how to use it [the pump]; *it's simple. The only difficult thing was carb counting. It always needs refreshing and following-up because we don't eat the same food everyday. But I can do it; there are many books and applications for how to calculate it* [carb]."
> [Female, age 28 years, 24 months of pump use; interview no. 43]

The infusion set of the pump can be attached in any fatty part of the body, such as the abdomen, thighs, buttocks, hips, upper arms or lower back (Rice and Sweeney, 2008). Although not all participants mentioned about it, some reported that they used to choose their abdomen, thighs or hips as sites for the infusion. All these parts are considered accessible, which allowed patients to change their infusion sets themselves without the need of any assistance. Although this was not raised during the interviews, from the psychological aspect, patient's attitude towards showing parts of body to others could be a factor that contributed to not involving family members in helping with pump-related tasks, such as changing the infusion set. Unlike children, adults may feel sensitive from showing parts of body to other people.

7.5 Insulin pumps and adherence to treatment

When comparing between insulin pumps and the previous insulin therapy, participants raised information regarding their adherence to treatment and SMBG. Analysing the interview transcripts systematically across all cases revealed factors that affected adherence to treatment and management responsibilities, which were related to the pump technology.

The majority of the participants (n=6) reported more flexible life with insulin pumps than with injections and pens. Factors contributed to rigorous life with injections and pens were doses schedules, and difficulty in transporting and storage. When they were using insulin injections or pens, three participants reported difficulties in transporting and storing of items, forgetting items was mentioned in two cases as a contributing factor for non-adherence to doses, and one participant stated that administering doses in public areas was inconvenient, as it should be taken in parts of body, which should be covered according to Islam:

> "It [the pump] *eases my life, unlike insulin injections; I was always worrying about administering my doses outside home. To take my dose via injection or pen, I needed to discontinue the gathering and look for a private place, while with the pump it's more comfortable."*
> [Female, age 47 years, 24 months of pump use; interview no. 26]

> "When I used the [insulin] *pens, I was a little bit relieved, but it was still annoying in terms of carrying them all the time, and keeping them away from sun light and hot weather. Sometimes, I was putting them in my pockets, and when I wanted to take my dose, I found the needle bended or broken due to sitting on it. With the pump, I don't have any of these worries, and I got used to it; it's better than injections/pens."*
> [Male, age 28 years, 72 months of pump use; interview no. 39]

"Life now is easier. When I was on [insulin] *pens, I was always worrying about taking my doses outside, especially if I wanted to go to the university. It needed to be stored in a fridge, which was difficult to find everywhere. I had to take all my lectures in the morning to get back home early and taking my doses."*
[Female, age 28 years, 18 months of pump use; interview no. 42]

"The pump makes my life. It's attached to me all the day, so there is no way to forget it. Injections and pens were annoying because I had to carry and use them 5 times a day. I forgot the needles or the insulin ampoule or everything at home many times."
[Female, age 28 years, 24 months of pump use; interview no. 43]

Being attached all the time, having the feature of continuous administration of insulin doses, the vibrating alarm, and the requirement to change the infusion set every 2-3 days only, made the use of insulin pumps more flexible than injections and pens. Although they are small items, insulin injections or pens require carrying many items (e.g. insulin vial and syringe, prefilled pen and needles, or insulin cartridge and refillable pen), and paying attention to doses schedules, in which stress could be initiated, and the possibility of forgetfulness increased. All those factors in addition to difficulty in administering doses outside, particularly for women constituted barriers to adherence to treatment.

Other reasons related to the complexity of doses preparation and calculation with insulin injections and pens were also found to affect patients' adherence to therapy. In this study, most participants (n=6) reported that simplicity of doses administration via insulin pumps, by pressing few buttons, and having the feature of automatic doses calculation (the pump Bolus Wizard) contributed to reducing the complexity of the treatment regimen. The use of injections and pens required participants to perform several steps, e.g. dose calculation, withdrawal of dose with caution, and inserting the needle, in addition it requires paying attention and accuracy. The use of insulin pumps helped the participants to avoid laborious dose calculations, and enhanced their beliefs about accuracy in dosing. In addition, the participants reported their ability to adjust their bolus doses according to their meals and activities easily. Taking correction doses, which was a dilemma to most participants (n=7) with insulin injections and pens, became easier with the pump. The participants reported that they only needed to monitor their blood glucose level and immediately adjust their insulin level accordingly. Thus, simplicity of the pump use, and its developed technology contributed to improved adherence of most participants in this study:

> *"Using the pump is better and easier than using injections. With the injections, I didn't know what to do if I experienced high* [blood] *glucose level, especially at night, when I already took all my doses. I didn't know how to take the correction dose or how to calculate it. The pump gives insulin over the day, and it's easy in terms of correction doses. Also, I can adjust it* [basal rate] *according to my activity level."*
> [Female, age 49 years, 72 months of pump use; interview no. 38]

> *"[Insulin] pens don't calculate doses, my* [blood] *glucose level was always uncontrolled. The pump calculates and administers the correct dose, according to the calories one eats, and that's it. So, it's [the pump] more comfortable and accurate."*
> [Female, age 34 years, 12 months of pump use; interview no. 40]

> *"It* [the pump] *gives the accurate dose according to the carbohydrate percentage in the meal. It's* [% carb] *already written* [in the food label]; *I just need to type it* [in the pump]. *With* [insulin] *pens, I might inject more/less than what I need, that's why my* [blood] *glucose* [level] *deteriorated. But with the pump, it became ok."*
> [Female, age 28 years, 18 months of pump use; interview no. 42]

Unwanted side effects, such as pain, swelling, bleeding and bruising were reported to contribute to treatment non-adherence with insulin injections and pens. Two participants mentioned that they were deliberately omitting doses due to fear of side effects. Anxiety about self-injection created a barrier to adherence to treatment (Brunton, 2008). In contrast, with insulin pumps, the side effects were either reduced or disappeared:

> *"With* [insulin] *pens I never felt comfortable, 4 injections* [doses] *per day; it was painful. Sometimes I got swelling I skipped doses to avoid pain and swelling. With the pump, there is no pain or swelling."*
> [Female, age 25 years, 1 month of pump use; interview no. 41].

The use of insulin pumps not only improved participants' adherence to treatment but also improved their self-care behaviour, such as SMBG. Frequent monitoring of blood glucose level during the day is recommended with insulin pumps to avoid risk of diabetic ketoacidosis (Brunton, 2008; Didangelos amd Iliadis, 2011). The majority of the participants (n=6) provided different reasons behind this improvement. For instance, one participant reported that when she was on injections, she was avoiding monitoring her blood glucose level regularly, due to fear of detecting hyperglycaemia, in which she needed to take a correction dose via the injection, and being vulnerable to its side effects:

> *"Before I use the pump, I rarely monitored my blood glucose level because I was always worrying about getting high reading, in which I needed to take a correction dose, which I hated. With the pump, I monitor my blood glucose level 2-3 times a day."*
> [Female, age 47 years, 24 months of pump use; interview no. 26]

Other reasons provided by the participants were realising the importance of such task, and fear of hypoglycaemia. One participant felt that monitoring blood glucose level is connected to the use of the pump and is necessary. Another participant believed that the continuous delivery of insulin exposed her to hypoglycaemia, in which she needed to monitor her blood glucose level more frequently:

> *"When I was on injections, I didn't monitor my blood glucose level, but with the pump, I monitor it 8 times on daily basis; I believe it's necessary."*
> [Female, age 49 years, 72 months of pump use; interview no. 38]

> *"Before using the pump, I monitored my blood glucose level twice a day, but now I monitor it more frequently, because I heard that the pump delivers insulin 24 hours, so, I worried about getting hypoglycaemia."*
> [Female, age 28 years, 18 months of pump use; interview no. 42]

However, two participants reported that the pump impacted negatively on their adherence to SMBG. Factors contributed to reduced adherence were the improved awareness of hypo-/hyperglycaemic episodes and the improvement in general health:

> *"Before using the pump, I monitored my* [blood] *glucose* [level] *more frequently. Now, I feel safe, comfortable and strong most of time, and that my* [blood] *glucose level is good. So, I don't need to monitor it regularly."*
> [Male, age 67 years, 6 months of pump use; interview no. 37]

> *"With the pump, I'm much better feeling and recognising hypoglycaemia and hyperglycaemia. So, I don't need to monitor my* [blood] *glucose level frequently; I only monitor it when I feel the symptoms, just to double-check."*
> [Male, age 28 years, 72 months of pump use; interview no. 39]

One participant mentioned that although it was sometimes annoying, she gets used to monitor her blood glucose level regularly. However, the participant reported that she heard about the pumps that outfitted with sensors, which gives a continuous measurement of blood glucose levels, and liberates the patient from performing SMBG several times during the day, and that she would like to use it.

7.5.1 Factors contributed to improved adherence on insulin pumps

As determined by the WHO, adherence is a multidimensional phenomenon determined by the interaction of five sets of factors termed 'dimension' **(Chapter 1; Table 1.2)**. In this section, the focus will be on dimension four, therapy-related factors. Examining the factors under 'Therapy-Related Dimension' **(Table 1.2)** explained why the participants' adherence to therapy was improved on insulin pumps. Correlating between these factors and reports of participants **(Section 7.5)** revealed the reasons for the better adherence on the pump. For instance, the

complexity of the treatment regimen, in terms of doses calculation and administration, and number of daily doses were less with insulin pumps compared to injections and pens. Regarding the techniques required to operate the pump, the majority of participants found it easy. Although there were some difficulties in some cases, these were at the start of using the pump and became easier over time **(Section 7.4.3)**.

Insulin pumps avoided the participants from frequent changes in their medications, and all changes they required were in their doses only, which they were able to adjust according to their meals and activities. Moreover, with insulin pumps, the participants could adjust their doses themselves, without returning to the doctor, which enhances the flexibility of the treatment. The majority of participants perceived the immediate benefit of insulin pumps, manifested in their improved HbA1c levels, blood glucose readings and general health. However, even when there were cases in which a period of poor control was experienced at the beginning, a subsequent improvement in HbA1c level and/or blood glucose monitoring was reported.

In this study, insulin pumps had almost no impact on participants' psychological wellbeing, and did not cause any stigmatisation for the majority of participants. Regarding side effects, insulin pumps were not free from these effects (e.g. bruising), but based on the participants' views, they were much less than those caused by injections and pens (e.g. pain, swelling, bleeding and bruising). Although the use of insulin pumps introduced mechanical problems, which were not experienced with injections and pens, the occurrence of these problems was uncommon, no serious consequences were reported, and replacing the pump with a new one was easy and feasible.

With regard to weight gain, the most perceived clinical problem with insulin pumps, the participants were not completely depressed for putting some weight. This could be because weight gain did not cause an immediate harm, and that the participants perceived the benefits of insulin pumps in achieving better control easily with less and/or no side effects or psychological impact, and providing a more flexible life outweigh the risk of weight gain. The last factor in the dimension, interference of the treatment with lifestyle, was more experienced with injections and pens. The majority of the study participants reported that the insulin pump was more convenient for daily routine, and provided a more flexible life.

Before ending up the interviews, the participants were asked whether they prefer to continue on insulin pumps or return to insulin injections or pens. All the participants commented that they were happy with using the pump, and never thought about switching to injections or pens. Reasons identified for preferring insulin pumps ranged between glycaemic control and flexible lifestyle. Two participants added that they had negative experiences with replacing the pump with insulin pens temporarily. The participants commented that their health had deteriorated and their blood glucose levels fluctuated during that period. However, two participants mentioned occasions, in which they would like to replace the pump with insulin pens. One participant reported that annoyance in some airports, and look of the pump with wearing casual clothes discouraged him from using it during travelling. The other participant mentioned that she would like to replace the pump with insulin pens when she wants to practice her favourite sport, swimming. Although it was possible to disconnect the pump for an hour and re-connect it, the participant reported her frustration from this time limit.

7.6 Main findings

- Insulin pumps offered advantages for participants with type 2 diabetes, and were superior to insulin injections and pens in improving participants' health behaviour. Causing weight gain, being worn around-the-clock and inconvenient in swimming and wearing particular clothing were counterbalanced by achieved good glycaemic control, lifestyle flexibility, freedom from pain, and the portability of the pump. Overall, insulin pumps improved the satisfaction of the participants and their adherence to doses **(Section 7.5)**.

7.6.1 Contribution of this chapter to this study

- Describing the participants' views and experiences about the use of insulin pumps and comparing their use with MDIs enabled the researcher to:

  -Inform policy and guidelines modifications to consider insulin pumps as an option for adults with type 2 diabetes.

  -Appraise which groups of patients should be offered the pump therapy based on the study findings. For example, to avoid weight gain, the most serious problem associated with the pump use, insulin pump should be considered for:

    √ A patient with type 2 diabetes who is poorly controlled with MDIs AND

    √ Has the commitment to perform all the pump tasks (e.g. carb counting, frequent checks of blood glucose) AND

    √ Maintain a good health behaviour (e.g. adhering to dietician visits, diet and exercise)

  -Discuss a recommendation of (informing patients about the availability of an insulin pump and involve them in decision-making) and obtain its importance and practicality from the perspectives of HCPs **(Chapter 8, Section 8.1.8)**.

7.6.2 Contribution of this chapter to the literature

- Although there were many international published studies revealing consistent results with this study regarding efficacy, convenience and acceptability of insulin pumps among adults with type 2 diabetes, patients' preferences characteristics and problems associated with the pump use have not been adequately reported in the Middle East (only two studies). This study provides an update data among Eastern Mediterranean patients with type 2 diabetes that may add a benefit to the local literature **(Chapter 9, Section 9.2.3)**.

Chapter 8: The perspectives of healthcare providers on the key findings and their recommendations

This chapter describes the results of the interviews with HCPs, which were conducted at the final stage of this research. As outlined in **Chapter 2; Section 2.6**, the aim of this stage was to explore the perspectives of HCPs on the issues identified from the interviews with patients, in wording the key findings, concerns of the participants and problems experienced in the management of type 2 diabetes in the MOH. Also, it aimed to include recommendations from different HCPs, and obtain their views and experiences about the practicality of the recommendations made by the researcher, in order to propose service development.

Ten HCPs were interviewed, specialities and working areas of the HCPs is outlined in **Chapter 3, Section 3.3.3, Table 3.2**. Overall, when statements 1 to 10 were discussed with the HCPs, half of the statements were agreed by most HCPs (n=6-10), while the remaining five statements were appropriate from the perspectives of some HCPs (n=3-5). Responses of the HCPs to the listed statements and their frequency are shown in **Appendix 21**. **Figure 8.1** shows the number of agreements for each of the identified issue.

Statements:
1. Non-adherence to treatment and healthy lifestyle is due to specific beliefs about the normalcy of the disease and lack of awareness about its seriousness and complications.
2. Non-adherence to treatment and healthy lifestyle is due to cultural factors, e.g. fasting in Ramadan, use of herbals and social gatherings.
3. Non-adherence to treatment is due to personal factors, such as forgetfulness, laziness, fear of or perceived side effects.
4. Non-adherence to diet is due to lack of individualised diet plans, which conform to patient's social and educational requirements.
5. Delivery of healthcare services is delayed, especially when referrals are needed.
6. Pen devices are not prescribed/dispensed for all insulin-dependent patients with type 2 diabetes in hospitals.
7. Certain items, such as small-sized pen needles are mostly unavailable in the pharmacy.
8. Although it is available in Medical Stores, Victoza^R pen is not dispensed to patients treated in the MOH.
9. Patients using insulin pumps gain weight due to different reasons, e.g. non-adherence to diet and exercise due to belief in control provided by the pump, lack of awareness about carb-counting and not using pump properly.
10. Consultation time is not enough to discuss all pump-related issues with the doctor.

Figure 8.1: Number of HCPs who agreed with the provided statements

8.1 The perspectives of the HCPs about the provided recommendations

Depending on the issues raised from the interviews with patients, the researcher highlighted some recommendations that were derived from data to improve the delivery of healthcare services, patients' care, and consequently health outcomes. During the interviews with HCPs, the researcher asked them to obtain their views and perceptions about the recommendations, in order to describe their importance, practicality, relevance and acceptability. Furthermore, the HCPs were asked to add further recommendations that were not included when they believed would be valuable. Information obtained at this stage helped to identify the most effective and locally workable interventions, which were believed likely to improve patients' care, and to address the barriers of employing such services. Generally, most of the recommendations were rated by most HCPs (n=6 or more) as 'Most important' **(Appendix 22)**.

A description of the views and experiences of the different HCPs regarding the importance of the recommendations, and the facilitators and barriers for applying each recommendation is provided below.

8.1.1 Recommendation 1- to improve patients' awareness about the seriousness of type 2 diabetes and its complications

Half of HCPs (n=5) reported that education is already feasible via lectures and campaigns. However, during the interviews with nurses, dieticians and pharmacists, themes, such as 'lack of continuity', 'lack of specificity', 'lack of educators' and 'lack of support' from MOH and MOI emerged as barriers for developing education programmes in the MOH:

> *"When the information or advice is delivered more frequently, the patients could feel how serious their disease is. The main persons who can provide patients with continuous education are educators; there are no educators in the Ministry* [MOH]. *Patients see their doctors every 3 months or less, but the educators can follow-up patients more frequently via telephone calls, visits, etc."*
> [HCP 3, nurse, urban area]

> *"We need help from media, radio and TV to show warning video clips. Also, before launching any campaign, we need an approval letter from the Ministry* [MOH], *and you know how long these procedures take. Campaigns are already doable in public areas, such as the World Diabetes Day, but they're not specific to educating patients about how serious diabetes is. Besides, campaigns need a budget from the Ministry* [MOH] *or sponsors."*
> [HCP 8, pharmacist, urban area]

A dietician believed group-sessions are the most effective way for educating patients with diabetes. If these served, individuals will have the opportunity to share

their experiences and thoughts about the disease and its treatment. However, there were challenges for providing this kind of education such as 'lack of staff, support and the appropriate facilities':

> *"Lectures and campaigns are already available but not in a continuous manner. Group-sessions are really helpful for patients, especially if they're from the same age group, and have different experiences according to the duration of their disease. Sometimes, patients don't want to talk about their disease with family members or even to their doctors, but it's ok if they talk to peers, who have the same condition. The big challenge to apply these* [group-sessions] *in the Ministry* [MOH] *is that it needs time, staff, place, and complete organisation and commitment. Once, we tried to do it* [group-session] *here in the hospital but it didn't go smoothly. There were not enough facilities; the area was crowded, and there was disorganisation: some rooms were occupied by other departments without previous reservation. Also, some patients asked for these* [group-sessions] *in the evening because they were not able to come in the mornings, but we* [staff] *can't run it after working hours; we need approval from the Ministry* [MOH]. *We also need staff who agree to work evenings."*
> [HCP 1, dietician, urban area]

From a psychologist's viewpoint, to make patients with type 2 diabetes feel the seriousness of their disease, they should be aware about its influence not only on their health by causing other co-morbidities but also on their family and social life. In addition, the psychologist emphasised the importance of improving patients' awareness about their mental health, as it could affect the management of their disease:

> *"We should improve the awareness of patients about the seriousness of type 2* [diabetes] *because it really affects the patient's social life. I know many cases of divorce because of type 2 diabetes. We should increase the patients' awareness about the importance of mental health as well; cases of fear and obsessions could make the disease worse."*
> [HCP 7, psychologist, urban area]

Overall, all HCPs believed that educating patients about the seriousness of their disease is a very important issue to consider. Some HCPs reported that education is already doable in the MOH, others added that it needs improvement, in terms of quantity and quality. Providing patients with general information about diabetes only when they firstly diagnosed with the disease is insufficient. Also, the MOH should allow diversity in interventions, e.g. supporting education through group-sessions and TV programmes. Helping patients to recognise the psychological impact of their disease on their lives was also recommended by HCPs to improve the awareness of patients about how serious is their disease.

8.1.2 Recommendation 2- to address the social and cultural beliefs and the lifestyle of patients

Social and cultural barriers can interfere with diabetes self-management and quality of life (Glasgow et al., 2001). Because patients have different socio-cultural lives and needs, it was found that identifying social and cultural beliefs and practices of patients, including them in their medical notes, and applying them in constructing their care plans would optimise the management of the disease, and help patients in maintaining behavioural change. Eight HCPs rated this recommendation as 'Most important' but the challenges from the perspective of nurses, physicians and pharmacists were 'lack of time' and 'lack of social workers':

> *"Doctors definitely talk about these things* [cultural/social beliefs], *but they don't have time to write these down in the notes. Doctors spend about 15 minutes with each patient, and focus more on clinical investigations."*
> [HCP 3, nurse, urban area]

> *"Lack of time, diabetes coaches, and social workers are big challenges for addressing the socio-cultural factors of patients."*
> [HCP 10, pharmacist, mixed area]

One physician commented that some HCPs neglect the socio-cultural part of the patients' biography because they are unaware about its significance in the management process:

> *"The medicine family, such as doctors and nurses need to be aware of the importance of considering the cultural and social beliefs in the management of diabetes; most of them are unaware of it."*
> [HCP 6, physician, rural area]

Although most HCPs recognised the importance of taking socio-cultural aspects of patients into consideration when constructing their care plans, one physician outlined that not all HCPs are aware about its significance in the management process. However, some HCPs found this recommendation difficult to achieve, mainly due to lack of HCPs' time. Employing social workers and involving them in the healthcare team was recommended to help in eliminating the 'lack of time' barrier.

8.1.3 Recommendation 3- to initiate 'Pre-Ramadan' training courses for HCPs

During Ramadan fasting, many physiological changes occur in patients with diabetes. The secretion of insulin is disrupted leading to increased gluconeogenesis, hyperglycaemia and ketoacidosis (Meo and Hassan, 2015). Therefore, medicine-taking behaviour of some patients during Ramadan could be dangerous, leading to serious complications. Different HCPs should be aware about the physiological

changes and help patients in managing their disease properly during fasting. From the perspective of different HCPs, training courses are helpful to update their information and generate consistency in advice that they will provide to patients, which helps patients taking the appropriate actions during this month:

> *"We all* [medical staff] *should make sure that we are not providing patients with conflicting information, which confuses them."*
> [HCP 1, dietician, urban area]

From the perspective of a dietician, these courses are available in the MOH since last year and that the 'availability of diabetes consultants' facilitated the implementation of such intervention:

> *"Yes, this's* [pre-Ramadan training course] *doable; it started last year. I attended it; it was a 1-day lecture in one of the primary-care units. The audience was the junior physicians, dieticians, and nurses, and the lecturers were diabetes consultants. They* [consultants] *talked about how to help patients in managing their disease during Ramadan, their diet and medicines."*
> [HCP 2, dietician, rural area]

On the other hand, physicians found that 'lack of resources, educators, incentives and time' was the main barrier for developing such an intervention, and they believed that it might need 5-10 years to be developed:

> *"Lack of resources is the big barrier to provide such programmes. To educate a huge number of doctors, we need educators; we don't have well-trained doctors who are able to educate. Also, there's lack of incentives; the consultants receive their salaries whether they provide this education or not, some consultants would say: why should I educate? Also, it needs commitment from all the staff; not all of them wish to attend workshops because of their busy schedules."*
> [HCP 5, physician, urban area]

Generally, all HCPs found that conducting Pre-Ramadan courses for HCPs is very important to improve patients' behaviour during Ramadan fasting. However, although physicians and dieticians emphasised the availability of these courses since a year, most HCPs reported challenges. The limited number of diabetes consultants and lack of support from the MOH may interrupt the development of these courses.

8.1.4 Recommendation 4- to reinforce motivation and education verbally and in writing

From the perspective of psychologists the 'lack of continuity' in providing motivation and education and the 'generality of information' provided were the main challenges in educating patients in the MOH:

"These [brochures and leaflets] *are available but not continuously. Also, patients need something more specific to their cases, and not just general advice. Each patient has a different social life and health factors. What we've got now is beneficial for patients who are just diagnosed with diabetes. So, it needs to meet all the population needs. Also, some patients are uneducated, and they interpret pictures more than writing."*
[HCP 7, psychologist, urban area]

During the interviews with nurses and dieticians, 'lack of support' theme emerged as a 'barrier' for improving patient education, from which the following sub-themes 'lack of resources, incentives, nurses and time' emerged:

"We should have more nurses. Nurses can follow up patients' cases more than doctors; they can call them every 3 days, once a week, or every 2 weeks and have a chat with them about their medicines or any query. Our nurses do this themselves; they have a list of the registered patients, and they call them regularly, but when there's a lot of work, and the clinic is busy, they can't do."
[HCP 2, dietician, rural area]

"We need a budget for this. Sometimes we receive brochures and leaflets from the pharmaceutical companies. If we have time, we print-out some advice from the Internet and distribute this to patients. It's all personal effort."
[HCP 4, nurse, rural area]

Physicians and pharmacists commented that reinforcing motivation and education might take as long time as 5-10 years. From the perspectives of those HCPs, 'lack of an education department' and 'lack of specialised staff/educators' were the main barriers:

"We need educators; they're the most important members to provide education. The Ministry of Health must be aware that lack of educators may affect adherence and reduce the efficacy of the treatment."
[HCP 5, physician, urban area]

"The big challenge that we face is the ratio of patients to the number of doctors; it's too huge. It's not just five patients per clinic; it's 10's of them! I don't know how we can manage that [reinforcing education with each visit] *easily. We need an education department to work in collaboration with the clinical department of diabetes in each hospital."*
[HCP 6, physician, rural area]

"We lack the availability of trained professionals in patient motivation and empowerment."
[HCP 9, pharmacist, mixed area]

Overall, most HCPs (n=7) rated reinforcing education verbally and in writing as 'Most important' recommendation. Regarding the practicality of such an intervention, most HCPs reported that lack of educators who can help in taking the responsibility of educating patients continuously and relieve the burden on other HCPs is the main barrier.

8.1.5 Recommendation 5- to train dieticians to individualise care plans that recognise the socio-cultural needs of patients

From the perspective of physicians, psychologists and pharmacists, it is crucial that dieticians undergo training to know how to deal with each patient as an individual case, in order to help patients maintaining their behavioural change. However, from physicians' and pharmacists' viewpoints, this recommendation might take 5-10 years to be implemented due to 'lack of qualified personnel', who can provide training for dieticians and shortage of staff:

> *"I think the problem is the staff shortage. For example, here* [in the hospital] *we have only 4 dieticians, but according to the increasing number of patients, we need 10. Sometimes, the staff takes sabbatical leave, or maternity leave, which further reduces the number of staff."*
> [HCP 6, physician, rural area]

> *"To provide dieticians with the required training, we need qualified dieticians to educate others, dieticians who are specialised in diabetes care."*
> [HCP 8, pharmacist, urban area]

When dieticians were asked during the interviews about the importance of applying such recommendation, they commented that they are aware of the importance of taking socio-cultural factors of patients into consideration. They also added that they managed patients' according to their needs, when possible:

> *"We have fixed diet plans of 1200, 1500, and 1800 calories. I meet with the patient and discuss his/her lifestyle, then, decide which regimen I should give him/her according to their lifestyle. If the patient's lifestyle is unsteady and very changeable, I bring an A4 paper and try to create a diet plan specific to the patient's requirements."*
> [HCP 1, dietician, urban area]

The role of dieticians in providing patients with the appropriate advice, in terms of their socio-cultural needs, was supported by the perceptions and views of nurses. Nurses commented that the dieticians are competent, and well educated about the management of patients according to their needs. However, one dietician reported that 'lack of time' was the main factor that hindered them from managing patients according to their needs all the time:

> *"We are well educated about how to treat each patient as an individual case, but sometimes the time limits us. Sometimes, we have many patients on the waiting list. Attending training courses is beneficial for refreshing our information, but if we would attend courses, then, we should run more clinics to serve the high number of patients, which means we need more staff."*
> [HCP 2, dietician, rural area]

Although training dieticians how to individualise care plans according to patients' socio-cultural needs was perceived as 'Most important' by most HCPs, barriers such

as lack of qualified dieticians and time identified to interrupt the practicality of implementing this recommendation. Dieticians believed that they were meeting the patients' needs when possible, which means that they did not consider these issues during clinic rush hours. However, dieticians were eager to attend training regularly if this is supported by the MOH.

8.1.6 Recommendation 6- to involve family members when constructing care plans

Adherence to lifestyle modifications, e.g. diet and exercise and maintenance of appropriate behaviour requires support and encouragement from the family. Low levels of family support constitute a strong psychosocial barrier that could impact self-management and quality of life (Glasgow et al., 2001). In the current study, awareness of family members about the patients' needs helped them in changing and maintaining their behaviour.

From the perspective of the majority of HCPs (n=9), this was a very important recommendation, as they believed that social support could help patients in making decisions and maintaining behavioural change. The HCPs were aware about the importance of social support, and they were attempting to involve family members in their appointments:

> *"I usually tell my patients to ask one of their family members, or their partners to accompany them in the counselling session, specially if the member is part of the problem, which we're trying to resolve."*
> [HCP 7, psychologist, urban area]

A dietician found that involving a family member would be helpful only if she/he has the responsibility for managing the patient. For instance, in Mediterranean culture, it is common that women are responsible for cooking. Therefore, the dietician believed that making those responsible women aware about what should be eaten and what should be avoided would help in the management of patients. Therefore, that dietician was asking male patients to invite their wives to accompany them, but was not asking women to invite their husbands, as this was perceived as unhelpful:

> *"It depends on the patient. For example, for men, I ask them to bring their wives with them because they're responsible for cooking their food. But it's not always applicable because their wives do have other responsibilities, or they can't leave their work. For ladies, I don't ask them to call their husbands, but sometimes, especially if they have other family members having diabetes, they ask me to allow them to come along and share the consultation. I said: it's OK, I tell them it's good to have someone who supports you."*
> [HCP 2, dietician, rural area]

Overall, involving family members in the management of patients was perceived important by the majority of HCPs. However, some HCPs, such as nurses and physicians reported 'time-constraints', 'cultural beliefs', and 'self-reliant feelings' as the barriers to involve family members in the consultation. The HCPs added that patients frequently give excuses that their family members have no time to accompany them, as they have their jobs, or housework. Also, the patients feel they are independent, and that the presence of a family member was unnecessary or an intrusion. In addition, in the Mediterranean culture, females usually feel jealous of other females, especially if they were younger than them and more attractive. So, they do not prefer to bring their husbands with them during the visits:

> *"Sometimes when I asked female patients to tell their husbands to accompany them on their visits, they stared at me and said: Why do you want my husband?"*
> [HCP 3, nurse, urban area]

> *"The patients themselves don't want to cooperate, even if we keep reminding them about to ask their family members to accompany them, they don't listen to us. The patients feel they're independent, and they just want to take the information and go."*
> [HCP 6, physician, rural area]

Therefore, the presence of these personal and cultural barriers hindered some HCPs from involving family members in the consultation of patients' care plans although they believed in its significance.

8.1.7 Recommendation 7- to coordinate the delivery of healthcare services between different departments

Delays in the delivery of healthcare services, particularly when patients were referred to other departments, e.g. cardiovascular, renal or the ophthalmology department was prevalent in this study. The researcher explored HCPs' perspectives on the importance and practicality of coordinating the care services to improve patients' care. HCPs such as dieticians, nurses and physicians working in different areas (e.g. urban and rural) reported several challenges. From the responses of HCPs, it was concluded that the failure was not perceived to originate with the diabetes team. Different HCPs that they make referrals for patients immediately when they required it, because they were aware of how significant is to refer patients with diabetes, in order to prevent disease complications:

"In the case of my patients, if I find the patient needs a referral to other department or doctors, I refer him/her for further investigations without any delay. However, the appointments schedule there is crowded [other departments]! I don't know what to do, and I can't interfere. For example, if the patient needs to see a cardiologist, I refer him/her to the cardiovascular diseases department, but making an appointment is not my business. It's their job."
[HCP 5, physician, urban area]

However, the HCPs reported some barriers, which were out of their control and needed input from the MOH. Physicians, dieticians and nurses reported a 'lack of connection' between different departments, 'lack of resources' such as medical equipment and staff and 'lack of an appropriate facility', a building that incorporate all the departments that patients with type 2 diabetes need, such as cardiovascular and renal departments. One nurse reported that when some patients were referred to other departments or for further investigations, they were annoyed because buildings are too distant from each other:

"We need more staff, and we need to be linked to other departments/clinics, because it's much easier to take decisions within the same team than between different departments."
[HCP 1, dietician, urban area]

"For each speciality we only have one doctor. One doctor only in the whole hospital! For example, there is only one ophthalmologist for the ophthalmological examination, the fundoscopy, and the fundus photography. This doctor now is on study leave, and the Ministry [MOH] hasn't employed anyone instead. So, if the case is urgent, we refer the patient to Al-bahar Hospital [the Ophthalmology Hospital], which is so far from here. Also, there is delay in fixing machines. Once, the fundoscopy machine stopped working, so, we postponed the appointments until they [MOH] sent the technician to fix it. So, we need more staff."
[HCP 3, nurse, urban area]

"It's very important to put all the departments, which the patients with diabetes need, in one building, such as the foot care, ophthalmology, diet, etc., to facilitate patients adhering to their appointments. The patients excuse their non-adherence to appointments with reasons such as: 'the departments are too far from each other'. We suggested this idea to the Management [Department] in the Ministry [MOH] many times but no one replied to us. In this hospital, we barely got these two rooms [clinics] for receiving our patients; one room for the doctor and the other for the nurse. Sometimes, if we have enough staff [doctors], we use the rooms [clinics] of other departments, such as the Internal Medicine Department to receive our patients there. Also, we need cooperation from the MOH. Once we ordered a blood pressure monitor but no one replied to us, we waited for 2 years until one of the companies provided it to us!"
[HCP 4, nurse, rural area]

"We have limited resources, for instance, we have only one machine for the x-ray and MRI [Magnetic Resonance Imaging] in the hospital for examining diabetic feet."
[HCP 6, physician, rural area]

One dietician added information regarding coordinating delivery of healthcare services within the same department. This dietician mentioned that patients sometimes avoided dietician appointments because they were on different days to their appointments with doctors, and they could not attend to the hospital frequently. Also, the dietician found that sending reminder messages to patients played a role in improving their adherence to appointments. However, the 'lack of resources' theme repeatedly emerged, as the dietician mentioned that she was using her private mobile phone:

> *"Healthcare professionals should cooperate together and be more flexible with patients in arranging their appointments. Patients usually skip their appointments with us because it doesn't match with their appointments with physicians, and they can't come to the hospital more frequently, but if the appointments were on the same day, they would be more likely to be adherents. Also, sending reminding messages to patients is useful; patients like it when they feel that the staff are taking care of them. Yet, we need support from the Ministry of Health. I used to text patients from my mobile phone because the land line here* [in the hospital] *has not been working for a while, and no one has taken care of it yet!"*
> [HCP 1, dietician, urban area]

Generally, all HCPs believed that coordinating delivery of healthcare services is an important issue to improve patients' care and adherence to appointments. However, The majority of HCPs reported deficiencies in the healthcare system, such as lack of equipment and appropriate facilities, which should be taken into consideration by policy makers in the MOH.

8.1.8 Recommendation 8- to inform patients about different insulin delivery methods and involving them in decision-making

When HCPs were asked during the interviews to provide their perceptions about informing patients about different insulin delivery methods, conflicting opinions emerged. For example, some HCPs, such as nurses and physicians disagreed with this recommendation. Those HCPs reported that patients were not sufficiently aware of the issues to select the appropriate method, and that prescribing and deciding on the appropriate option is in doctors' hands only:

> *"I don't think this would be applicable. For example, the pump only suits patients who are dedicated to perform all the tasks related to it, such as carb counting. Some patients might choose the pump, but then they don't use it properly, which causes problems such as hypoglycaemia and coma."*
> [HCP 4, nurse, rural area]

> *"We know better than patients, and we have to decide, not they."*
> [Physician 5, physician, urban area]

Other HCPs, such as dieticians, psychologists and pharmacists emphasised the importance of involving patients in deciding on the appropriate method. They argued that patients would choose the option that is acceptable to their psychosocial needs, and it would help them in adherence to their treatment:

> *"I think this is very important; the patients should use the method which they feel more confident about, and not be embarrassed or stigmatised using it in public areas. If they* [patients] *were involved in the decision, it would much improve their adherence."*
> [HCP 7, psychologist, urban area]

However, those HCPs believed that implementing this recommendation would need a time, in order to overcome the cultural barriers, such as the 'physician-patient relationship', which gives the doctors the locus of control, and 'doctors oppression':

> *"Our doctors want to prescribe what they have in mind only; don't agree to discuss it with the patients. They* [doctors] *might discuss the patient's concerns, but at the end they believe they are prescribing the best for the patient."*
> [HCP 8, pharmacist, urban area]

Generally, dieticians, pharmacists and psychologists believed that involving patients in deciding the appropriate insulin delivery method is an important issue that should be considered by doctors. On the other hand, doctors and nurses believed that doctors could decide the most appropriate method for patients better than patients themselves. This informs an implication towards the paternalistic approach of doctors.

8.1.9 Recommendation 9- to reinforce pharmacists/nurses/psychologists' roles in the management of type 2 diabetes

Roles of HCPs in the MOH compared to doctors is very limited and services, such as pharmacist/nurse-led diabetes clinics are lacked in Kuwait. Providing patients with such services was efficacious in improving health outcomes in different countries in the world and the Middle East (Gill et al., 2008; Al Mazroui et al., 2009). Therefore, the researcher listed this recommendation (reinforcing roles of all HCPs in the disease management) in the interview schedule for HCPs to discuss it with them and obtain challenges of implementing such services in the MOH. All the HCPs considered this a crucial issue, as it would improve the awareness of patients, their adherence, the management of the disease and consequently health outcomes. Also, this would relieve the burden on doctors as well:

"Patients must be referred to pharmacists. This is doable abroad, where patients meet with the pharmacists and discuss with them different treatment options, side effects, and interactions. The patients there are so educated about their medicines. It's different here [in Kuwait]; *the patients are not given more than one option and that's it. The patients should decide on the option they'd like to go for."*
[HCP 1, dietician, urban area]

"Psychologists are strongly needed to deal with patients with diabetes; I experienced many cases, where the patients thought of committing suicide, at least once in their life. Also, amongst the important staff is educators."
[HCP 3, nurse, urban area]

"This will have a great value as it will allow doctors to spend more time with each patient, and discuss more important issues."
[HCP 6, physician, rural area]

One dietician reported that including other HCPs, such as psychologists in managing patients with type 2 diabetes could be they key for improving patients' adherence and health outcomes. The dietician reported that she experienced many cases of mild depression, stress or anxiety, for which patients were not having any treatment or counselling sessions:

"I think that involving psychologists would further help patients. There are some patients who are difficult to treat because they feel stressed and depressed."
[HCP 2, dietician, rural area]

However, there were some differences between urban and rural areas in this issue. For instance, the role of psychologists was more apparent in urban areas than in rural:

"We have a psychologist who comes every Thursday, and follows up our patients in the clinic, but this is not the case in other hospitals. There, they refer the patients who have depression or anxiety to the Psychiatric Hospital."
[HCP 5, physician, urban area]

Most HCPs (n=6) reported that there were barriers to implementing clinics led by HCPs other than doctors. These were related to patients and the healthcare system. For example, from psychologists and nurses' viewpoints, patients have cultural beliefs, which prohibited them from visiting HCPs, such as 'social stigma' and 'beliefs in doctors only':

"The patients here might reject this idea, or they might not participate in it [nurse/pharmacist-led diabetes clinic], because they only trust the doctors. Many times when I gave the patients information, they said: We'd like the doctor to confirm it, or they just listened but then, they would return to the doctor."
[HCP 4, nurse, rural area]

"The problem is with our patients; they feel stigmatised visiting the psychologist. Most people said: we're not crazy, why should we visit the psychologist? Also, when they visit me they don't do it regularly; but they see me only when they have time or when they have a problem."
[HCP 7, psychologist, urban area]

In addition to the patient-related barriers, there were healthcare system-related barriers, such as 'lack of training' and 'lack of qualified staff':

"We asked the Ministry [MOH] *many times to qualify us* [nurses experienced in diabetes] *as 'diabetes educators', but the discussion is useless. The process just needs criteria for testing nurses, and if the nurses pass the exam, they get a certificate for this qualification. Here* [in Kuwait], *there are no criteria or test for this purpose. Once nurses are employed, they just give them a license for practising the career, and that's it, they don't get any follow-up training or tests to become diabetes-specialists or educators!"*
[HCP 3, nurse, urban area]

"I don't think this [clinics led by HCPs other than doctors] *would be workable at the moment because we have shortage in qualified persons. For instance, the pharmacist-led clinic needs a qualified pharmacist to manage the patients, not just a general pharmacist. Pharmacists should do a training programme, and be experienced in the management of diabetes, but we don't provide such programmes at the Ministry* [MOH]. *It might be a matter of time; perhaps it takes 5-10 years."*
[HCP 10, pharmacist, mixed area]

On the other hand, from the perspective of a dietician there were some facilitators for having pharmacist-led diabetes clinic in the MOH, such as 'competent pharmacists', 'availability of facility' and 'availability of staff':

"We have enough pharmacists; all they need is a corner in the pharmacy where they can meet the patients to discuss their treatments. Our pharmacists are good; they [MOH] *should employ some full-time pharmacists for this purpose."*
[HCP 1, dietician, urban area]

Overall, involving different HCPs in the management of type 2 diabetes was agreed by all the interviewees and perceived as a crucial issue to improve patients' awareness and adherence. However, most HCPs believed that lack of staff and the image of HCPs other than doctors would be the main problems to implementing such services. This informs an implication to modify the HCPs-patient relationship and improve patients' awareness about the competency of all HCPs and their significance in managing their disease.

8.1.10 Recommendation 10- to initiate a 24-hours help-line service managed by diabetes specialists

In this study, some HCPs were very cooperative with patients to the extent that they provided them with their private phone numbers, in order that they could be called with any query. However, these personal efforts from the HCPs were mostly limited to working hours. Therefore, the researcher recommended establishing a 24-hours service managed by diabetes specialists. However, HCPs provided conflicting views regarding this proposed service. Most HCPs (n=6) found it important to be implemented:

> *"Sometimes the patients have very simple queries, so they don't have to come all the way to the hospital to discuss it."*
> [HCP 1, dietician, urban area]

One pharmacist and one physician commented that a help-line service managed by specialists is 'less important', because they found that general practitioners, who work in the Emergency Department of the hospitals and those who work in the call centre of the MOH are competent and could manage urgent cases of diabetes temporarily until they could see their doctors:

> *"It's* [help-line service managed by specialists] *not important. In each hospital, we have an Emergency Department. The physicians who work there are able to treat all the cases, and to stabilise the patient until the next working day, when the diabetes consultant attends."*
> [HCP 6, physician, rural area]

> *"There's a phone-line (105) in the Ministry* [MOH]*, which general practitioners use to answer all patients' enquiries, not just patients with diabetes. I think this is fine; all physicians have the urgent information that any patient needs, not necessarily diabetes specialists."*
> [HCP 10, pharmacist, mixed area]

To identify the feasibility of implementing such a service, themes such as 'lack of staff' and 'lack of resources' emerged as barriers to this service in the MOH:

> *"No, I don't think this could be workable; such a service needs staff able to work night shifts, and they must be paid."*
> [HCP 6, physician, rural area]

> *"I think such a service needs many resources: computers, a system including all patients' information and disease history, staff, and salaries. So, it might take 5-10 years to be implemented."*
> [HCP 7, psychologist, urban area]

From the interviews with some nurses, physicians and dieticians, it was found that 'willingness to help' was the factor that could facilitate the implementation of such service. It was noted that most HCPs were eager to help patients. However, 'lack of

incentives' was mentioned by those HCPs as a barrier for maintaining such assistance, and that lack of awareness of policymakers about the importance of the service might prevent its implementation:

> *"Such a service needs a budget from the Ministry of Health. The policymakers need to initiate it; it requires a special team, doctors, nurses and dieticians because we can't balance between our jobs in the hospital and this service."*
> [HCP 1, dietician, urban area]

> *"We* [dieticians] *and the nurses usually provide patients with our mobile phone numbers to call us or send a WhatsApp for any query, during 12 working hours. But it is personal effort, and we don't get paid for it. But maybe in a year, the Ministry* [MOH] *will recognise the importance of such a service and utilise it."*
> [HCP 2, dietician, rural area]

Although a 24-hour help-line service managed by diabetes specialists was perceived important by most HCPs, they reported different challenges to implementing such service, e.g. lack of staff and resources.

Overall, recommendations provided in this study were discussed with different HCPs who were involved in the management of adults with type 2 diabetes. The recommendations were examined by the HCPs for significance (e.g. whether they are needed to improve patients' behaviour) and practicality (e.g. whether there are barriers to implementing these recommendations). In order to identify the most important and feasible interventions, **Table 8.1** was constructed.

Table 8.1: The importance and practicality of the recommended interventions from the perspective of HCPs

Intervention (no. HCPs rated the item as 'Most important')	Barriers	Facilitators
1. Health awareness of patients, e.g. awareness about short and long-term diabetes-related complications needs to be improved continuously through campaigns, group sessions or lecture courses at hospital clinics, primary-care units, KDS, or via audio-visual aids, e.g. educational programmes in radio and television. **(10)**	-Lack of educators -Shortage of staff -Lack of HCPs' time -Inappropriate facility -Lack of cooperation from MOH to support out of working hours sessions	-Motivated HCPs
2. Social and cultural beliefs and lifestyle concerns should be addressed and included in patients' medical notes. **(8)**	-Lack of social workers -Lack of HCPs' time -Poor awareness of some HCPs	-Awareness of some HCPs
3. HCPs should undergo Pre-Ramadan training programme, and cooperate together, in order to optimise care provided to patients during this month. **(6)**	-Lack of incentives	-Availability of consultants
4. Educational and motivational advices regarding adherence to treatments should be provided verbally and written (e.g. brochures/leaflets), and reinforced with each clinical visit/prescription of medicines. **(7)**	-Lack of incentives -Lack of support from MOH (budget) -Needs preparation -Lack of time -Lack of educators -Needs education departments	-Motivated HCPs
5. Dieticians need to be educated about the educational and social differences when dealing with patients, and how those differences could impact self-management behaviour of patients. Also, they need to be aware about how to individualise care plans that conform to each patient's needs and life. **(6)**	-Shortage of staff -Lack of qualified personnel to train dieticians -Lack of dieticians' time	-Competent dieticians
6. Family members should be involved when constructing care plans and lifestyle modifications. **(5)**	-Cultural beliefs of patients (women jealous) -Time-constraints of family members -Self-reliant feeling of patients	-Awareness and commitment of HCPs
7. The delivery of healthcare services should be further coordinated particularly, when patients needed referrals to different HCPs/department. **(8)**	-Lack of connection between departments -Shortage of staff -Lack of medical equipment	-
8. Patients initiated on insulin should be informed about the different methods that are available for insulin delivery, e.g. pens and pumps. Also, they should be involved in making decisions related to the selection of the device. **(4)**	-Doctors' oppression	-
9. Services, such as pharmacist/nurse-led diabetes clinics, or psychological interventions that take care of this group of patients by incorporating different HCPs in the management process should be implemented. **(7)**	-Lack of training programmes for HCPs to be more qualified -Beliefs of patients in doctors experience only -Social stigma about visiting psychologists	-Motivated staff (nurses, pharmacists and psychologists)
10. A 24-hours help-line service managed by diabetes specialists for urgent and between appointments enquiries should be considered. **(6)**	-Lack of awareness about its importance -Lack of resources (computer system, staff, salaries)	-

Most HCPs identified improving patients' awareness about diabetes-related complications continuously through campaigns, group sessions or lectures, addressing socio-cultural beliefs of patients in their medical notes to consider them when managing patients, coordinating care services between different HCPs and departments, reinforcing motivational advices verbally and written with each clinical visit/prescription of medicines and reinforcing roles of other HCPs by establishing diabetes-led clinics, as the most important interventions that need to be considered to improve patients' management behaviour **(Table 8.1)**. However, there were challenges for implementing such recommendations, these are discussed in **Section 8.2**.

8.2 Theory-informed behavioural change intervention

This stage enabled the researcher to develop a theory-informed behavioural change intervention to implement evidence into practice. For this purpose, the Theoretical Domains Framework was used (French et al., 2012). The steps of the framework are outlined in **Table 8.2**, and below is an explanation for how this framework was adopted in this study.

Table 8.2: Steps for developing a theory-informed intervention

Step 1	Who needs to do what differently?
Step 2	Using a theoretical framework, which barriers and enablers need to be addressed?
Step 3	Which intervention components could overcome the modifiable barriers and enhance the enablers?
Step 4	How can behaviour change be measured and understood?

From findings of this study and the perspectives of HCPs, patients' poor management behaviour (e.g. non-adherence to treatment and lifestyle) was due to: specific beliefs about the normalcy of the disease and lack of awareness about its seriousness and complications, cultural factors (e.g. fasting in Ramadan, use of herbals and social gatherings) and personal factors (e.g. forgetfulness, laziness, fear of hypoglycaemia and perceived side effects). Therefore, most HCPs agreed with recommendations: 1, 2, 4, 7 and 9 **(Table 8.1)**, in order to improve patients' management behaviour and health outcomes. The researcher examined the implementation of those recommendations in the light of the Theoretical Domains Framework, in order to further assess the practicality of the interventions and inform specific recommendations **(Table 8.3)**.

Table 8.3: A description of the steps used to choose the behavioural change techniques

Target groups	Domains	Intervention components
Patients with poor HbA1c levels, who have:	1. Knowledge 2. Beliefs	-Continuous/attractive educational/motivational advices delivered via lecture, campaigns, group-sessions, brochures and leaflets.
1. Low awareness about seriousness of diabetes and its complications		
2. Beliefs about fasting in Ramadan		
3. Beliefs in efficacy and safety of herbal medicines		
4. Forgetfulness, laziness and fear of side effects		
HCPs with poor awareness about importance of considering patients' socio-cultural factors	Knowledge	-Training courses/workshops for HCPs to improve their awareness, delivered by senior consultants. -Observations of doctors' consultations.
Policy makers	Governmental context	-Addressing HCPs' needs to policymakers in the MOH, e.g. employ educators, increase staff, increase resources (equipment, hotline, facilities) and incentives. -Enhancing role of psychologists, pharmacists and nurses via diabetes-led clinics.
Outcome measures		
Primary - Improved adherence measured via interviews with patients - Improved HbA1c level measured via blood test Secondary - Reduced rate of hospital admissions measured via medical records		

Table 8.1 summarises the barriers that need to be addressed and modified, such as shortage of staff, lack of educators and social workers, poor awareness of some HCPs about patients' socio-cultural needs, lack of education departments and disconnection between different departments. Also, it clarifies the factor that may facilitate behavioural change, which was the competent HCPs (e.g. dieticians, physicians and nurses), who had the willingness to educate patients and follow them up. **Table 8.3** shows the intervention components that may overcome the modifiable barriers and enhance the enablers. For instance, to overcome lack of HCPs' time and shortage of staff, policy makers need to realise the importance of employing more staff and involving all the healthcare team in the management process. Also, to enhance the enablers (e.g. motivated HCPs) for implementing the interventions, incentive and compensation plans need to be designed by the

government. The outcome measures would be assessing adherence to medicines, diet and exercise via self-report methods, e.g. interviews, and measuring HbA1c levels as primary outcome measures and rate of hospital admissions as secondary outcome measures. Overall, in this section the required recommendations for improving patients' management behaviour were identified, discussed with the HCPs and the most practical interventions were addressed. Barriers to implement these interventions were identified from the perceptions of the HCPs.

8.3 Discussion

This chapter helps to inform healthcare provision through recognising the interventions required to initiate behaviour change in patients with type 2 diabetes to improve their health outcomes. Most HCPs recommended improving educational programmes and involving all the health team in the management process by establishing services, such as nurse/pharmacist led-diabetes clinics. To assess the benefits of these services, the researcher examined the fundamental parts in improving quality of healthcare services, e.g. Donabedian's Model (Visnjic et al., 2012). The results revealed that implementing such services in the MOH would need more resources including staff and facilities. Details of the process of each of the services are shown in **Appendix 23**. The outcomes of implementing those services would be improvements in health outcomes, in terms of glycaemic control and HbA1c levels as a consequence to improvement in patients' knowledge and adherence to treatment and lifestyle modifications. In the management of diabetes, providing education by a multidisciplinary team help in exploring barriers that physicians failed to diagnose and consequently promote behavioural change (Bernabeo and Holmboe, 2013).

However, a service such as pharmacist-led diabetes clinic may need more than the required resources of staff and facilities. To implement such service in Kuwait, the pharmacy practice and policy need to be modified and the concepts of pharmaceutical care, which defined as 'the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient's quality of life' should be interpreted by the government and policy makers (Harding and Taylor, 2016). Although there are different classifications for pharmacists working in the MOH (e.g. pharmacist, chief pharmacist and consultant pharmacist), there is no legislation that defines the professional roles of each category (Katoue et al., 2014). For instance, the role of pharmacists, in all categories, is limited to dispensing prescribed medicines to patients and giving instructions on how to use them, in

addition to preparing formulations and other administrative procedures, such as annual counting of medicines and registering orders of medicines. In addition, there is no national policy that distinguishes between pharmacy technicians and pharmacists duties, and both of them can undertake the same responsibilities (Katoue et al., 2014). Health care is continuously developing and pharmacists should take new responsibilities, in order to influence in their occupation. For instance in the UK, consultant pharmacist has advanced roles in patient care, professional education and research. Independent pharmacist prescriber can prescribe any medicine autonomously for any condition, with the exception of controlled drugs for the treatment of addiction (Harding and Taylor, 2016).

In Kuwait, the pharmaceutical care concept is not yet interpreted and further improvement in terms of pharmacist-physician and pharmacist-patient relationship is needed. In 2006, a study describing the pharmacy practice in hospitals in Kuwait revealed that lack of time and lack of staff were the main barriers to implementation of pharmaceutical care practice (Awad et al., 2006). In 2014, a study conducted among hospital pharmacists to evaluate their contribution to the management of patients with type 2 diabetes (Al-Taweel et al., 2014). The study showed that pharmacists were enthusiastic to contribute to delivery of pharmaceutical care. However, the pharmacists reported barriers to implementing pharmaceutical care services, such as pharmacist-physician interaction, pharmacists' confidence and pharmacists' image by patients. Pharmaceutical care requires development of inter-professionalism by reinforcing pharmacist-physician partnership, in which both take responsibility of patient care (Katoue et al., 2014). Pharmacists in Kuwait believed that continuous training and education would help them in increasing their confidence when discussing pharmaceutical care issues with physicians. Pharmacists are still seen by patients and doctors as dispensers. To change this image, the role of pharmacists needs to be improved to include other services, such as prescribing and medication review.

Clinical pharmacy in Kuwait is still not well established. Hospital pharmacists cannot undertake clinical activities on wards, e.g. access to patients' medical records and monitoring drug therapy until a proper job classification is set. Pharmacists can only dispense medicines through typical dispensing windows. This approach of medication delivery limits the privacy of counselling and constitutes a barrier in the pharmacist-patient relationship (Katoue et al., 2014). Services, such as Medicines Use Reviews (a consultation between a pharmacist and patient about the prescribed

medications, and giving feedback to the prescriber) and New Medicines Service (providing support to patients with long-term conditions receiving new medicines aiming to improve their adherence) are internationally accepted (Harding and Taylor, 2016). The paternalism of doctors in Kuwait constitutes a barrier to implement pharmaceutical care services. From the perspectives of pharmacists, doctors will not accept their new responsibilities and roles (Katoue et al., 2014).

Effective team working requires that HCPs understand the roles of each other, combine their knowledge and skills, and share the responsibility for outcomes (Harding and Taylor, 2016). However, the leadership concept of doctors in Kuwait may introduce tensions within the team. This concept is historical and needs time to be changed. Doctors need to recognise the importance of inter-professional communication. For instance, in hospitals in Kuwait, patients with type 2 diabetes are still managed through manual medical notes and prescriptions, which written by doctors. Even for a repeated prescription, pharmacists have to obtain doctors' approval to dispense it. The complete authority of doctors imposes the communication between them and pharmacists in different situations. For example, to discuss unclear handwriting, unavailable prescribed medicine/item, etc. Communications between doctors and pharmacists usually ended up with pharmacists' frustration, as a result to doctors' autonomy. This may reduce the motivation of pharmacists to be involved in communication with doctors. Lack of communication may create situations of medication errors and constitute a threat to patients' safety and satisfaction (Gallagher & Gallagher, 2012).

Putting patients at the heart of care delivery, working in partnerships with them and ensuring that their care choices are respected, which is identified as the patient-centred professionalism, is recommended in all aspects of health professions (Hutchings and Rapport, 2012). The significance of engaging patients in their treatment choices, after being provided sufficient information, should be addressed. In the UK, embedding the patient-centred professional approach became a part of good medical, nursing and pharmaceutical practice (Hutchings and Rapport, 2012). In order to provide the best healthcare, it is crucial to obtain patients' perceptions about what is important in the treatment they receive. For example, in the USA, it was reported that good communication skills and compassion was what patients perceived important in their doctors (Wiggins et al., 2009). In the UK, in the context of pharmacy, receiving the correct prescription was perceived as the patient-centred professionalism to patients (Rapport et al., 2010).

In Kuwait, moving from paternalistic approach, where clinicians make decisions with little or no input from patients, toward patient-centred professional approach should be emphasized. Nowadays patients have broader access to information (e.g. Internet), so, they prefer to work in partnerships with their doctors and make their health-related decisions based on their beliefs and preferences (Bernabeo and Holmboe, 2013). To implement such approach in the MOH, efforts need to be directed on the professionals' part. HCPs will need specific knowledge, beliefs and attitudes to engage patients and identify the degree of engagement. Cultural differences, age, sex and education may affect the degree of patients' engagement. Lack of knowledge and self-efficacy and the perception about lack of providers' respect to their preferences may all impact the engagement of patients in their treatment choices (Bernabeo and Holmboe, 2013). This may inform implications for future research, policy makers and the government. Future research should be conducted to identify skills required by patients, HCPs and healthcare system to adopt such an approach. Policy makers should then organise consultation workshops to professionals and stakeholders to inform them about these skills and make it a part of continuous professional development. The government should ensure introducing such information in the development of medical curricula.

Different organised approaches towards delivering high quality diabetes care can be used as alternatives to traditional approaches of doctors' consultations. Implementing models that promote empowerment, such as Shared Medical Appointments (SMAs) have been identified superior in improving knowledge and behaviour of patients with type 2 diabetes than traditional provider visits (Ridge, 2012). SMAs involve the implementation of educational interventions, which through behavioural strategies enhance patients' coping and problem-solving, leading to behavioural change. There are no standards for delivering such model of care, and it can be applied in different ways. For instance, it can be delivered as a group of 10-20 patients. Various HCPs can be a component of the healthcare team of this model, such as physicians, nurses, dieticians and psychologists. Implementing such model does not require any training beyond standards of diabetes care. Taking into consideration such model of care by policy makers in the MOH will facilitate the interactions between patients and their HCPs and support the cooperation between them (Ridge, 2012).

From findings of this study and the perspectives of the HCPs, this chapter introduced a theoretical framework for what should be done and how, in order to

improve the management of type 2 diabetes in Kuwait. The interviews with HCPs confirmed the issues emerged from this study regarding the prevalence of non-adherence and misuse of medicines and devices by adults with type 2 diabetes. It has been concluded from this chapter that improving health awareness and beliefs about type 2 diabetes is the key towards improving medicine-taking behaviour of patients, and their health outcomes. Considering patients' attitudes and beliefs about their disease and treatment by HCPs is crucial to promote behavioural change and treatment adherence as a consequence to improved satisfaction (Wens, et al., 2005; Bernabeo and Holmboe, 2013).

Implementing educational services, which are not based on research evidence may not give the desired outcomes (Cooper et al., 2008). In Kuwait, diabetes education is provided to all newly diagnosed patients with type 2 diabetes but no comprehensive evidence-based programme is used. Therefore, the potential behaviour change techniques that were identified in this study and discussed with HCPs will assist in informing the most practical and locally relevant interventions. Many barriers were identified, which makes the implementation of such interventions and partnerships between patients and professionals challenging. These barriers should be targeted by the government, in order to improve the quality of diabetes care and the health outcomes.

An overall discussion and conclusion is provided in the next chapter **(Chapter 9)**.

Chapter 9: Discussion and conclusion

This chapter provides an overall review of the study findings, discusses the results in the light of literature and highlights the policy and practice implications of the study.

9.1 Overview of the study findings

Conducting this study was vital as there is a lack of published studies that explore patients' experiences on the use of medicines and devices in the Middle East and particularly in Kuwait. Targeting patients with type 2 diabetes was significant, as this disease becomes a pandemic in the Arab world **(Chapter 1)**. Although care services are accessible to all patients in Kuwait, health outcomes are not propitious and the majority of patients could not achieve target levels of HbA1c. This study aimed to explore the factors that impacted the patients' management behaviours, to examine the role of insulin devices in improving patients' behaviour and to identify the perspectives of HCPs on the issues identified. This is crucial for revealing the factors that contributed to poor health behaviour, highlighting the benefits of insulin devices and proposing service development, in order to improve health outcomes. Evaluating the implementation of targeted interventions was also considered. This is important to inform the concerns of the HCPs and the utilisation of healthcare resources.

Assessing non-adherence to medicines, using different methods in this study showed that there was a proportion of patients who did not use their medicines properly. MMAS-8 classified the participants' adherence level from low to high; the majority of participants (n=26) had low to medium adherence level. Obtaining data on HbA1c levels revealed that more than half of participants (n=24) had uncontrolled disease. When assessed using semi-structured interviews, 19 participants reported different practices and behaviours that were inconsistent with their doctors' recommendations.

To understand the factors that influenced patients' management behaviour, a systematic approach to data analysis was undertaken. This revealed a number of overarching themes, such as impact of beliefs/culture on medicine-taking behaviour, impact of using insulin pens/pumps on patient's life/health behaviour, problems of using insulin pens/pumps and other self-care behaviours. To understand the factors that impede the delivery of a high quality diabetes care, from the perspectives of

HCPs, the overarching themes (facilitators/barriers to implementing behavioural interventions) were firstly allocated. Designating the overarching themes aided in understanding the broad picture of the topic and allowed to confirm that all the study objectives have been met. Also, it helped to identify factors of different levels (e.g. health profession, social, personal) that might influence behavioural change and to avoid overlooking important factors. This was important, as it led to identifying all the techniques that might work and assessing their acceptability and feasibility. As data analysis processed, new themes were identified and fitted into the overarching themes. For example, beliefs about the disease, medicines and self-beliefs were fitted under (impact of beliefs/culture on medicine-taking behaviour). Shortage of staff and lack of time were allocated under (barriers to implementing behavioural interventions). **Table 9.1** shows a comprehensive data on the identified themes as reported in the result chapters of this thesis.

Table 9.1: The themes identified under each overarching theme

No.	Overarching themes/Themes	Chapter (where themes have been discussed)
(1)	**Impact of beliefs/culture on medicine-taking behaviour** Themes: -Beliefs about the disease -Beliefs about medicines -Perceived barriers -Self-beliefs	5
(2)	**Impact of using insulin pens/pumps on patient's life/health behaviour** Themes: -Glycaemic control/hypoglycaemia -Ease of use and convenience -Dosing accuracy and confidence -Daily activities -Impact on family members -Overall preference and acceptance	6+7
(3)	**Problems of using insulin pens/pumps** Themes: -Pain -Injection-site reactions -Weight gain -Mechanical problems	6+7
(4)	**Self-care behaviours** Themes: -Awareness about the benefits of SMBG, diet, exercise -Perceived barrier to regular SMBG, diet, exercise	5
(5)	**Facilitators to implementing behavioural interventions** Themes: -Availability of consultants -Motivated HCPs (physicians, nurses, pharmacists and dieticians)	8
(6)	**Barriers to implementing behavioural interventions** Themes: -Lack of educators -Shortage of staff -Lack of facilities -Lack of support/incentives -Cultural beliefs -Time-constraints	8

The HBM was used in this study as a tool to help in constructing the emerged themes under the identified components of the model. For instance, under perceived threat, beliefs about the disease were organised. Under the perceived benefits, different beliefs about medicines were explained. Adverse effects, fear of

hypoglycaemia and social gatherings were considered as perceived barriers. Self-beliefs about the ability to control the disease were explained according to self-efficacy construct of the model. The HBM is the most comprehensive model for understanding the predictors of health-related behaviour. It provides a systematic method of moving from the belief to the motivation to do the action to the target health behaviour. It has been recommended to use the HBM as a framework for explaining and improving the behaviour of patients with diabetes by focusing on relevant attitudes and beliefs (Jalilian et al., 2014). In this study, the use of such model enabled to identify minimising the severity and low self-efficacy as the most influential predictors of poor heath behaviour. However, there is a limitation in using the HBM, as it does not predict the impact of subjective norms, although the role of social support in predicting health behaviour has been identified in this study. Overall, taking into consideration the factors that affected patients' management behaviours, the advantages of using insulin devices and the recommendations of the HCPs will assist in improving the management of type 2 diabetes and health outcomes.

9.2 Study findings in the context of published literature

9.2.1 Medication adherence and health beliefs

Results of this study, about non-adherence to treatment among the participants, were not surprising and were comparable to results obtained from other researchers in the Middle East. Many authors who assessed adherence of patients with type 2 diabetes reported poor adherence levels (Shams and Barakat, 2010; AlHewiti, 2014; Sweileh et al., 2014; Ashur et al., 2015). For instance, Shams and Barakat (2010) reported that 61% of participants had poor adherence. However, that study included patients using OHAs only, and used invalidated questionnaire for assessing adherence (the Measure Treatment Adherence scale). In Saudi Arabia, about 43-51% of participants had low adherence scores on MMAS, while in Libya 36% of participants had low medication adherence (AlHewiti, 2014; Ashur et al., 2015). Only one study, which was conducted in Qatar, reported good adherence among patients with diabetes (Bener et al., 2014). However, Those authors did not provide an overall percentage of adherence but reported the responses to each individual item of MMAS-8. Also, that study included patients with both type 1 and type 2 diabetes.

Assessing adherence of patients would have no advantage if reasons behind non-adherence were not explored. Thus, the focus of this study was to examine the

factors that impacted health behaviours of participants, in order to propose target interventions. Particularly, the study explored factors related to health awareness, beliefs and culture. Results of this study revealed that lack of health awareness about diabetes and its complications resulted in normalising the disease and underestimating its seriousness, and consequently non-adherence to treatment. Type 2 diabetes is a silent disease, the lack of unpleasant symptoms might make the disease seen as not serious by the patients and consequently reduce their motivation to adhere to self-management behaviour (Dunning and Martin, 1998; Virginia, 2013). Realising the seriousness of diabetes motivate patients to accommodate diabetes and its treatment, and to introduce necessary changes in their daily routines (O'Connor et al., 1997). Poor awareness about medicines was also identified. In this study, some insulin-dependent participants were omitting their insulin doses when they missed their meals or snacks without monitoring their blood glucose levels, due to fear of hypoglycaemia. Patients using insulin perceive the disadvantages to outweigh the benefits (Dunning and Martin, 1998). Other authors also reported an association between patients' knowledge about diabetes and its complications, the awareness about the consequences of poor adherence, beliefs about medicines and adherence to OHAs (Shams and Barakat, 2010).

Sweileh et al. (2014) reported that patients with low beliefs about the necessity of medicines, and high concern about their adverse effects were more likely to misuse their medicines. Another study reported low adherence prevalence among patients with negative beliefs about medicines as a consequence of inadequate information supply. The author concluded an association between patients' knowledge about their treatment, their beliefs about medicines and adherence (AlHewiti, 2014). When patients were given sufficient information about the use of their medicines and their potential problems, they had strong beliefs about the necessity of taking them, and low concerns about their adverse effects (Khan et al., 2012).

One of the common beliefs expressed in this study, which was specific to patients in all Middle-Eastern countries and impacted their medicine-taking behaviour, was belief about herbal medicines. People in the Middle East use herbal medicines in the treatment of minor ailments, such as common cold and flu and for treating chronic diseases, such as hypertension, asthma and diabetes (Saad et al., 2005). In a study by Abahussain and El-Zubier (2005) in Saudi Arabia, it was found that patients stopped taking their anti-diabetic treatment, and controlled their diabetes with herbals only. The authors commented that the behaviour of those patients was

a consequence to their lack of awareness about the role of medical medicines. Results of the current study were consistent with what was found in the literature. A significant proportion, nearly half of the study sample, used herbal medicines to manage their diabetes. Some participants delayed their medical treatment until the failure of the herbal treatment, or they abstained from their medical treatment while using herbals. The strong belief in the efficacy and safety of herbal medicines, and the confidence in what people negotiate between each other encouraged the participants to attempt these products without informing their doctors. Although there were no hazards as a consequence to the use of herbals from the perspective of some participants, their use should be addressed and further regulated.

Practising holy ordinances such as fasting in Ramadan could affect adherence behaviour of patients; a study revealed that 25-33% of patients using OHAs or insulin changed their medicine use, e.g. reducing their OHAs intake in Ramadan (Salti et al., 2004). In that study, it was found that 20% of patients using OHAs and 37% of patients using insulin have changed their doses in Ramadan without experiencing severe complications due to these changes. Some patients feel more comfortable consulting their friends or family rather than HCPs regarding their behavioural changes with respect to Ramadan and medicines. Only few patients changed their medication intake during Ramadan according to their doctor's advice (Mygind et al., 2013). However, one of the explanations that patients made to explain their behaviour is that during fasting, they do not eat traditional foodstuff, thus, taking their OHAs as usual will affect them and expose them to side effects (Lawton et al., 2005).

Results of the current study were very similar to those obtained by other authors (Lawton et al., 2005; Mygind et al., 2013). Most participants reported behavioural changes, e.g. missing OHAs and/or insulin doses in Ramadan without consulting their doctors. The participants believed in the necessity of making such changes, otherwise they would be more likely to get hypoglycaemia. From the perspectives of participants, eating fewer meals in Ramadan exposes them to hypoglycaemia; thus, they were missing doses of OHAs and/or insulin without checking their blood glucose levels and without considering the amount and type of food they were eating during this month. However, it can be predicted that lack of severe complications during this month could contribute to continue on poor management behaviours.

As this study examined health behaviours in the light of HBM, other studies that used this model to examine behaviour of patients with diabetes were reviewed. In one study, it was found that patients with type 2 diabetes who perceived that diabetes is a serious disease, had less perceived barriers, and who were given more frequent information, were most likely to engage in diabetes self-management behaviour (Ayele et al., 2012). The study suggested that social cues or prompts to self-management were most important for determining the behaviour. This is a construct that is considered within the HBM but has not been adequately studied (Jones et al., 2015). Low social support, low self-efficacy and barriers to self-care were also determinants of poor management behaviour in Hispanic women with diabetes (Mansyur et al., 2015). According to findings of Harwood and colleagues in 2013, in a Cambridgeshire practice, it was suggested that all patients with diabetes should be screened for perceived barriers to self-management behaviour, and that this information should be used to tailor patients care to suit their individual needs (Harwood et al., 2013). Perceived barriers, such as weight gain and hypoglycaemia were found to be significant risk factors for insulin injection omission among patients with type 2 diabetes (Farsaei et al., 2014).

In the current study, viewing the results through the lens of the HBM suggests that perceived severity and beliefs about the seriousness of type 2 diabetes are strong predictors of medication adherence followed by high self-efficacy. Perceived barriers, such as fear of hypoglycaemia, side effects and social stigma were equivalent in importance as beliefs about the benefits of taking medicines in influencing participants' health behaviour. These results are slightly different than what Dehghani-Tafti et al. (2015) found in their study. When they examined the impact of the HBM constructs on self-care behaviour of patients with diabetes using a questionnaire, self-efficacy and perceived barriers were the strongest predictors of patients' self-care behaviour and that severity and benefits were of less significance. Self-efficacy was also a strong predictor of patients' self-management behaviours and glycaemic control in Jordan and Libya (Al-Khawaldeh et al., 2012; Elkharam et al., 2013). Other authors found that patients with type 2 diabetes who went through an educational programme to improve their knowledge about severity, susceptibility, benefits, barriers and self-efficacy showed significant improvements in self-management behaviour (Jalilian et al., 2014). On the other hand, although they perceived the seriousness of type 2 diabetes, and believed in the benefits of medicines, patients in Saudi Arabia had poor glycaemic control and developed

complications, as a consequence to poor adherence to treatments (de Villiers and Halabi, 2015).

Because they are integral parts in the management of type 2 diabetes, the current study investigated to a less extent the impact of knowledge, beliefs and culture on adherence to other self-management behaviours, such as SMBG, diet and exercise. Many participants in this study were not performing SMBG regularly because they lacked the awareness about its importance. Also, there were other barriers, such as pain and unavailability of the test stripes in the MOH. Although most of the study participants were aware and confident in the role of diet and regular physical activity in achieving and maintaining glycaemic control, they poorly adhered to healthy lifestyle. It was found that the participants lacked the nutritional awareness and believed that abstaining from sweets and fatty food is sufficient to provide control. In addition to poor health awareness there were some specific beliefs, which reduced the participants motivation to adherence to healthy lifestyle such as God-locus of control, stress as a contributor to elevated blood glucose levels, and the sufficiency of housework in providing control, particularly in women. Moreover, cultural factors that were found to affect participants' adherence to diet and exercise were social gatherings, lack of time and hot weather. This was supported by findings of Shams and Barakat (2010), where about three-quarter of the participants found to poorly adhere to SMBG, diet and exercise because they lacked the awareness of their importance in managing and controlling diabetes.

Type 2 diabetes is a psychologically and behaviourally challenging chronic disease that affects the patient's quality of life. In order to achieve glycaemic control and avoid the disease complications, such as retinopathy, nephropathy and peripheral neuropathy, patients are required to follow a lifelong and complex treatment regimen including daily taking of medications and or insulin administration, SMBG, regulation of diet and regular exercise. Coordinating all these behavioural tasks is challenging to many patients (Peyrot et al., 2005). This study supported the hypothesis regarding the role of illness and treatment perceptions in explaining behavioural changes, and that health beliefs and culture affected the management behaviour of the participants.

9.2.2 Insulin pens in the management of type 2 diabetes

The role of pen devices in insulin delivery has become vital, and outweighs the use of syringe and vial in many parts of the world. It has been found that pen devices

enhanced patient comfort and reduced the daily burden of diabetes management (Luijf and DeVries, 2010). To compare the investigated results with those existed in the literature, a comprehensive literature search was performed. Initially, the search was limited to studies conducted in the Middle East, but due to the scarcity of the published studies; only two studies (Hamdy et al., 1994; Tschiedel et al., 2014), the search was extended to international areas.

<u>Glycaemic control</u>

Although the current study revealed improved glycaemic control on insulin pen, this was only reported by the participants during the interviews, and was mostly inconsistent with clinical data obtained from the participants' medical notes. Reports from the literature had revealed no significant differences in glycaemic control when a group of insulin-dependent patients were randomised to use insulin pen, and the results were compared with a control group who continued using the syringe and vial. Hamdy and colleagues (1994) in their study reported non-significant changes in HbA1c levels after the 3-months study period. The authors added that changes in the mean daily plasma glucose were also non-significant (8.5 +/- 2.3 at baseline versus 8.2 +/- 2.1 mmol/l after the pen use). However, in some studies where the use of insulin pen was examined on patients over 60 years old, it was associated with perceived clinical efficacy, quality of life, and an improvement in metabolic control as measured in HbA1c levels (Corsi et al., 1997; Rubin and Peyrot, 2004). In addition, in a study by Lee et al. (2009), a significant reduction in fasting blood glucose levels has been reported in the group who used insulin pen than the group who continued using syringe and vial, reduction in HbA1c levels has also been reported but were not significant.

Regarding hypoglycaemic events, the current study reported less or the same frequency of hypoglycaemia in most participants, who were converted from syringe and vial to insulin pen. From participants who directly used insulin pens, about half of them reported no or rare hypoglycaemic events, while the other half reported experiencing hypoglycaemia sometimes. Consistent results were also reported in other studies, where the substitution of syringe and vial with insulin pen provided patients with better metabolic control and fewer hypoglycaemic episodes (Albano and Orbiter Study Group, 2004; Lee et al., 2006; Cobden et al., 2007; Bastian et al., 2011). However, Hamdy and colleagues (1994) reported that using insulin pen caused no clinical differences in the frequency and severity of hypoglycaemia in Egypt.

Quality of life

Quality of life is distinctly reduced in patients with diabetes, particularly those who are treated with insulin. Developing flexible and easy to use devices, such as insulin pen helped in improving patients' impression about low quality of life (Albano and Orbiter Study Group, 2004). Switching from syringe and vial to pen devices had a significant positive impact on patients' perceptions, and improved their health-related quality of life (p<0.05) (Albano and Orbiter Study Group, 2004; Lee et al., 2009). In a study by Hamdy et al. (1994), quality of life was determined by how using insulin pen affected patients' lives and their confidence that they have good control over their symptoms. The previous authors reported a significant improvement in the quality of life in the studied group. In other studies where no clinical differences were reported between the syringe and vial and pen devices, more than half of patients were more confident in their ability to control their blood glucose levels with using the pen than with using the syringe and vial (Korytkowski et al., 2003).

The current study revealed compatible results with those reported in the literature, where 14/18 participants perceived better control on their symptoms when using insulin pen. In addition, in the current study quality of life was determined by how using insulin pen improved patients' general health and reduced or prevented their hospital admissions due to diabetes complications. The study revealed that of the 18 participants, only four required hospital admissions due to experiencing hypo- or hyperglycaemic events. Other authors have also reported that the replacement of syringe and vial with pen device significantly reduced the utilisation of healthcare resources due to hypoglycaemic events, emergency department visits, and physician visits (P<0.05). Also, there was a reduction in the hospitalisation rate and outpatient visits due to hypoglycaemia, but the change was not significant (Lee et al., 2006; Cobden et al., 2007).

Ease of use, portability, convenience, and dosing accuracy

The current study showed that using insulin pens was simple, in terms of involving less steps than those required with the syringe and vial, and more convenient for transporting and using in public, in terms of carrying less items, being more hygienic in use and less conspicuous than syringe and vial. Other authors have also reported consistent results where the use of insulin pen was simple, easy, more convenient for transporting and using in public, especially for socially active patients, and it relieved some of the burdens of patient's daily life (Hamdy et al., 1994; Bohannon et

al., 2000; Albano and Orbiter Study Group, 2004). In a review of literature comparing the dose accuracy between the pen device and syringe and vial, pen injection devices showed better dose accuracy (Pfutzner et al., 2008). It has been reported that 80% of patients with diabetes incorrectly administer their insulin doses using the syringe and vial. Errors are more common in old people who are over 60 years of age, or when administering low doses of insulin (Korytkowski et al., 2005).

In the current study, almost all the participants were more confident about the accuracy of their insulin doses with the insulin pen than with the syringe and vial. The participants added that it was more common to administer an inaccurate insulin dose using the syringe due to different reasons, such as drawing up less or more than the required amount of insulin due to mistakes in reading the unit markings of the syringe, which were too small, and discarding the air bubbles, which sometimes led to expelling some units. On the other hand, with the insulin pen, doses are easily dialled-up and read. Only one participant in this study was more confident about the accuracy of dosing with the syringe and vial, as she was observing a little of insulin remaining in the reservoir of the insulin pen after each injection. However, the results of this study are relatively comparable to those obtained in Korytkowski et al. (2003) study, where 82% of patients felt more confident in setting the required dose on a pen, and that the pen device delivered the accurate dose of insulin versus 11% who were more confident with using the syringe and vial. Furthermore, in that study 85% of patients reported that the dose scale was easier to read on the pen.

In a qualitative study by Tschiedel et al. (2014), the patients identified the ease of use, such as ease of dialling and reading the dose, and the correct dose delivery provided by the pen device, as the essential characteristics of insulin pen, which contributed to the ease of self-injection. Hamdy and colleagues (1994) have also found that insulin pen delivered the accurate dose properly, and that it was recommended for delivering less than 36 units per injection. However, in the present study, insulin doses administered by the participants ranged from 8-80 units. There were complaints from few participants that administering small doses (e.g. 5-10 units) via the pen was difficult to the extent that one participant was disposing of the pen and used a new one to administer the next dose, and another participant was withdrawing the remaining amount of insulin with a syringe. In order to obtain the factors that contributed to those difficulties, a search was undertaken regarding the accuracy of pen devices in delivering small units. Some studies have shown that insulin pen had greater accuracy than the syringe and vial in the delivery of 10 units

doses (Asakura et al., 2009). Other studies reported that administering small doses (e.g. 1-2 units) via the pen was more accurate than via the syringe and vial, while both methods were equal in accuracy when a 5-units dose was administered (Keith et al., 2004).

Problems of insulin pen use

Problems of insulin pen and barriers to appropriate injection have not been widely discussed in the literature, particularly in the Middle East. In the current study, using insulin pen was not free from side effects, such as pain and bruising but when compared with the problems of the syringe and vial, the frequency and severity of the side effects were much less. Being less painful is not a surprising feature of the pen device. It has been found that the disposable needles that are available with insulin pens are shorter (2-8 mm) than the standard-length needles (12 mm) and less painful. In addition, the pen needles does not have to puncture a stopper before injection as in the syringe and vial, and the needle keeps its sharpness and bevelled angle to increase patient comfort. Patients perception of pain was significantly reduced when using a pen, compared with the syringe and vial (Korytkowski et al., 2005).

Although it is mechanically more complex than the syringe and vial and is prone to malfunction over time, there were no reports of mechanical malfunctions in the current study. This is in agreement with the results revealed by Hamdy et al. (1994), where the use of insulin pen was associated with minimal mechanical problems, and less pain. In another study, where patients who used insulin pen reported adverse events to their physicians, none were related to the pen use (Bohannon et al., 2000). However, there were reports of mechanical malfunctions of insulin pen, which contributed to deterioration of metabolic control in patients. In a group of 10 patients who were converted from syringe and vial to pen device, one experienced technical difficulty with the pen, and 10 pens needed to be replaced for 7 patients. In another study, 3 cases of metabolic deterioration in pregnant women have been reported due to pen malfunction (Korytkowski et al., 2005).

Insulin pen and adherence to treatment

Generally, insulin pen was associated with great acceptance; especially for those who were using MDIs, and it reduced resistance to insulin therapy, improved patients' satisfaction with treatment, and subsequently improved medication adherence and glucose control (Hamdy et al., 1994; Bohannon et al., 2000;

Korytkowski et al., 2005; Shaghouli and Shah, 2009; Farsaei eta al., 2014). In many parts of the World, trials that examined the use of pen for the delivery of insulin reported greater adherence with the pen than with the syringe and vial (Hamdy et al., 1994; Asche et al., 2010; Baser et al., 2010; Bastian et al., 2011; Farsaei eta al., 2014). Different features contributed to the improved adherence with the insulin pen, such as portability, convenience, simplicity and ease of use. In the current study, most participants reported that using insulin pen helped them in administering their doses in time, while before using the pen, they were re-scheduling doses due to difficulties in carrying and using the syringe and vial when they were away from home. Patients with diabetes do not like self-injection in public areas, due to fear of stigmatisation as a "sick person" or a "drug user", which may result in missing doses. Insulin pen is compact in size, more portable, and diminish social anxiety associated with using the syringe in public (Korytkowski et al., 2005).

The results of this study are consistent with those reported by other authors. It has been reported that the ease of use, convenience and flexibility of insulin pen devices, in terms of transportation and using in public led to a significant improvement in patients' adherence and consequently better glycaemic control (Albano and Orbiter Study Group, 2004; Rubin and Peyrot, 2004; Lee et al., 2006; Asche et al., 2013). Using the syringe and vial required titrating doses, mixing two types of insulin (if necessary), drawing up and injecting insulin, which is time-consuming (Lee et al., 2006; Asche et al., 2013). Insulin pen is accurate, easier to use, time saving, and provide more convenience (Korytkowski et al., 2005). Complexity of the treatment regimen is associated with non-adherence to treatment (WHO, 2003; Asche et al, 2013). In addition, experiencing side effects, such as pain causes fear of injection and anxiety of self-injection, which could negatively affect on medication adherence. Insulin pen helped in lowering injection pain and improved patients' quality of life (Lee et al. 2006). Farsaei and colleagues' study about the psychological barriers to adherence to insulin injections revealed on different factors. Some of these factors were dissatisfaction, embarrassment and difficulties in preparing injections, which could all be alleviated by changing to insulin pens (Farsaei et al., 2014).

Patient's preferences

Overall, the participants of the current study reported their preference to continue using insulin pen, and not returning to the syringe and vial, also, they had the willingness to recommend it to other patients. This was due to different reasons,

such as the ease of use of the pen, its convenience and accuracy in dosing. Being combined in a single item, e.g. the insulin reservoir and the needle, the pen improved dosing accuracy, convenience, patients' preference, treatment satisfaction, user confidence, ease of use, and provided greater stability during injection (Lee et al., 2006; Bastian et al., 2011; Asche et al, 2013). In a review of 29 studies, 28 studies reported that a majority of patients preferred pen devices to syringe and vial, and would like to continue on it, some of the studies identified the ease of use as the feature that contributed to the patients' preference (Molife et al., 2009). In the study of Albano and Orbiter Study Group (2004), the analysis of the Diabetes Treatment Satisfaction Questionnaire (DTSQ) revealed positive results, particularly in the "continuation" and "recommendation" parameters, as a result of the flexibility and convenience of the pen device. In another study, when patients were asked to provide their views about managing their type 2 diabetes with insulin pen compared to previous treatment regimen, the patients reported that they vigorously preferred the pen to their prior treatment strategies (Rubin and Peyrot, 2004). Likewise, about three quarter of the participants preferred using the pen to the syringe and vial, they would continue using it in the future, and recommended it to other patients (Bohannon et al., 2000; Korytkowski et al., 2003).

9.2.3 Insulin pumps in the management of type 2 diabetes

Although it accounts for 90-95% of all diabetes cases, and that number of patients using insulin pumps is growing, studies discussing the use of these devices in the treatment of type 2 diabetes are scarce. This is because the use of insulin pumps is mostly recommended for patients with type 1 diabetes in several countries around the world, supported by the extensive evidence on their effectiveness particularly for this type (Barnard and Dixon, 2010; Wolff-McDonagh et al., 2010; Didangelos and Iliadis, 2011; Reznik et al., 2014). The National Diabetes Information Service Insulin Pump Audit reported 35 patients with type 2 diabetes using insulin pumps in England in 2009 versus 5,667 patients with type 1 diabetes. In Turkey, 99.5% of pump users have type 1 diabetes. The literature search of studies that discuss the use of insulin pumps in adults, which conducted among populations similar to the present study, resulted in three studies only (Wainstein et al., 2005; Merheb et al., 2008; Reznik et al., 2014). However, as the focus of this study was type 2 diabetes, one study was excluded because it was conducted on patients with type 1 diabetes. Therefore, it was necessary to extend the search further to include studies that were conducted internationally, taking into considerations the differences in the

populations and lifestyle (Raskin et al., 2003; Herman et al., 2005; Nielsen et al., 2005; Berthe et al., 2007; Wolff-McDonagh et al., 2010).

Efficacy of insulin pump use

Findings of this study suggest that insulin pump therapy for adults with type 2 diabetes, who were poorly controlled on insulin injections and pens, can be effective overall. In the current study, all the participants who had valid clinical data achieved good glycaemic control, manifested by HbA1c readings of 7.5% or less. In addition, the participants reported that the achievement of target blood glucose levels was easier with the pump compared to injections and pens, and that control was maintained longer. Although there was a debate regarding the benefits of these devices over injections and pens, insulin pumps were found to be valuable in the treatment of type 2 diabetes, in terms of improving HbA1c levels (Nielsen et al., 2005; Wainstein et al., 2005; Berthe et al., 2007; Wolff-McDonagh et al., 2010; Reznik et al., 2014). When Reznik and colleagues (2014) examined outcomes for HbA1c in patients with poor glycaemic control randomised to either insulin pump or MDI, significant reductions in HbA1c levels for the insulin pump group (55%) compared with the MDI group (28%) were reported. Because insulin resistance is a major component of type 2 diabetes, especially in obese patients, the achievement of target levels with insulin pumps could be attributed to the enhancement of insulin absorption and sensitivity. In light of data provided by that study, insulin pumps should particularly be considered in patients with type 2 diabetes, who have consistently experienced challenges in achieving glycaemic targets. However, some researchers showed conflicting results, where both therapies, insulin pump and MDI, found to be equally effective in improving HbA1c levels (Raskin et al., 2003; Herman et al., 2005). In addition, those researchers indicated that the safety profile was similar for both therapies, and that insulin pumps were not superior to MDI, especially in patients who were able to control their glycaemic level well with daily injections. This indicates that insulin pumps may not be required in some patient groups.

However, in the current study, there were cases of delayed achievement of glycaemic control. Also, there were cases in which the participants experienced hypo-/hyperglycaemic episodes during the pump therapy. Based on reports from the participants, the episodes were fewer in frequency and severity compared to those that occurred with injections and pens. In addition, the majority of participants noticed improvements in their awareness of hypoglycaemic episodes on insulin

pumps. Results of this study are consistent with Berthe and colleagues' study, where reduced rates of hyperglycaemia were reported with insulin pump use. Experiencing less hyperglycaemia on insulin pumps could be attributed to the easier access to insulin due to being attached all the time, so that doses are less likely to be omitted. The results on reduced hypoglycaemic episodes on insulin pumps might be predictable because the continuous delivery of insulin with the pump simulates the work of pancreas of normal persons who do not have diabetes (Berthe et al., 2007). Traditional delivery of insulin with injections or pens cannot simulate the body in the same way, and larger doses are injected daily over periods of time, in which probability of hypoglycaemia increased (Barnard and Dixon, 2010; Didangelos and Iliadis, 2011). This was supported in this study by reports of some participants who identified reasons for experiencing poor glycaemic control on insulin injections and pens, which were related to lack of awareness in calculating doses according to meals and body requirements, in which the participants were injecting either less or more insulin than what did they actually need. However, results found by other researchers were partially consistent with this study's findings. Other researchers reported less hyperglycaemic episodes on insulin pumps, but no significant differences in the occurrence of hypoglycaemia between insulin pump and MDI groups (Raskin et al., 2003; Reznik et al., 2014). Likewise, studies by Herman et al. (2005) and Wainstein et al. (2005) reported no significant differences in hypoglycaemic episodes between insulin pump and MDI groups.

Exploring why glycaemic control was not achieved promptly, and at all times, in the current study revealed different reasons related to the pump technology, lifestyle or the participant's status. Incorrect or not counting carbohydrate, the need to adjust insulin basal rates, non-adherence to diet, and pregnancy were some of the identified reasons. This study found that the overall improvement in glycaemic control on insulin pumps affected positively on patients' quality of life and general health, manifested by reduction in hospital admissions due to diabetes complications.

Problems associated with insulin pump use

In the present study, mechanical problems were experienced by half of the study sample, and were related to button problems. The risk of mechanical malfunction is that it might cause a complete lack of insulin delivery, in which ketoacidosis could occur (Barnard et al., 2007). However, although the encountered mechanical

problems led to suspended pumps (n=3), no serious effects were reported in this study, and new pumps were provided to the participants easily.

The most prevalent clinical problem associated with insulin pumps was weight gain (n=5) followed by bruising, and inflammation at the administration site (n=4 and 1, respectively). Barnard and Skinner (2007) reported a small possibility of marking and scaring at cannula insertion sites with insulin pumps. However, based on reports from the participants in the current study, bruising and inflammation resulted from administering injections or pens were worse than those caused by the pump, also, they could resolve it by changing the infusion site. Similarly, Raskin et al. (2003) reported episodes of skin reactions, such as redness or soreness with insulin pumps, which were mild and resolved spontaneously by patients.

Regarding the findings of weight gain in this study, these were consistent with the results of Wolff-McDonagh et al. (2010), who noticed significant increase in BMI of patients with type 2 diabetes after the initiation of insulin pump therapy. Use of insulin in general leads to hyperinsulinemia and weight gain due to increased appetite and low thermogenesis (Russell-Jones & Khan, 2007). However, continuous delivery of insulin could result in better control using less insulin, and thus, causing less weight-gain (Wainstein et al., 2005; Didangelos and Iliadis, 2011). While this was not the case in the present, and in Wolff-McDonagh et al. (2010) studies, other researchers provided different results. When comparing insulin pumps and MDI in a group of 40 obese patients with type 2 diabetes, no significant changes in weight were reported for both groups (Wainstein et al., 2005). Similarly, other researchers observed no differences in weight between patients who randomised to use insulin pump and those who continued on injections (Herman et al., 2005; Reznik et al., 2014). Based on those researchers' findings, weight gain reported for patients using insulin pumps may not differ from weight gain that would occur if the patient had continued to use MDI. This means that treatment of patients with type 2 diabetes with insulin may result in weight gain regardless of the insulin delivery method. However, examining factors that contributed to weight gain in most participants of the current study revealed that lack of nutritional awareness, health beliefs and lifestyle were major reasons for gaining weight on insulin pumps.

To further explain and validate these factors, a comparison between the affected group and the non-affected one was performed, and the following results were obtained. Participants who gained weight on the pump lacked the awareness of

carbohydrate counting. Participants were misunderstanding the importance of this task, and were either not counting carbohydrate or counting calories instead. Not counting carbohydrate could lead to consuming more carb from food, and consequently increases bodyweight (Johnson, 2000). In addition, some participants believed that cutting down sugar is enough to maintain glycaemic control and bodyweight, and they were consuming the other elements of nutrition, such as carbohydrate, fat and protein as usual. Other kind of belief, which was raised by some participants, was the belief in the efficacy of the pump, and the accuracy of its insulin dosing. Having this belief in mind along with achieving improved glycaemic control with less complications encouraged patients to enjoy eating as normal persons, who do not have diabetes. Consumption of calories due to fear of hypoglycaemia could be a factor for gaining weight in insulin-dependent patients, but this was not raised in this study. Non-adherence to diet and exercise was prevalent among the participants who gained weight. Consumption of calories more than burning them increases bodyweight, while regular and moderate physical activity helps in losing weight (Lee et al., 2010).

Patient's social life

Being a relatively new treatment option, with little information regarding their use in similar populations, it was interesting in this study to examine the impact of insulin pumps on patients' psychosocial life. Psychosocial factors, such as social support and body image play a role in the success of treatment. There are few studies, which examined how insulin pump affects the patient's life, particularly adults (Ritholz et al., 2007). However, being worn around-the-clock, it was presumed that insulin pumps caused a dilemma to their users, whether in special occasions or at particular times. Findings of this study revealed that insulin pumps had no impact on patients' confidence; the majority of participants had no irritations or felt ashamed from administering their doses in front of people. In addition, a psychosocial improvement, compared to insulin injections was reported by one participant. The high prevalence of type 2 diabetes among adults, and the popularity of insulin pumps avoided the participants from feeling stigmatised. While this was consistent with Merheb et al. (2008) study, where all patients reported satisfaction in terms of emotional and social well-being on insulin pumps, in Turkey, patients using insulin pumps felt different than others (Yilmaz and Oguzhan, 2008).

Moreover, this study suggested that insulin pumps were almost convenient during sleeping and exercising, and caused no problems. However, in half of the cases,

insulin pumps were found inconvenient in wearing particular clothes. The participants provided conflicting point of views; some participants found the pump more suitable with traditional dresses (*Dishdasha* for men and *Abaya* for women), as it would be well covered, in which the sense of self-consciousness would be decreased. Others found it uncomfortable to wear the pump with traditional dresses, as they preferred to clip it in a trouser or a skirt rather than using its belt. However, the public image of being noticed due to wearing the pump was raised in three cases. Those participants explained that the pump was visible, annoying, and looked unacceptable in wearing particular clothing, e.g. dresses for women and jeans and t-shirt for men. In this study, women were more concerned about body image than men (2 women versus a man). This could be because females are more concerned about body esteem and fashion inconveniences than males.

Conflicting results were equally obtained regarding the suitability of the pump for travelling. Some participants found insulin pump more suitable for travelling due to achievement of good glycaemic control, improvement of general health, and the convenience of the pump for transport. In contrast, insulin pumps were disadvantageous during travelling due to the difficulties experienced in some airports, and the unsuitability of the pump in wearing casual clothes. Use of insulin pumps had no impact on family members; most families were neither worrying about the patient nor involved in the management responsibilities. In some cases, worrying and helping of family members were even reduced compared to insulin injections and pens. Achieving good glycaemic control, improving general health, and causing less hypoglycaemic events were all contributed to reduce anxiety and help of some families, in terms of reminding the patient about doses administration, and taking care of the patient when experiencing hypoglycaemia.

Patient's satisfaction and adherence to treatment

Although the use of insulin pump was associated with many tasks, participants in this study showed better adherence to treatment and SMBG compared to insulin injections and pens. The improved adherence of most participants was attributed to the improvement in their satisfaction. Reduced burden of dose tracking and scheduling, and enhanced flexibility of the participants' life led to improved satisfaction. In general, studies exploring patients' perceptions of advantages of insulin pumps reported more flexibility, better freedom, ease with meals, and consequently better quality of life (Ritholz et al., 2007; Brunton, 2008; Yilmaz and Oguzhan, 2008; Didangelos and Iliadis, 2011). Barnard and Skinner (2007) also

reported the feelings of a more 'normal' lifestyle among insulin pump users due to freedom from interruptions of insulin injections. In addition, reduced side effects with insulin pumps relieved patients from fear of needles, and contributed to better satisfaction and adherence as well. In this study, most cases found the pump more convenient, and consistent with daily routines than injections and pens, which were associated with greater workload and side effects. These results are consistent with Reznik et al. (2014) study, which concluded that insulin pumps were more convenient than injections. Also, in another study, patients who randomised to insulin pump reported higher satisfaction scores for convenience, flexibility, and ease of use. Overall, satisfaction of patients indicates their acceptance to treatment and consequently their adherence (Raskin et al., 2003; Yilmaz and Oguzhan, 2008). Patients who are satisfied with their treatment in relation to low burden and easy consolidation with daily routine will likely to better manage their treatment, and consequently maintain positive physical and psychological health (Anderson et al., 2004). However, Herman et al. (2005) in their study, which compared the satisfaction of older patients with type 2 diabetes using insulin pumps with those using MDI, revealed a high level of satisfaction in both groups.

Non-adherence to doses due to forgetfulness was also raised in the current study, the participants reported better adherence with insulin pumps due to being attached all the time. Insulin doses omissions, mainly due to forgetfulness contributed to lack of glycaemic control and an increase in HbA1c levels (Randlov and Poulsen, 2008). Although some had a generally favourable view of insulin pump, and others fluctuated between a favourable and an unfavourable view, all the participants in this study reported that they never thought about switching back to insulin injections or pens. Participants' preference to continue on the pump is an evidence of their satisfaction with the therapy. This is nearly consistent with Barnard et al. (2007) study, where only 1-2% of patients who used insulin pump switched back to MDI. In contrast, in Turkey, about 15% of patients discontinue using insulin pumps yearly (Yilmaz and Oguzhan, 2008).

Because not all the participants in the current study achieved target levels of HbA1c, at the onset of pump use, this indicates that insulin pump may not be a panacea for addressing the needs of every patient receiving this therapy. Drawbacks associated with the use of insulin pumps including challenges related to maintaining bodyweight, consistency in glycaemic targets throughout the day, mechanical failure, and annoyance from using the pump in situations, such as swimming and

wearing certain clothing suggest that introducing this therapy may, in some instances, further complicate the care of the patient.

However, although there were some caveats involved in utilising insulin pump therapy, this study reported an overall better glycaemic control, quality of life, satisfaction and consequently adherence of patients who were poorly controlled on insulin injections and pens. The main alert raised in this study was weight gain. Weight gain may consequently lead to obesity, which can exacerbate the ability of patients to achieve good glycaemic control. However, the health benefits of insulin pumps, which perceived in this study, outweigh the potential of weight gain. Because glycaemic control is a crucial issue for maintaining health and preventing development of serious complications, there is an impetus to ensure that those having difficulties achieving target HbA1c levels are provided with the resources needed to better accomplish these goals. In patients experiencing difficulty controlling their blood glucose targets, insulin pump therapy may provide the most effective tool for achieving these goals. In addition, glycaemic control is associated with better quality of life, which is an important health outcome, measured by perceived physical and mental well-being (Rubin, 2000). Complications of diabetes are specific determinants of quality of life. Last but not least, patients' preference and adherence to treatment are essential for achieving and maintaining glycaemic control.

The improvement of the participants' satisfaction and adherence to treatment in this study emphasises the need for further studies to be conducted on a larger sample of poorly controlled adults with type 2 diabetes, to evaluate the onset and risk of weight gain. In addition, further research is essential to understand whether the use of technology in treatment of diabetes affects patients' responsibilities regarding other self-care behaviour, e.g. diet and exercise. Although it was not the aim to evaluate the cost effectiveness of insulin pumps, generally, this study reported less hospital admissions due to diabetes complications. Reduced rate of emergency department visits and inpatient admissions after initiation of insulin pump therapy were also reported by lynch et al. (2010). Preventing complications is more cost effective than treating them (Gray et al., 2000). In addition, a study conducted by Medtronic in the United States revealed that the number of OHAs used by patients with type 2 diabetes had decreased by 46%, and more than one-third of patients had discontinued their oral treatment after the initiation of insulin pump therapy. Therefore, it is essential to perform studies that identify whether insulin pumps are

more economically effective than the use of injections and pens in patients with type 2 diabetes in the Middle East.

9.2.4 Perspectives of HCPs

Results of this study revealed that there were deficiencies in the management of type 2 diabetes in Kuwait. From the perspectives of HCPs, shortage in staff, patients-to-HCPs ratio, the limited role of some professionals (e.g. pharmacists and psychologists), lack of time, expertise, resources and incentives, and lack of awareness about cultural beliefs amongst some HCPs were the main barriers to providing patients with better management, and improving their health outcomes. International physicians also identified time and remuneration as the main barriers to optimum diabetes management (Wens et al., 2005). However, when searching in Middle Eastern countries, those results were not surprising, and were consistent with other authors' findings. In 2011, a systematic review in the States of the Co-Operation Council for the Arab States of the Gulf reported that the quality of the management of type 2 diabetes was sub-optimal, and needs to be improved (Alhyas et al., 2011). Alhyas and colleagues (2012) also recommended enhancing the quality of diabetes care in UAE, in terms of glycaemic control.

In the current study, lack of appropriate facilities, such as enough rooms for doctors or nurses or for using in patients education and group-sessions, and delays in appointments were mentioned by some HCPs as barriers for good management of type 2 diabetes in the MOH. In Oman, a study reporting factors that contributed to poor management of type 2 diabetes from the perspectives of patients revealed on delays in getting appointments, lack of proper utilisation of waiting areas for education, and lack of group-based education. Patients' education is the key for initiating behavioural changes and improving adherence. Using waiting areas for targeting education, and conducting group-sessions showed to be effective in improving the knowledge and building the confidence of patients with type 2 diabetes about their disease and treatment (Al-Azri et al., 2011). The importance of educational interventions in improving health outcomes was also mentioned by international HCPs, who described educational centres as valuable resources for referring patients with type 2 diabetes (Wens et al., 2005).

The lack of patient-centred care was also raised in this study, where the socio-cultural beliefs of patients were not taken into consideration by all HCPs, and involving patients in decision-making was unacceptable to some of them. This was

consistent with Alhyas and colleagues study (2013), where lack of cultural understanding of health beliefs among HCPs was reported to reduce the quality of care provided. Treating patients as full partners with the doctors in taking decisions about their treatments improve their medicine-taking behaviour (Bernabeo and Holmboe, 2013). Other issues, which reported by some HCPs in this study, were lack of educators in the MOH and the limited role of pharmacists and psychologists in the management process. This lack in the teamwork increased the workload on doctors and nurses, and reduced the quality of care provided. A multidisciplinary team approach is highly recommended especially in diabetes care, as it facilitates providing patients with better management and high quality services (Alhyas et al., 2013).

In Oman, consistent results, in terms of short consultation time, lack of teamwork, lack of patient-centred care, and inappropriate facilities were reported as barriers to better management of type 2 diabetes. In that study, it was found that only in one out of ten consultations, the patient was asked about the possible effects of his/her medicines. Fear or perceived side effects impacted the patients' medicine-taking behaviour, and reduce their adherence to treatment. Some patients would not talk about such issues, if not investigated by doctors themselves (Abdulhadi et al., 2006). Although it was not investigated in the current study, whether doctors discuss adverse effects with patients, non-adherence to treatment because of fear/perceived side effects emerged among most participants.

Poor management of type 2 diabetes is prevalent in the Middle East, particularly in the GCC countries, and needs many steps to be improved (Alhyas et al., 2011; Klautzer et al., 2014). Findings of this study emphasised that management of type 2 diabetes is sup-optimal. Barriers to optimum management were identified from the perspective of HCPs. Taking these barriers into consideration and attempting to go beyond them could help in improving management of this disease in the MOH. The government has to increase staff and resources to meet the tremendous expansion in patient population. One of the factors that may contribute to reduced quality of care provided at secondary levels in Kuwait is the poor care services at primary levels. Some participants in this study highlighted the poor management of diabetes in primary-care units. Some participants reported their dissatisfaction when they were managing their disease in primary care, explaining that competency and motivation of doctors working in primary care is low compared to that of doctors working in hospitals. A study evaluated quality of diabetes care at primary levels in

Kuwait, in terms of glycaemic, lipid, and blood pressure control and the screening of nephropathy revealed that more than half (55%) of patients with type 2 diabetes had poor control with regard to HbA1c levels. In 2012, only 25% of patients performed kidney function testing as part of their annual check, which reflected the poor management of patients in those settings (Badawi et al., 2015). Poor management of type 2 diabetes was also mentioned in primary clinics in Saudi Arabia (Ali et al., 2012). In UAE, patients with type 2 diabetes preferred to manage their disease in more specialised units rather than primary care, which increased the workload on secondary-care units, and reduced the quality of care provided to patients (Alhyas et al., 2013).

Summary of study findings are shown in **Table 9.2**.

Table 9.2: Summary of study findings

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43 patients with type 2 diabetes have:

Knowledge→lack of awareness about disease/nutrition
(e.g. diabetes-related complications, nutritional information)
Beliefs→Specific beliefs about disease and medicines
(e.g. HLOC, necessity/safety)
Culture→barriers to adherence to medicines, diet and exercise
(e.g. social gatherings, Ramadan fasting, lack of time)

Treatment regimen / Finding	Syringe/vial (S/V)	Insulin pen	Insulin pump
Preference	Least preferred insulin delivery method	More preferred than S/V	Most preferred insulin delivery method
Adherence	Depends on perceived barriers	Depends on perceived barriers	Eliminate barriers & improved adherence than MDIs
Problems	-Pain and bruising at injection site -Dosing inaccuracy -Complex preparation -Inconvenient in transportation & travelling -Stress of injection times	-Pain & bruising at injection site (less than S/V) -Unavailability of fine needles (2-8 mm) -Stress of injection times	-Weight gain -Mechanical problems
Satisfaction	Least satisfaction level	Better satisfaction level	Best satisfaction level
Advantages	-	-Convenient in transportation & travelling -Dosing accuracy	-More convenient in transportation & travelling -Easy to use -Automatic calculation of doses -Improved glycaemic control -Less hypo-/hyperglycaemia -Eliminate stress of injection times

10 HCPs involved in the management of type 2 diabetes:

√   Approved the identified issues
√   Discussed recommendations
√   Identified barriers to better management

9.3 Study strengths and limitations

9.3.1 Strengths of the study

This study primarily depended on semi-structured interviews in collecting data, which provided a deeper understanding of the participants' perceptions and experiences. Also, this is the first paper to incorporate self-management behaviour of patients with type 2 diabetes in the Middle East within the context of the HBM. This provided a framework to assist in understanding the complexity of illness and treatment representation in patients with type 2 diabetes who had poor management behaviour, and helped in proposing the most effective interventions and services.

In addition, this study is the first to examine the use of devices (insulin pens and pumps) among this group of patients. Insulin pens were introduced approximately 15 years, prescribed, and dispensed to patients with type 2 diabetes in secondary-care units in the MOH. Insulin pumps were introduced approximately 10 years, prescribed and dispensed by diabetes consultants to patients with type 1 diabetes, according to Kuwaiti Clinical Practice Guidelines for diabetes (Al-Wotayan, 2011), and to patients with type 2 diabetes, based on decision agreed by two consultants. The study reviewed the use of such devices by the patients and provides a broad picture on how patients perceived benefits, advantages and disadvantages of such devices. Furthermore, the study identified the barriers to optimum management of type 2 diabetes in the MOH from the perspectives of HCPs. Addressing such barriers to policy makers may assist in targeting the defects in the healthcare system and contribute to the development of services and health outcomes.

Finally, participants in this study were from different backgrounds, using different treatment options and recruited from all health regions, which indicates the generalizability of findings to all patients with type 2 diabetes in Kuwait and in the Middle East.

9.3.2 Limitations of the study

- As this study primarily depended on semi-structured interviews in collecting data, it was time-consuming and expensive in terms of collection and analysing. Also, this is may be prone to recall bias, as self-reporting may overestimate adherence.

- The recruitment of the participants in this study was undertaken from hospitals, which means that only patients who visit their doctors were included. This might introduce bias to results, as those participants might indicate the proportion of patients who adhere to their appointments and treatment. This means that results may not be generalised to other patients who did not adhere to their appointments and treatment.

- Few participants were illiterate, in which they could not understand some of the questions.

- The validity of the Arabic version of both, the adherence and beliefs scales has not been confirmed among patients in the Arab world.

- Other factors that could contribute to non-adherence, such as age, sex, education, duration of the disease, control status, presence of other complications and polypharmacy were not fully investigated.

- Adherence of the participants to other management behaviours, such as regular check-ups to blood pressure, feet, cholesterol and kidney test were not investigated.

- Due to lack of published studies on the use of insulin pens/pumps in adults with type 2 diabetes in similar populations, the results of this study were mostly compared with international studies. Therefore, the differences between the populations in socioeconomic, cultural, and lifestyle factors should be taken into considerations.

- Data on HbA1c levels was recorded retrospectively and this may bias results about achievement of glycaemic control with insulin devices. This is because HbA1c readings were not measured or obtained within particular timelines of the treatment (e.g. before and during the period of using insulin device) and the researcher depended mainly on reports from participants.

- In addition, the retrospective collection of the clinical data (HbA1c levels) might bias the results when they were triangulated with self-report methods.

9.4 Implications for practice and policy

First of all, type 2 diabetes should be a priority at the governmental level. It is crucial that the MOH realises the importance of education for this group of patients. In order to provide the required education, the MOH has to employ adequate numbers of staff in each hospital, in order to lower patient-to-staff ratio, develop the role of HCPs, such as pharmacists and psychologists, and employ educators.

HCPs should be trained to address the health beliefs of patients in a way that meets all educational levels, in order to modify erroneous beliefs and improve medicine-taking behaviour. Taking into account the health beliefs that emerged in this study, and were specific to patients in Kuwait, the following evidence-based recommendations might be effective:

- Improving patients' awareness about the short and long-term complications of type 2 diabetes, to help in enhancing their perception of the severity and seriousness of their disease. HCPs, especially physicians should convey the message clearly to the patients regarding the seriousness of type 2 diabetes. Terms such as 'mild' diabetes were found to discourage patients from engaging in self-management behaviour, and increased their risk of developing diabetes complications (Dunning and Martin, 1998). Introducing insulin as a possible treatment option that may be needed at some stage could encourage patients using OHAs only to adhere better to their treatment and lifestyle modifications.

- The importance of perceived barriers in the current study suggests that HCPs should regularly ask patients whether they have barriers to self-management behaviour and make recommendations to support them in overcoming these barriers.

- Improving patients' awareness about their medicines. The patients should be aware about benefits of taking their medicines, their common side effects, and how they work, e.g. how rapid- and long-acting insulin works, so that, patients can make the appropriate adjustments to their doses, and be more careful regarding doses omissions.

- Improving patients' nutritional awareness and helping them to recognise and consume food with low glycaemic index and high fibre content and reduce consumption of food of higher glycaemic index and lower fibre content.

One of the most prevalent problems in this study was the inappropriateness of the meal plan provided by the dietician. The majority of participants explained that they were provided with a general, rigid meal plan, which was distributed to all patients regardless of their gender, age, bodyweight, psychosocial characteristics, and other co-morbidities. Adherence to healthy diet could be highly improved by individualising healthy eating to patients and providing flexibility, in order to meet the needs of all individuals depending on their education and socio-economic level (Johnson, 2000). Also, it is recommended that nutritional education should involve patient-centred

approach and a variety of learning styles, such as educating patients how to read food labels, or using food models. Today's lifestyle usually does not allow three structured meals, and some patients might be overwhelmed with carbohydrate counting. With these patients, using the food pyramid for carbohydrate servings, or developing a structured meal plan on the individual basis is recommended. One of the effective tools that could be practised is suggesting that patients write food diaries on their meals/snacks for a week, in which the dietician can make adjustments based on them, and relating these adjustments to pre-and post-meal blood glucose levels (Johnson, 2000). Involving other family members in the education could also improve the self-efficacy of patients and assist in the management process.

However, it is worth noting that there were a big proportion of patients who fail to appreciate the role of dietician and HCPs other than doctors. In this study, many of the participants did not keep their appointments with the dietician. Because most patients accept and follow their doctors' advice, this imposes an implication for doctors to take more care in making important referrals to other HCPs continuously and emphasising their significance.

- The awareness about herbal medicines, their risks and problems, should be improved among HCPs. The use of such medicines among patients should be addressed and taken into consideration. Doctors and pharmacists should increase their efforts in questioning patients about any other medicines that they use, to help in avoiding the delayed onset of treatment and the possible serious interactions with other conventional medicines.

- Taking patients' beliefs and perceptions regarding Ramadan fasting into account. For example, instead of preventing patients from fasting according to the 'Islamic exemptions', physicians could advise patients who insist to fast to keep monitoring their blood glucose levels and visit their primary care-units when they feel unwell, or break their fast and take their medicines. Most recent studies supported that fasting in Ramadan is clinically acceptable as long as the patient receives counselling on use of medicines and glucose monitoring during fasting (El-Taher and Zabut, 2013).

- Helping patients in planning for their medicine use during Ramadan, by making appropriate changes to the patients' treatment regimen, e.g. time of administration, and doses adjustments according to their individual needs, e.g.

food intake and physical activity. Also, providing patients with nutritional advices such as consuming complex carbohydrates at the predawn meal and more simple ones at the sunset meals.

- Improving adherence of patients to the other management behaviours, such as SMBG, diet and exercise by improving their awareness about their importance. For example, in the current study, some doctors were asking patients to monitor and record their blood glucose levels in the yellow booklet, which is provided to all patients with diabetes in the MOH, then they discuss the results with them in each visit, if possible. The implementing of such practice by all doctors would have a great role in keeping patients aware about their disease by investigating the effect of their behaviours on their blood glucose levels.

However, implementing good practices could not be fruitful at all times. Interestingly, in this study, there was a case in which a mother of one participant who came to the doctor and admitted that her daughter was cheating by recording 'false' normal blood glucose levels. The mother reported that her daughter was cheating because she was afraid that the doctor becomes angry on her if he detected her bad behaviour or non-adherence. This case may highlight the importance of improving the consultation skills of some HCPs.

Pen devices were firstly introduced in the MOH in 2000, and have only been dispensed in secondary-care units. To date, syringes and vials are dispensed for insulin-dependent patients in primary-care units. Reasons for not introducing the pen devices in primary care units were neither established nor examined in this study. Policy makers should consider policies for the distribution of insulin pens to all levels of healthcare units. For instance, there are numbers of primary care units in each health region of Kuwait, from which some are specialised and others are general. Specialised primary care units are the first line treatment options that deliver healthcare services to patients with type 2 diabetes. Therefore, distributing pen devices to primary care units, mainly specialised ones may have an impact on patients' satisfaction, adherence to treatment, and consequently on health outcomes.

In addition, many patients may benefit from using insulin pens particularly, old patients with impaired vision and dexterity, and those who have difficulties in administering their doses using the syringe and vial, and do not have any one to help them. Also, another suggestion for starting the distribution of pen devices in

primary-care units could be through helping those patients who cannot self-administer their doses, do not have carers to help them, and visit their primary-care unit to administer their doses. The service could be initiated by recruiting patients who are still administering their insulin doses in the primary-care unit, offering them the pen device, and allowing them to use it for a period of time. Then, if the patient prefers the device and knows how to use it, he/she can continue on it. Patients who do not prefer the pen should have the opportunity to return to the syringe and vial. Applying such service could save the time of nurses who help the patients in administering their doses, and spend time in registering their information. Also, it could reduce the congestion of the patients in the primary-care unit, and save the energy and time of all patients.

Although this study was carried out in secondary-care units, where insulin pens are available as an option for all patients with type 2 diabetes, it was noted that some participants were still using syringe and vial. Because it was not an objective of this study to investigate the factors that affect the prescribing of insulin pen, this could be due to a lack of knowledge of physicians about the potential benefits of pens, so they do not consider them as an option, or that patients are unaware about the availability of these devices, so they do not discuss about them with their doctors. This raises an implication for the MOH to monitor healthcare services, in terms of prescribing and dispensing pen devices in hospitals.

Doctors should discuss with patients the available options of insulin delivery methods, identify the benefits of pen devices, leave the choice for the patient to decide on the appropriate method for him/her, and allow them a trial period, by which they can decide on the delivery method that they prefer to continue on. Because they are associated with greater preference and social acceptability, less painful, and may improve glycaemic control, insulin pens should be considered when prescribing insulin (McCoy and Wright, 2010). In addition, providing patients with insulin pens could also help in saving doctors time, because the pen is easy to train and requires less time for teaching instructions on use than the syringe and vial. Thus, doctors may have more time to address other concerns related to the management of the disease or to the initiation of insulin (Bohannon et al., 2000; Lee et al., 2006).

It has been found in this study that some participants were not being dispensed the adequate amount of insulin pens which they required, and had been prescribed by

their doctors. For example, when participants were prescribed insulin pens for 2 months, the pharmacy dispensed to them an amount for 1 month or two weeks only. One participant mentioned that he required additional amount of insulin pens in cases of travelling. In addition, some participants reported that they were always being dispensed the large needles of the pen (5-6 mm), which causes pain to them, while they preferred the small ones (2-4 mm), and some were even buying them from private community pharmacies. One participant mentioned that he required the larger needles (8-12 mm), particularly if he wants to administer his doses in the belly, but he was always given the 5-6 mm ones. This raises an implication for pharmacists working in hospitals to review the availability of the required items regularly and inform pharmacists in Medical Stores about the unavailability of any item, in order to discuss the feasibility of providing adequate amount of insulin pens to the patients, and to provide them with the small or large needles according to their requirements.

In addition, patients need to be well educated about the injection technique using the insulin pen, such as renewing the needle before each use, perform air shots and leave the needle in place after injection for 10 seconds to achieve the optimum delivery of insulin. If pharmacists emphasise this information with each prescription, this could improve the patients' use to the device, and take the maximum benefit of its accuracy. Accuracy of insulin doses is important for achieving glycaemic control and avoiding hypoglycaemia (Luijf and DeVries, 2010).

This study showed that 16/26 participants, who were using insulin injections or pens, were above target levels of HbA1c (>7.5%). Insulin pump therapy proved to be as or more effective than MDI in lowering HbA1 levels, in poorly controlled patients with type 2 diabetes. Particularly, there is a proportion of patients with type 2 diabetes, in whom insulin pump works well, such as patients with high HbA1c levels on MDIs, patients with very high insulin requirements, and those who suffer from other conditions, which contribute to difficulty in controlling diabetes (Chait, 2006). This informs an implication to policy makers to introduce insulin pump therapy in these groups of patients, as this will help them in achieving glycaemic control, and avoiding other complications. Despite the small sample size enrolled in the present study, results are suggestive for modifications of current guidelines to consider a group of poorly controlled patients, who are using large amount of basal insulin daily, for insulin pump therapy.

In Kuwait, insulin pumps were firstly introduced in 2005/2006, and are provided free from the MOH for patients based on their suitability and personal choice, regardless of their region. Due to lack of evidence on the effectiveness of insulin pumps in type 2 diabetes, the guidelines for insulin pumps coverage have been strict for type 1 diabetes to date. The guidelines indicate that candidate for insulin pump therapy should have type 1 diabetes, evaluated by a diabetes specialist. In addition, the patient should have history of hypoglycaemia or hypoglycaemia unawareness, history of dawn phenomenon, extreme insulin sensitivity or willingness to comply with self-care behaviours related to the pump, in addition, pregnant women can apply for the pump therapy (Al-Wotayan, 2011). In some practices, adults with type 2 diabetes, who had been uncontrolled with MDI for a period of time, and had the willingness to comply with the pump-related tasks, were provided insulin pumps. So, insulin pumps are provided to patients with type 2 diabetes on a case-by-case basis, and two specialists should agree on their prescription.

The results of this study revealed that insulin pumps were effective in achieving an overall improvement in glycaemic control, satisfaction, and consequently adherence of adults with type 2 diabetes, who were poorly controlled on insulin injections and pens. Therefore, the guidelines could be re-evaluated and further developed to put this group of patients in the line of insulin pump therapy, and expand their access to this delivery tool. Although there were cases of type 2 diabetes, who were offered the pump therapy in some practices, modifying the guidelines will result in extending the recruitment of this group of patients to such therapy, and make it more accessible to them. However, based on the study findings, 5/8 participants reported weight gain after initiating the pump therapy. These results have implications for the treatment of obese patients in particular. Weight gain is an independent risk factor for coronary artery diseases, hypertension, dyslipidaemia and other co-morbidities (Ezzati and Riboli, 2013). In addition, obesity was prevalent among the study participants regardless of their treatment regimen. Therefore, selecting candidates for the pump therapy is of paramount importance. Some cautions could be introduced, such as for morbidly obese patients, with BMI>40 kg/m^2, or for those with other disorders that promote weight gain, such as hypothyroidism.

Another implication for doctors with regard to weight gain in patients using insulin pumps could be suggesting a combination therapy with OHAs during the day, for patients willing to use insulin pump, and who are at risk of weight gain. OHAs were found to reduce weight gain, particularly in patients who still had some response to

sulphonylurea or had evidence of relative endogenous secretion ability (Wainstein et al., 2005). In addition, doctors should address patients' beliefs about the total dietary freedom before initiating the pump therapy, in order to reduce the possibility of gaining weight. Doctors also should emphasise on the demand of a high level of commitment from the patient to maintain good health on the pump by constant balancing mealtimes and energy consumption.

Although there were no reported serious consequences among participants who had experienced mechanical malfunction of their insulin pumps, and that they replaced it easily, this has an implication to pharmacists. Patients using insulin pumps could be supplied with insulin injections or pens, or allowed to have access to them at all times, as a substituent for insulin pump. Downloading the patients' pump data, if possible may play a role in addressing issues related to the patient's adherence, and help the HCPs to mediate with personalised educational intervention (Reznik and Cohen, 2013).

One of the main concerns of the participants was the disorganisation of clinical visits. The participants reported that they were given appointments as other patients with diabetes, who were not using insulin pumps, and they spent as much as their time in the consultation. Most participants were concerned about the limit of the consultation time, and they mentioned that they required a special day for them to discuss more issues related to the pump. Currently, there is no particular programme followed in the MOH for providing care to patients using insulin pumps.

A major drawback of diabetes care in this study was the lack of diabetes educators, which was a problem in other Middle Eastern countries as well, such as UAE (Assaad-Khalil et al., 2013). The shortage in numbers of diabetes educators leaves doctors in a one-to-one situation with the patients. Therefore, based on the study findings, it would be feasible to establish a nurse clinic particularly for patients using insulin pumps, run one or two days a week, and managed by at least two diabetes nurses specialised as educators. So, after the specialist decides on dispensing insulin pump to the patient, the patient could be directly enrolled to the nurse clinic for further investigations. The following protocol could be initiated and adapted in the nurse clinic, to improve care services and outcomes **(Figure 9.1)**. The involvement of nurses in the care of patients using pumps will help in filling the gaps in their knowledge, receiving the required monitoring to reduce incidence of problems such as weight gain, reducing the burden on doctors, and allowing patients to discuss

other important issues during their clinical visits, to get the maximum benefit. Patients with diabetes control their disease better with the support of multidisciplinary medical team (Wilmot et al., 2014).

Before the pump
- Evaluation of patient's health parameters, e.g. BMI, BP, cholesterol
- Evaluation of the patient's cognitive awareness
- Evaluation of the patient's motivation to perform all the tasks

On the pump
- Liaise with the pump company, and enroll the patient to a 3-days training programme: technical part, carb counting, and hypo-/hyperglycaemia
- Fine tuning* visits weekly for the first month, then monthly

On the pump
- Monitoring BMI, BP, and cholesterol monhtly for the first 3 monhts, then quarterly
- Perform HbA1c blood test every 3 months
- Funduscopy prformed yearly

*Issues to consider in fine-tuning visits: review records of SMBG, doses (bolus/basal/correction) checking/adjustments, carb counting, monitoring for mechanical functions.

Figure 9.1: Protocol for treatment and management of patients with type 2 diabetes using insulin pumps in the nurse clinic

One of the main findings in this study was the non-adherence of most participants to SMBG due to perceiving barriers, such as pain, annoyance and marks on fingers and unavailability of test stripes in the MOH. This inform an implication for pharmacists or policy makers to consider providing the stripes in the MOH and the sensor-augmented insulin pumps, which provide continuous glucose monitoring would be of a great value. Currently, all insulin pumps provided to patients are without sensors, in which patients needed to carry out at least 4-8 times finger pricks. There is clinical evidence that sensor-augmented insulin pumps provide better glycaemic control, and eliminate several finger pricks during the day (Bergenstal et al., 2011). The significant role of dieticians in teaching and educating patients using insulin pumps was manifested in this study. The insufficient and inappropriate education provided by dieticians contributed to lack of patients' awareness regarding important pump-related tasks, such as carbohydrate counting. Most participants emphasised on their needs for more education. This problem could be resolved by firstly providing continuous training and education to the

dieticians themselves. Then, dieticians should educate patients the basic nutritional information, emphasising on the importance of counting carbohydrate, and re-enforce education with each visit.

9.5 Suggestions for future work

It is hoped that this study findings prompted further studies on diabetes management in Kuwait, with particular attention to cultural beliefs of adults with type 2 diabetes and the use of technology among them. Also, it is recommended to use a behavioural change model to predict health-related behaviour of patients in Kuwait. Below is a description of some recommendations:

- As it was not considered in this research because it is time-consuming, future research should consider recruiting patients who do not adhere to their clinical visits. This can be achieved by identifying those patients from medical records and collecting data from them through home-visits. This will ensure including the proportion of patients who experience more barriers to adherence and therefore more reliably describing the non-adherence phenomenon.

- As the study had a cross-sectional design, the views and experiences of participants on medicine/device use represented those at the time of the study and could be changed over time. Therefore, conducting a longitudinal study would allow the assessment of patients' adherence, perceptions and beliefs over time. This is important in order to detect changes in patients' behaviour and linking these changes to a circumstance or a characteristic (e.g. to conclude cause-and-effect relationships).

For example:

(1) Conducting a longitudinal study to examine patients' perceptions and use of OHAs and insulin over a specific period of time. So that, Patients' beliefs could be assessed at the start of the diagnosis with type 2 diabetes, after a year and after 5 years. Changes in patients' beliefs could be then linked with their clinical characteristics/presence of complications and medicine-taking behaviour. This will assist HCPs to identify when patients require more interventions (e.g. at the diagnosis, or after a period of time) and to identify targeted educational interventions to each group of patients (e.g. those with/without complications, those who use OHAs or insulin).

(2) Conducting a longitudinal study on the use of insulin pens/pumps on adults with type 2 diabetes for a period of 12 months. This will allow detecting changes in patients' device use and linking these changes with HbA1c levels at the onset of the device use, and as the use continued over time. This is crucial to inform HCPs about the time that those patients need educational interventions (e.g. at the beginning of the device use).

(3) Conducting a longitudinal study on the use of insulin pump and its impact on patient's weight. This can be achieved by examining a group of obese patients (e.g. BMI>35 Kg/m^2) with type 2 diabetes for a period of 12 months. This will allow detecting changes in patients' weight, starting at the onset of using the pump and as the use continued over time and interpreting the causes behind weigh gain. This is important to inform healthcare provision and guidelines modifications.

- Although it has not been investigated in this study, it has been reported that switching from syringe and vial to insulin pen/pump is associated with a reduction in the overall health care costs (Lee et al., 2006; Bastian et al., 2011; Asche et al., 2013; Pickup, 2014). Use of insulin pumps in this study helped participants to achieve lower HbA1c levels and decrease the recurrence of hypoglycaemic episodes. Research evaluating the cost-effectiveness of insulin pens and pumps in the Middle East should be conducted. This is important to help in resource allocation decisions, estimate future healthcare expenses and improve the quality of diabetes care delivery.

- Researchers should consider the effect of demographic variables, such as age, sex, and educational level on patients' beliefs and adherence. This is significant to inform policy, identify which group of patients needs particular attention and to design targeted interventions that meet needs of each group of patients (e.g. males/females, those with high/low education level, etc.).

- In the current study, it was found that semi-structured interviews were better at describing medicine-taking behaviour of patients and obtaining health beliefs that impacted health behaviour. In addition, it was noted that some participants were not interested in the completion of questionnaires. Future research may focus on interviews only, as this would be more practical and minimise paperwork.

- Studies about clinical benefits of herbal medicines should be conducted to affirm their role in the management of type 2 diabetes, their efficacy and safety. This is crucial to inform policy (e.g. restrict their widespread and inappropriate use among patients with type 2 diabetes).

- Studies that target patients' health behaviour during Ramadan and examine the impact of such behaviour on health outcomes should be performed. This is important to identify the clinical effects of patients' poor behaviour during this month and target educational interventions that motivate patients to follow their doctors' advice regarding breaking fast during Ramadan or using medicines according to their instructions.

- As this is the first study that examined the advantages and disadvantages of insulin pumps in the management of adults with type 2 diabetes in the Middle East, it will be interesting to conduct more studies on larger sample of the same population. Although insulin pumps showed comparable efficacy and safety to MDI therapy for type 2 diabetes internationally (Raskin et al., 2003; Pickup and Renard, 2008), conducting studies on the efficacy and cost-effectiveness of this technology will be of a great interest, given that the socio-cultural backgrounds of Mediterranean patients is different from those in published international studies.

- Although services and interventions recommended in this study were assessed for practicality from the perspectives of HCPs and were effective in other countries **(Chapter 8, Sections 8.2, 8.3)**, the efficacy of these services should be assessed in Kuwait among adults with type 2 diabetes. For example, research should be conducted on the efficacy of pharmacist/psychologist led-diabetes clinic for a period of 12 months. This can be achieved by recruiting patients to these clinics and examining changes in their clinical characteristics (e.g. HbA1c levels, blood pressure, cholesterol level, BMI) and adherence at the beginning of visiting the clinic, and thereafter until the end of the study. Then, comparing those patients' results with a control group. This is crucial to inform policy and better healthcare resources utilisation.

9.6 Conclusion

Many factors were found to affect the management behaviour and health outcomes of adults with type 2 diabetes in Kuwait. The current study provided evidence that non-adherence to medicines among adults with type 2 diabetes is a significant problem, with a rate of 44.2%. Lack of health awareness, specific health beliefs and cultural factors that impacted patients' medicine-taking behaviour and other management responsibilities, such as SMBG, diet and exercise were identified in this study. In addition, it was found that using insulin devices, such as pens and pumps played a role in improving patients' decision-making and health outcomes. From the perspectives of patients, use of pens and pumps had many advantages over traditional injections and a role in improving their medicine-taking behaviour.

Therefore, the key issue towards improving patients' management behaviour is to address the gaps in patients' awareness, their health beliefs and socio-cultural needs by different HCPs. In addition, extending the use of insulin devices among this group of population may have a role in improving health outcomes. From the perspectives of HCPs, there are many barriers that impede the employment of services and targeted interventions. By addressing HCPs' concerns and make the policy makers in the MOH aware about them, findings of this study will inform decisions for service development, better healthcare resources utilisation and consequently better management of type 2 diabetes and health outcomes.

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Appendices

Appendix 1: Studies of determinants of adherence to treatment and self-management behaviour among patients with diabetes in Middle Eastern countries

Study/setting/country	Sample	Methods/measures	Study findings and conclusions
Abahussain & el-Zubier. 2005 School health clinic, Saudi Arabia	91 patients with diabetes	Knowledge of females with diabetes, school teachers about the disease and adherence to medications, diet and exercise measured by a structured questionnaire.	73% of patients know about the symptoms of hypoglycemia, 52.7% of patients complied with treatments, 50% followed diet and 5.5% complied with exercise. 25% using herbs for the management of diabetes.
Abdulhadi et al 2006 Primary health care clinics, Oman	90 consultations between doctors and nurses involved in the management of patients with type 2 diabetes	Observational study. Healthcare providers interactions with patients focusing on consultation environment and some aspects of care and information measured by checklists.	52% of doctors' consultations were sub-optimal.
Abdulhadi et al 2007 Primary health care clinics, Oman	27 patients with type 2 diabetes	Qualitative research. Perceptions of patients with type 2 diabetes regarding quality of care provided measured through focus group discussions.	Weaknesses identified by patients include: health education and professional competency of healthcare providers.
Aflakseir 2012 Outpatient clinic, Iran	102 patients with type 2 diabetes	Not stated. Illness perceptions, beliefs about medicines and medication adherence measured by IPQ, BMQ and MARS.	Patients having concerns about negative effects of medicines show low levels of adherence to medications.
Aflakseir 2013 Retirement club, Iran	178 patients with diabetes, coronary heart disease, chronic pain and hypertension	Not stated. Illness perceptions and medication adherence using IPQ and MARS.	42% of patients reported non-adherence to their prescriptions, 58% adhere to their medicines. Illness perceptions such as timeline, perceived consequences and treatment control predicted patients' adherence to their medications.
AlHewiti 2014 Family medicine clinics, Saudi Arabia	408 patients with chronic diseases including diabetes	Cross-sectional study. Adherence to treatment and beliefs about medicines using MMAS-8 and BMQ.	51% of participants who had diabetes were low adherents. Low adherence was associated with negative beliefs about medicines.

Study/setting/country	Sample	Methods/measures	Study findings and conclusions
Alhyas et al 2013 Diabetes centre, United Arab Emirates	9 healthcare professionals providing care to patients with type 2 diabetes	Qualitative research. Barriers to healthcare professionals' motivation measured by semi-structured interviews with healthcare professionals.	Barriers that affect healthcare professionals' motivation in providing good quality care are: heavy workload, lack of patient compliance, awareness and cultural beliefs and attitudes about diabetes.
Ali et al 2010 Primary health care clinics United Arab Emirates	75 women at high risk of type 2 diabetes	Qualitative study. Weight management behaviors and perceptions of women at high risk of type 2 diabetes using focused-group interviews.	Low motivation, lack of social support, competing demands, lack of culturally sensitive exercise facilities and sociocultural norms are the main barriers cited by participants.
Al-Kaabi et al 2008 Diabetes Outpatient Clinics United Arab Emirates	409 patients with diabetes	Cross-sectional study. Dietary practices and risk profile measured by an interviewer-administered questionnaire.	24% of patients read food labeling, 76% reported being unable to distinguish between high and low carbohydrate index food items and no one reported counting calorie intake, 46% reported never seen by a dietician since their diagnosis.
Al-Khawaldeh et al 2012 A national diabetes centre Jordan	223 patients with type 2 diabetes	Cross-sectional study. Diabetes self-efficacy & self-management behaviours using structured interviews & a questionnaire including self-efficacy scale & self-management behaviour scale.	Patients with higher self-efficacy showed better self-management behaviours than those with low self-efficacy.
Al-Qasem et al 2011 Middle Eastern countries	Patients with chronic diseases	Review.	Non-adherence to medications among patients with chronic diseases in Middle Eastern countries constitutes a problem.
Al-Saeedi et al 2002 Primary health care clinics, Saudi Arabia	1039 patients with diabetes	Cross-sectional study. Patterns of treatment-related misconceptions measured by interviews using a structured questionnaire.	39% of patients had a high treatment misconception score. 16.5% think that cure from diabetes is expected following a short course of treatment and 23% think that they could eat as long as medications are taken.

Study/setting/country	Sample	Methods/measures	Study findings and conclusions
Al-Saeedi et al 2003 Primary health care clinics Saudi Arabia	1039 patients with diabetes	Not stated. Beliefs in traditional herbal medicines measured by a structured questionnaire.	15.6% of patients believe in the safety and efficacy of traditional medicines. 25.8% believe that they might be beneficial.
Al Shafaee et al 2008 Health care centres Oman	563 adults (general populations)	Not stated. Knowledge & perception of diabetes using a questionnaire.	Knowledge of diabetes was suboptimal. Only 47%, 58% and 55% responded correctly to questions on diabetes definition, symptoms and complications respectively. Only 5, 21 and 17% identified obesity, physical activity and family history respectively, as risk factors for diabetes.
Al-Shookri et al 2011 Oman	Patients with type 2 diabetes	Review.	Lifestyle and behaviour of patients with type 2 diabetes in Oman and other Middle East countries contribute to the high prevalence of this disease.
Ashur et al 2015 A national centre for diabetes & endocrinology, Libya	Patients with type 2 diabetes	Cross-sectional study. Patients' illness perceptions using the Revised Illness Perception Questionnaire & adherence to treatment using 8-MMAS.	Low adherence to medicines was found in 36.1% of the sample. The participants reported high perception of diabetes timeline as chronic & a moderate perception of the diabetes course as unstable.
Badran & Laher 2012 Arabic-Speaking Countries	Patients with type 2 diabetes	Review.	Several socioeconomic, dietary and lifestyle factors are associated with type 2 diabetes in Arabic-speaking countries.
Biderman et al 2009 Health care organizations, Israel	630 patients with diabetes, hypertension or ischemic heart diseases	Systematic random sample from computer database. Diabetes treatment satisfaction measured by telephone interviews using DTSQ and adherence to treatments and lifestyle measures.	51.9% reported difficulties in changing their dietary habits, 50.3% in changing their physical activities, 22.7% in attending follow-up visits and 9.8% in taking medications. Patients taking OHAs were more satisfied than those taking OHA and insulin.

Study/setting/country	Sample	Methods/measures	Study findings and conclusions
de Villiers et al 2015 Ambulatory care clinics, Saudi Arabia	1,409 patients with type 2 diabetes	Descriptive-correlational study. Adherence to treatment & factors affecting on it using a questionnaire.	Findings revealed on different factors that affected patients' adherence, such as poor knowledge about diabetes and external locus of control.
Elis et al 2008 Maccabi healthcare services, Israel	41,936 patients with diabetes	Cross-sectional study. Rate of reaching all glycemic, lipids and blood pressure target levels among diabetic patients.	13% of patients achieved all three target levels. This was significantly associated with compliance to treatments and medical visits.
Elliott et al 2013 Primary health care clinics, Oman	309 patients with type 2 diabetes	Prospective survey. Diabetes self-management and education assessed by a questionnaire.	26% of patients unaware how to recognize/respond to hypoglycemia, 49% and 60% do not recognize hyperglycemia/respond to it respectively, 62% do not monitor their blood glucose levels, one-third of patients using insulin, independently adjust dosages.
Hui et al 2010	Patients with type 2 diabetes	Review.	Structured education should be focused to patients who wish to fast in Ramadan, for better managing their condition while fasting.
Ibrahim et al 2011 Al-Qassimi hospital, United Arab Emirates	240 patients with chronic diseases	Cross-sectional study. Factors affecting patients' compliance to treatments measured by a validated questionnaire.	Forgetfulness is the main reason for non-intentional non-compliance (75%) and polypharmacy is the main cause for intentional non-compliance (13.3%).
Jamous et al 2011 Military medical services clinic, Palestine	131 patients with diabetes	Cross-sectional descriptive study. Adherence and treatment satisfaction using MMAS-8 and treatment satisfaction questionnaire.	38% of patients had high adherence, 58% had medium and 16.9% had low adherence rates.
Jeragh-Alhaddad et al 2015 Primary health care clinics and hospitals, Kuwait	20 patients with type 2 diabetes	Qualitative study. Assessing adherence to medicines and health beliefs of patients using face-to-face interviews.	Many factors were found to impact patients' adherence to medicines. These were related to healthcare providers and system, culture and the patients themselves.

Study/setting/country	Sample	Methods/measures	Study findings and conclusions
Jimmy et al 2014 Household Oman	158 patients with type 2 diabetes	Cross-sectional study. Adherence to medicines using questionnaire-based pilot survey.	Adherence to medicines of patients with type 2 diabetes was good. Forgetfulness was the main factor that contributed to non-adherence followed by low beliefs about the necessity of taking medicines, and the perceived side effects.
Kamel et al 1999 Diabetes clinic, Egypt	300 patients with diabetes	Cross-sectional study. Adherence to medication measured by patients' self-report using questionnaire.	1.7% of patients had poor, 20% satisfactory and 78.3% very good compliance.
Khattab et al 1999 Primary health care centre, Saudi Arabia	294 patients with diabetes	Cross-sectional study. Adherence to medications measured by self-report questionnaire and pill count.	1.4% of patients had poor compliance, 14% fair compliance and 84.2% good compliance.
Khattab et al 2010 The National Centre for Diabetes, Endocrinology, and Genetics, Jordan	917 patients with type 2 diabetes	Systematic random sample. Medication adherence, barriers to adherence and attitude towards diabetes measured by pre-structured questionnaires.	65.1% of patients not following eating plan as recommended by dietician, had negative attitude towards diabetes, increased barriers to adherence scale scores and poor glycemic control.
Mabry et al 2010 Gulf Cooperation Council	Not stated	Review.	The physical activity, which is a modifiable risk factor for several chronic diseases, of patients in the GCC States is very low.
Mishali et al 2011 Maccabi health care services, Israel	119 patients with diabetes	Not stated. Self-efficacy measured by questionnaires and resistance to treatments measured by RTQ.	Self-efficacy impacts on patients' adherence to their treatments.
Roaeid & Kablan. 2007 Diabetes centre, Libyan Arab Jamahiriya	805 patients with diabetes	Cross-sectional study. Adherence to treatment measured by patient's self-report using interviews and questionnaire.	27.1% of patients do not take their treatments regularly.

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Study/setting/country	Sample	Methods/measures	Study findings and conclusions
Salti et al 2004 13 Eastern Mediterranean countries	12,243 patients with diabetes	Retrospective transversal survey. Fasting and adherence of patients to medications in Ramadan.	42.8% of patients with type 2 diabetes and 78.7% with type 2 diabetes fasted for at least 15 days. Less than 50% changed their treatment dose (one-fourth treated with oral anti-diabetic drugs and one-third using insulin.
Serour et al 2007 Family practice health centers Kuwait	334 patients with type 2 diabetes, hypertension or both	Prospective study. Adherence and barriers of complying with lifestyle recommendations measured by a structured questionnaire.	Barriers to adherence to diet: unwillingness, difficulty adhering to a diet different than rest of family, social gatherings. Barriers to adherence to exercise: lack of time, co-existing diseases and adverse weather conditions.
Shams and Barakat 2010 Specialized medical hospital, Egypt	226 patients with type 2 diabetes	Cross-sectional study. Adherence to treatment and other self-care behavior (eg, diet and exercise) using a multi-ple-choice graded questionnaire.	Adherence to treatment, diet and exercise were sub-optimal. Patients' knowledge about the disease and beliefs about medicines significantly affected therapeutic adherence.
Sweileh et al 2014 Primary health care clinic Palestine	405 patients with type 2 diabetes	Cross-sectional study. Adherence to medicines using MMAS-8, beliefs about medicines using BMQ and diabetes-related knowledge using MDKT.	42.7% of the participants were non-adherents (MMAS-8 score<6). Non-adherence was significantly associated with disease-related knowledge, beliefs about necessity of medicines and concerns about adverse consequences of medicines.
Turan et al 2002 Outpatient clinic at a government university hospital, Turkey	196 patients with diabetes	Cross-sectional study. Coping with diabetes using a Diabetes Coping Measure & adherence to diabetes treatment regimen using a questionnaire adapted from the Summary of Diabetes Self-Care.	Coping with diabetes was a good predictor of outcome. The effect of coping with diabetes on HbA1c levels was mediated by adherence to treatment.
Yekta et al 2011 Health care clinics, Iran	400 patients with diabetes	Cross-sectional study. Factors influencing self-care practices measured by a questionnaire.	Patients' self-care practices were good in 15.1%, moderate in 58.7% and poor in 26.2%.

Appendix 2: The project leaflet provided to the Heads of Diabetes Units

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"The Ministry of Health (MOH), Kuwait in cooperation with the School of Pharmacy, University College London (UCL) are conducting this study for healthcare, research and educational purposes"

The purpose of the study

Diabetes is rapidly increasing in the world and particularly in Kuwait, which suggests a defect in the management process. Patients behave differently regarding their diseases, medicines and in taking management responsibilities. It has been suggested that patient's medicine-taking behaviour may have an impact on the disease management.

I am conducting this research to explore how patients with type 2 diabetes manage their disease during their daily lives, and what problems they are experiencing, in terms of medicine-taking and other self-care behaviours. Results of this research will help in identifying the determinants of patients' poor health behaviour and recommending targeted interventions that could be applied in the MOH to help the provision of healthcare services and improving health outcomes.

If you have any further query, please do not hesitate to contact the project team.

Researchers contact details

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Thank you

Appendix 3: The patients' invitation letter

THE SCHOOL OF PHARMACY
UNIVERSITY COLLEGE LONDON
MINISTRY OF HEALTH (KUWAIT)

Use of medicines and devices by adults
in the management of type 2 diabetes
in Kuwait

{Thank you for taking time in reading this leaflet}

"I would like to invite you to participate in a research study. Information provided in the leaflet explains the purpose of the study and what it is required; please take your time in reading and understanding the information". If you have any query, please do not hesitate to contact me or my supervisors:

Mrs Zahra Alsairafi, UCL, School of Pharmacy
Tel: 66464640
E-mail: ucnvzka@ucl.ac.uk

Professor Felicity Smith, UCL, School of Pharmacy
E-mail: f.j.smith@ucl.ac.uk

Professor Kevin Taylor, UCL, School of Pharmacy
E-mail: k.taylor@ucl.ac.uk

To participate in the study is ***NOT OBLIGATORY*** and will not affect the delivery of the healthcare services, also you can withdraw at anytime. Your participation will help in improving the quality of care provided to patients with type 2 diabetes in Kuwait, and is greatly appreciated.

Please make sure that the information you will provide will be handled safely by the researcher, and nobody such as your doctor will know about it.

Thank you

رسالة الدعوة للمشاركة بالدراسة

كلية لندن الجامعية- مدرسة الصيدلة
وزارة الصحة- الكويت

استخدام المرضى البالغين لأدوية/أجهزة السكر لعلاج مرض السكر في الكويت

"أود أن أدعوك للمشاركة في هذه الدراسة، المعلومات المتوفرة بالدعوة تشرح الهدف من الدراسة وما هو المطلوب من المشارك. الرجاء أخذ الوقت الكافي لقراءة وفهم المعلومات، في حال وجود أي استفسار لا تتردد في الاتصال"

زهرة الصيرفي، تلفون: 66464640

يرجى الانتباه بأن المشاركة غير اجبارية و عدم المشاركة لن يؤثر في علاجك. كما يمكن الانسحاب في أي وقت ترغب.

مشاركتك سوف تساعد في تطوير جودة الرعاية المقدمة لمرضى السكر في الكويت وتشكر عليها.

أي معلومات تدلي بها سوف تكون سرية ولن يطلع عليها أحد غير الباحثون.

شكرا جزيلا

Appendix 4: The patients' information leaflet

"The Ministry of Health (MOH), Kuwait in cooperation with the School of Pharmacy, University College London (UCL) are conducting this study for healthcare, research and educational purposes"

The purpose of the study

Diabetes is rapidly increasing in the world and particularly in Kuwait, which suggests a defect in the management process. Patients behave differently regarding their diseases, medicines and in taking management responsibilities during their daily lives. It has been suggested that patient's medicine-taking behaviour may have an impact on the disease management. In this research, I am interested to know how are you managing your disease (e.g. how do you take your medicines, use you device, perform other management responsibilities). Results of this research will help in identifying determinants of patients' behaviour and recommending targeted interventions.

Why I have been chosen

In this study, we are interesting to include patients with type 2 diabetes using different treatment options. All patients who are visiting diabetes outpatient clinics are invited to take part.

If I agree to participate, what it will involve

As a participant, you will be interviewed by the researcher, who will ask you some questions regarding your anti-diabetic medications/device use, and the management responsibilities you are taking daily. Your personal views and experiences are our focus and there are no right or wrong answers. For your convenience, you will decide on the time and place of the interview, the estimated time for the interview is 20-30 minutes, followed by 10 minutes to answer two questionnaires. Also, the researcher will obtain some clinical data from your medical note.

For research purposes, the interviewer will ask you to audio-record the interview, only the researcher will access the information, and it will be wiped immediately after transcription.

<div align="center">Thank you</div>

وزارة الصحة- الكويت بالتعاون مع كلية لندن الجامعية- مدرسة الصيدلة تقوم بهذه الدراسة لأهداف صحية وتعليمية

<u>الهدف من الدراسة:</u>

مرض السكر ينتشر بسرعة في العالم وبالأخص في الكويت، مما يدل على نقص في علاج هذا المرض. يستخدم المرضى أدويتهم بطرق مختلفة في حياتهم اليومية. لقد أثبتت الدراسات السابقة أن استخدام المرضى لأدويتهم من الممكن أن يؤثر في السيطرة على هذا المرض. هذه الدراسة سوف تساعد في فهم كيفية استخدام المرضى البالغين لأدويتهم/أجهزتهم لعلاج السكر في الكويت مما يؤدي إلى استنتاج التصرفات الخاطئة التي تؤثر في العلاج و من ثم استهداف هذه التصرفات من خلال البرامج التعليمية.

<u>لماذا تم اختياري:</u>

في هذه الدراسة أي مريض يزور عيادات السكر ويأخذ علاج طبي للسكر سوف يكون مدعو للمشاركة.
ماذا يتطلب من المشارك:

في حال الموافقة على المشاركة سوف تقوم الباحثة بمقابلتك شخصيا في الوقت و المكان المناسبين لك. في هذه المقابلة سوف توجه لك الباحثة بعض الأسئلة عن كيفية استخدامك لأدوية السكر. المدة المتوقعة 20-30 دقيقة تتبعها 10 دقائق لتعبئة الاستبيان.

سوف تقوم الباحثة بتسجيل المقابلة لتسهيل عملية تحليل المعلومات ومن ثم سوف تقوم بمسح التسجيل.

<div align="center" style="color:red">شكرا جزيلا</div>

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Appendix 5: The HCPs' invitation letter

Invitation letter for healthcare professionals

Dear Sir/Madam;

I'm Zahra Alsairafi, a pharmacist in the MOH and a PhD student at University College London. I conducted a research project around the management of type 2 diabetes in Kuwait. I obtained the perspectives of patients about the use of their medicines during their daily life, and investigated the problems they were experiencing, in terms of disease management. In addition, I examined the use of technology (insulin pens and pumps) in the management of type 2 diabetes, and how the patients perceived their use.

I would like to take this opportunity to discuss with you the main findings of my research, to benefit from your experience, and to obtain your reflections and thoughts about these findings. The interview will last about 10-15 minutes, face-to-face or by telephone depending on your preference and at a convenient time for you.

If you have any further enquiries please do not hesitate to contact any of the research team:

Zahra Alsairafi

Mobile: 6 6464640

E-mail: ucnvzka@ucl.ac.uk

Academic supervisors:

Professor Felicity Smith

E-mail: f.j.smith@ucl.ac.uk

Professor Kevin Taylor
E-mail: kevin.taylor@ucl.ac.uk

<p style="text-align:center">Thank you</p>

Appendix 6: The HCPs' information leaflet

Information leaflet for healthcare professionals

1. All patients
Findings:
- More than half of the study sample had low-medium adherence to medications, HbA1c>7.5%, and diabetes-related complications.
- Most participants had difficulties in adhering to healthy diet and exercise, which impacted the management of their disease and health outcomes.

Issues:

Factors found to impact patients' medicine-taking behaviour were lack of health awareness, health beliefs and cultural factors:
- The majority of participants perceived their disease as a normal, prevalent and common health status, and not as a serious chronic disease, were only slightly concerned about its risk on their future health, and were unaware about the long-term complications.
- Patients did not have the motive to adhere to healthy lifestyle, and they thought they have to be isolated to be able to eat as diabetics because dieticians' plans were not individualised to conform with each patient's educational level and social life.
- Cultural factors affecting patients' medicine-taking behaviour: fasting in Ramadan, social gatherings, irregular daily routine, use of herbals, lack of connection between the provided healthcare services, and discontinuation of care when referred to other specialists.
- Other personal factors affecting patients' medicine-taking behaviour: perceived/fear of side effects, unexpected hyperglycaemia, forgetfulness and laziness.

2. Patients using syringe/vial and pen for insulin delivery
Finding: Insulin pens were advantageous compared to syringe and vial in terms of ease of use, portability, convenience, and overall preference.
Issues:
- Insulin pens are neither available in primary-care units nor dispensed to all patients in hospitals.
- Small-sized pen needles, which cause less or no pain, are mostly unavailable.
- Victoza[R] pen is available in Medical Stores, and helped in improving glycaemic control, particularly for obese patients but not dispensed for patients.

3. Patients using insulin pump
Finding: Insulin pump was an effective option, six of the eight participants using insulin pump could achieve HbA1c<7.5%, it provided patients with more flexibility in life, without increasing risk of side effects, and was the preferred option over multiple daily injections.
Issues:
- Five of the eight participants gained extra weight (BMI>30 kg/m^2) because they believed that as long as the pump controls the disease and maintains good blood glucose levels, diet and exercise could be neglected.
- Patients lacked the knowledge of carb counting, and they were either counting calories/or taking insulin shots without introducing their carbohydrate intake.
- Limit of consultation time, and not specifying particular days for patients using pumps.
- The prescription of insulin pumps for patients with type 2 diabetes is still limited.

Thank you for taking time in reading this leaflet

Appendix 7: The ineterview schedule of patients

Interview schedule for patients with type 2 diabetes using oral hypoglycaemic agents, insulin (injections/device) or both

Participant No.: _____   Date: _____/_____/2014

Place: _____   Time: _____

Before we start the interview, I would like to remind you briefly what the study is about

Diabetes is rapidly increasing in Kuwait, and we know very little about how patients are managing their disease, and what problems and difficulties they encounter. The results of this research will help us to suggest recommendations and target specific interventions to patients. So, we would like to know your views and experiences about your disease, medicines/device, healthcare providers and system.

Consent Form

Now before we start, we need to fill out this form. It confirms that you are happy to talk with me today, but you can stop the interview anytime you wish. Are you happy to sign the form?

Consent to audio-record the interview

I would like to audio-record this interview, I will be the only person who will listen to the record. This will help me to listen to you carefully now and then write down everything from the recording later. But if you don't wish to tape-record the interview, it's OK. Are you happy to record it?

Would you like to ask me anything before we start?

There are no right or wrong answers; I am interested to know your views and experiences regarding the use of your medicines/device.

Prompts are small and in italics
Blue texts are questions for patients using device (pen/pump) <u>ONLY</u>

General views and experiences

1. What do you know about the possible long-term effects of diabetes/what do you think the future holds in terms of your disease?

2. Diabetes is increasing nowadays in our country, why do you think this is the case?

- *Some people think that God is important in determining who gets diabetes; others believe it is more to do with heredity/themselves, what do you think?*
- *Some patients try to forget that they have diabetes, because they think it'll get worse if they worried about it, what do you think?*
- *How do you think we should address the problem in Kuwait?*

Day-to-day life

3. What effect has having diabetes had on your life?

- *Tell me about any changes you have made in your diet (the way you buy, cook and eat your food)*
- *Can you describe changes you have made in your physical activity, if any*
- *If you are a smoker, do you still smoke, have you attempted to stop, if you have quit, why?*
- *Have you made any other lifestyle changes?*
- *How do these changes fit within your daily routine?*
- *For all the changes that you have attempted, what has helped you to make them?*
- *For all the changes that you have attempted, what has been the easiest/most difficult thing to apply?*
- *In what ways it was easy/difficult?*
- *For the changes that you couldn't apply, what are the barriers to making these changes (barriers to: following healthy diet, practising exercise or stop smoking)?*
- *To what extent do you think that your lifestyle modifications are helping you manage your diabetes?*

Therapeutic regimen

4. For your diabetes, what medicines/device are you using currently?

- *Please, can you show me your medicines/device*
- *How do you use them?*
- *How long have you been using this device?*
- *Before using this device, how were you managing your diabetes?*
- *Tell me in what ways have you found your medicines helpful*
- *Are there any problems with taking your medicines, what are these?*
- *How do you feel about taking your medicines for a long period?*

- *What do you think the future holds in terms of your treatment, how do you feel about it (for patients using OHAs only)?*
- *Have you had a time when you got a different brand of your medicines? How did you feel about it?*
- *Have you experienced any problem while using your device (pain, skin infection, irritation, bruising, mechanical problems, others)?*
- *What did you do to solve these problems?*

5. How easy or difficult do you find using your device?

- *Was it easy/difficult to learn how to use it*
- *Any difficulty in measuring insulin dose correctly/other difficulties*
- *Are there things you find easier/harder to do now, compared to your previous therapy*
- *What are these and how are they easier/harder?*

6. How would you describe your life while using this device?

- *Is it easy/normal life, you can do what you want*
- *Do you feel stressed or overwhelmed because of using this device?*
- *Do you feel psychologically or physically uncomfortable because of using this device?*

7. Does your device interfere with your normal life activities?

- *Wearing clothes*
- *Eating*
- *Exercise*
- *Practising hobbies*
- *Sleep*
- *How does this compare to your previous therapy*

8. How do you fit taking your medicines into your daily routine?

- *Tell me how did you use your medicines yesterday*

9. In order to make life easier, patients sometimes use their medicines in their own ways. Do you remember a time when you have not used your medicines as prescribed, please tell me what you did, and why did this happen?

- *Do you change the way you take your medicines when you travel/at weekends?*

10. Tell me about changes you make in taking your medicines during the holy month of Ramadan.

- *Why are you making these changes?*
- *Do you think this has an impact on your diabetes?*

11. What do you think about the role of herbal medicines in the treatment of diabetes?

- *Have you ever used them, what did you use?*
- *When did you start using it?*
- *How often do you use it, instead of/with your regular medicines?*
- *How helpful do you think they are?*

Blood glucose monitoring & glycaemic control

12. Tell me about monitoring your blood glucose level.

- *How often do you monitor your blood glucose level and when?*
- *What result are you aiming for, and what do you consider a good/bad result?*
- *How often do you achieve your target, and what helps you achieving it?*
- *What do you do if you have not achieved your target?*
- *What hinders you from regularly monitoring your blood glucose level (lack of time, forgetfulness, impaired manual/visual dexterities, too complicated, too painful, stress, lack of awareness)?*
- *Do you feel that your device requires you to monitor your blood glucose level more often than you would like?*
- *How does this compare to your previous therapy?*

13. Describe how your device helps you in controlling your diabetes?

- *Achieving good blood glucose control*
- *Having hyper/hypoglycaemia*
- *Improving awareness of hypoglycaemia*
- *Avoiding weight gain*
- *Having hospital admissions due to poor control*

Social support

14. Can you tell me how your family and friends support you in managing your diabetes?

- *Calculating doses*
- *Administering doses*
- *Checking site of injection*
- *Monitoring blood glucose level*
- *Eating special food*
- *Exercising*

- *Accompanying you in your appointments*
- *Collecting your prescriptions*
- *How does this compare to your previous therapy?*

15. How do you feel about talking with others regarding your disease or administering your medicines/using your device in front of others?

- *Embarrassed*
- *Different from others*
- *Does diabetes interfere with your social life (social gatherings)?*

16. Does using your device have an effect on other family members?

- *How much they need to help*
- *How much they are worrying about you*
- *How does this compare to your previous therapy?*

Healthcare providers

17. Describe your experience with healthcare providers (physicians, ophthalmologists, dieticians, pharmacists, nurses,).

- *Who have you spoken with, and how regularly do you see them?*
- *What information have you been given (education about diabetes, complications, medicines use, insulin requirements, carbohydrate counting, lifestyle modifications and check-ups)*
- *Have you received sufficient training for the use of your device?*
- *Do you think that healthcare providers are helpful? In what ways?*
- *Does your physician discuss with you your treatment plan, how do you feel about it?*
- *Have you experienced a time when HCPs were unhelpful? In what ways?*

Healthcare system

18. Tell me about healthcare services that you have received.

- *Are there any services that you would like to get all the time?*
- *What other services you would like to have (receiving reminder phone calls for your appointment, telephone helpline)?*
- *Have you experienced any problems in accessing to health services, what are these (unavailability of medicines, inflexibility of appointments, discontinuity of care)?*

Final questions

19. In general, are you happy with your current device?

- *Do you think that you may change it at any time?*
- *Would you recommend your current device to other patients?*

20. Finally, would you like to add anything about your disease, medicines/device, healthcare providers or system that we have not discussed?

- *Any other good things*
- *Any other concerns/problems*

<u>Patient's information</u>

How old are you/date of birth?

How long have you had diabetes?

Sex: Male   Female

Nationality: Kuwaiti   Non-Kuwaiti

Residence area: rural   urban

Occupation: Student   employed   un-employed   retired

What is your educational level?

- ❑ Cannot read and write
- ❑ Primary school
- ❑ Secondary school
- ❑ Diploma
- ❑ University
- ❑ Postgraduate

Thank you for your participation

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أسئلة المقابلة لمرضى السكر (النوع الثاني)

رقم المشارك: التاريخ:

المكان: الوقت:

قبل البدء بالمقابلة، أود أن أذكرك بمضمون الدراسة باختصار.

مرض السكر ينتشر سريعا في الكويت. الدراسات والأبحاث حول كيفية استخدام المرضى لأدويتهم وما هي المشاكل التي يواجهونها قليلة. نتائج هذه الدراسة سوف تساعد في اقتراح البرامج والخدمات التي يحتاجها المرضى لتطوير استخدامهم لأدويتهم والتحكم بمرضهم.

الآن، هل من الممكن أن توقع هذا الطلب، للتصريح بالموافقه على المقابله، مع العلم أنه باستطاعتك الأنسحاب في أي وقت تريد. كما أني أود بتسجيل المقابلة لتسهيل أمور البحث، مع العلم أن لا أحد غيري سوف يطلع على هذه المعلومات أو التسجيل.

هل لديك أي سؤال قبل البدء؟

</div>

<u>معلومات عامة</u>

ماذا تعرف عن مرض السكر وأضراره بعيدة المدى؟

مرض السكر ينتشر بسرعه هذه الأيام، ماذا باعتقادك السبب؟
وراثي/ من الله/ من العادات الغذائيه الخاطئة/ القلق والتوتر

<u>الحياة اليومية</u>
كيف أثر مرض السكر على حياتك؟
النظام الغذائي (هل غيرته/ ماهي التغييرات)
الرياضة (هل مارست الرياضة نتيجة اصابتك بالمرض)
التدخين (هل كنت تدخن من قبل/ هل توقفت/ هل كان السبب الاصابة بالسكر)
هل كانت التغييرات ملائمة لنظام حياتك اليومي
ماهو أسهل/أصعب شي قمت بتطبيقه
هل ساعدك أي أحد
ماهي الصعوبات التي واجهتها
إلى أي مدى ساعدتك هذه التغييرات في التحكم في مرضك

<u>العلاج</u>
ما هو العلاج التي تستخدمه لمرض السكر؟
أسماء الأدوية/الجهاز
منذ متى تستخدمهم
قبل استخدامك هذا الجهاز ماذا كنت تستخدم للتحكم بالمرض
إلى أي مدى ترى بأن علاجك يساعد في التحكم بالمرض
ماهي المشاكل التي تواجهك مع العلاج
ماذا تشعر عندما تحس بأن دوائك سوف تأخذه لمدى العمر
هل تلقيت مرة دواء من شركة مختلفة/ كيف شعرت
هل عانيت من أي مشكله مع الجهاز
ماذا فعلت لحل هذه المشاكل

كيف تصف استخدام هذا الجهاز من حيث السهولة/ الصعوبة؟
هل كان من السهل التعلم على استخدامه
ماهي الأشياء الأسهل/الأصعب في استخدام هذا الجهاز مقارنة بالعلاج السابق

كيف تصف حياتك مع هذا الجهاز؟
حياة طبيعية/مضغوطة/غير مرتاح

هل يتعارض استخدام هذا الجهاز مع نشاطاتك اليومية؟
لبس الملابس/ الأكل/ الرياضة/ النوم
قارن مع العلاج السابق

كيف يتلائم أخذ العلاج مع روتين حياتك اليومية؟

لجعل الحياة أسهل، يقوم بعض المرضى بتغيير طريقة استخدامهم لأدويتهم، هل تذكر أي وقت قمت فيه بتغيير طريقة أخذك لأدويتك؟
هل تغير من أخذ علاجك في السفر/ العطل

هل تقوم بتغيير أخذك للعلاج في رمضان؟
لماذا تقوم بهذه التغييرات
هل تعتقد بأن هذه التغييرات تؤثر على تحكمك بالمرض

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ماذا تعتقد بالأدوية الأعشاب؟

هل استخدمتهم/ متى/ هل توقفت عن علاجك الطبي أثناء استخدامهم/ هل شعرت بأن الأعشاب ساعدتك في التحكم بالمرض

<u>**قياس السكر**</u>

أخبرني عن قياس السكر في المنزل؟

كم مرة تقيس السكر في اليوم

ماهي برأيك النتيجة الطبيعية

إلى أي مدى تحقق هذه النتيجة وما الذي يساعدك في تحقيقها

ماذا تفعل ان لم تحقق هذه النتيجة

ماهي الصعوبات التي تواجهها في قياس السكر

هل تشعر بأن استخدامك لهذا الجهاز زاد من حاجتك لقياس السكر

قارن مع العلاج السابق

هل تستطيع أن تصف كيف ساعدك هذا الجهاز بالتحكم في مرضك؟

تحقيق نتائج افضل (معدل سكر طبيعي)

تقليل نوبات هبوط/ارتفاع السكر

زيادة الوعي لنوبات الهبوط

تجنب زيادة الوزن

تجنب دخول المستشفى بسبب مضاعفات السكر

<u>**المساعدة الإجتماعية**</u>

هل تستطيع أن تخبرني عن مساعدة الأهل والأصدقاء؟

حساب الجرعة

أخذ الدواء

قياس السكر

الأكل

الرياضة

المرافقة بالمواعيد

صرف الدواء

ماذا تشعر عندما تتكلم عن مرضك أمام الناس أو عندما تأخذ دوائك أمامهم؟

محرج

مختلف عن الأخرين

مرض السكر يتعارض مع حياتك الإجتماعية

هل يؤثر استخدام هذا الجهاز على أي أحد من أفراد أسرتك؟

هل تحتاج مساعدة منهم

هل يقلقون عليك

قارن مع علاجك السابق

<u>**الطاقم الطبي**</u>

ماهي خبرتك مع الطاقم الطبي (الطبيب/الصيدلي/الممرض/اخصائي التغذية)؟

هل تزور طبيبك بانتظام

ماهي المعلومات التي حصلت عليها

هل تلقيت التدريب الكافي لإستخدام الجهاز

هل تعتقد بأن الطاقم الطبي متعاون

هل صادف وقت لم يكن فيه الطاقم الطبي متعاون معك/ كيف

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<u>الخدمات الصحية</u>

ما رأيك بالنظام الصحي والخدمات التي تتلقاها؟

هل يوجد أي خدمات تود أن تكون موجودة

هل واجهت أي صعوبات في تلقي العلاج/ ماهي هذه الصعوبات

<u>أسئلة نهائية</u>

بشكل عام، هل أنت سعيد باستخدام هذا الجهاز؟

هل تعتقد بأنك ستغيره يوما من الأيام

هل تقترح هذا الجهاز لمرضى آخرين

هل تود إضافة أي شيء آخر؟

<u>معلومات المريض</u>

كم عمرك؟

منذ متى تعاني من مرض السكر؟

الجنس: ذكر   أنثى

الجنسية: كويتي   غير كويتي

مكان السكن: مدني   قروي

الوظيفة: طالب موظف غير موظف متقاعد

مستوى التعليم:

لا أستطيع القراءة والكتابة

ابتدائي

متوسط

ثانوي

جامعة

دراسات عليا

شكرا جزيلا

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Appendix 8: The HCPs' interview schedule

Interview schedule for healthcare professionals

Healthcare provider:
- ❑ Physician
- ❑ Psychologist
- ❑ Pharmacist
- ❑ Dietician
- ❑ Nurse

Area:
- ❑ Urban
- ❑ Rural

Signature:

_____

Date:

_____

I would like to know you views and experiences regarding the following statements, in terms of agreement and importance.

Statement	Agreement				Importance of consideration			
	1= Agree	2= Agree to a certain extent	3= Dis-agree	4= Un-certain	1= Most import-ant	2= Very important	3= Important	4= Least important
1. Non-adherence to treatment and healthy lifestyle is due to specific beliefs about the normality of the disease and lack of awareness about its seriousness and complications.								
Comment:								
2. Non-adherence to treatment and healthy lifestyle is due to cultural factors, e.g. fasting in Ramadan, use of herbals and social gatherings.								
Comment:								
3. Non-adherence to treatment is due to personal factors, such as forgetfulness, laziness, fear of or perceived side effects.								
Comment:								
4. Non-adherence to diet is due to lack of individualised diet plans, which conform to patient's social and educational requirements.								
Comment:								
5. Delivery of healthcare services is delayed, especially when referrals are needed.								
Comment:								
6. Pen devices are not prescribed/dispensed for all insulin-dependent patients with type 2 diabetes in hospitals.								
Comment:								
7. Certain items, such as small-sized pen needles are mostly unavailable in the pharmacy.								
Comment:								
8. Although it is available in Medical Stores, Victoza^R pen is not dispensed to patients treated in the MOH.								
Comment:								
9. Patients using insulin pumps gain weight due to different reasons, e.g. non-adherence to diet and exercise due to belief in the control provided by the pump, lack of awareness about carbohydrate counting, and not using the pump properly.								
Comment:								
10. Consultation time is not enough to discuss all pump-related issues with the doctor.								
Comment:								

Would you please provide with your opinion regarding the following recommendations, in terms of their importance and practicability.

Recommendation	Importance				Feasibility			
	1= Most	2= More	3= Less	4= Least	1= Yes, now	2= Yes, within a year	3= Yes, within 5- 10 years	4=No
1. Health awareness of patients, e.g. awareness about short and long-term diabetes-related complications needs to be improved continuously through campaigns, group sessions or lecture courses at hospital clinics, primary-care units, KDS, or via audio-visual aids, e.g., educational programmes in radio and television.								
Challenges:								
2. Social and cultural beliefs and lifestyle concerns should be addressed and included in patients' medical notes.								
Challenges:								
3. HCPs should undergo Pre-Ramadan training programme, and cooperate together, in order to optimise care provided to patients during this month.								
Challenges:								
4. Educational and motivational advices regarding adherence to treatments should be provided verbally and in writing (e.g. brochures/leaflets), and reinforced with each clinical visit/prescription of medicines.								
Challenges:								
5. Dieticians need to be educated about the educational and social differences when dealing with patients, and how those differences could impact self-management behaviour of patients. Also, they need to be aware about how to individualise care plans that conform to each patient's needs and life.								
Challenges:								
6. Family members should be involved when constructing care plans and lifestyle modifications.								
Challenges:								
7. The delivery of healthcare services should be further coordinated particularly, when patients needed referrals to different HCPs/department.								
Challenges:								
8. Patients initiated on insulin should be informed about the different methods that are available for insulin delivery, e.g. pens and pumps. Also, they should be involved in making decisions related to the selection of the device.								
Challenges:								
9. Services, such as pharmacist/nurse-led diabetes clinics, or psychological interventions that take care of this group of patients by incorporating different HCPs in the management process should be implemented.								
Challenges:								
10. A 24-hours help-line service managed by diabetes specialists for urgent and between appointments enquiries should be considered.								
Challenges:								

Do you have any further recommendation (s) that you would like to add in order to:
- Improve patients' awareness, modify their beliefs and consequently their medicine-taking behaviour,
- Help patients to manage their disease during certain circumstances, e.g. Ramadan and social gatherings,
- Improve the delivery of healthcare services and linked them together,
- Expand the prescription of insulin devices (e.g. pens and pumps),
- Improve health outcomes of patients with type 2 diabetes.   **Thank you**

Appendix 9: The participant consent form

Use of medicines and devices
by adults in the management of type 2 diabetes
in Kuwait

Researcher: Zahra Alsairafi, MSc. Clinical Pharmacy International Practice & Policy, UCL

Co-researchers: Prof. Felecity Smith (UCL) and Prof. Kevin Taylor (UCL)

Consent Form

Please tick

box

- ❑ I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
- ❑ I understand that my participation is voluntary and that I can withdraw at any time.
- ❑ I understand that my refusal to take participate will not affect the delivery of healthcare services.
- ❑ I agree to be interviewed and answered questions at any convenient time to me, and that the interview being audio-recorded.
- ❑ I understand that the researcher will access my medical notes.
- ❑ I agree for using anonymised quotes in publications.
- ❑ I agree to take part in the above study.

Name of participant:
Date:
Signature:

<u>اقرار الموافقة على المشاركة</u>

عنوان الدراسة: استخدام المرضى البالغين لأدويتهم/أجهزتهم لعلاج السكر في الكويت

الباحث الأساسي: زهرة خليل الصيرفي (كلية لندن الجامعية، مدرسة الصيدلة)

الباحثون المشاركون: البروفسورة/ فلستي سميث (كلية لندن الجامعية، مدرسة الصيدلة)، البرفسور/ كيفن تايلور (كلية لندن الجامعية، مدرسة الصيدلة)

لقد قرأت وفهمت المعلومات المتعلقة بالدراسة و أتيحت لي الفرصة لتوجيه الأسئلة

لقد فهمت أن قرار مشاركتي بالدراسة اختياري، ويجوز لي أن أنسحب في أي وقت أرغب

لقد فهمت أن رفضي للمشاركة بالدراسة لن يؤثر في علاجي

أنا أوافق على أن تتم مقابلتي لأجاوب على بعض الأسئلة، في الوقت والمكان المناسبين لي، كما أوافق على تسجيل المقابلة

لدي علم بأن الباحثة سوف تقوم بالاطلاع على ملفي الطبي

أوافق على المشاركة بالدراسة

اسم المشترك:

التاريخ:

التوقيع:

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Appendix 10: Morisky Medication Adherence Scale (MMAS-8)

©**Morisky Medication Adherence Scale (MMAS-8-Item). This is a generic adherence scale.**

- **You indicated that you are taking medication(s) for your (diabetes). Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences.**
- **There is no right or wrong answer. Please answer each question based on your personal experience with your [diabetes] medication.**

(Please mark your response below)

	No=1	Yes=0
1. Do you sometimes forget to take your [diabetes] medication(s)?		
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your [diabetes] medication(s)?		
3. Have you ever cut back or stopped taking your medication(s) without telling your doctor, because you felt worse when you took it?		
4. When you travel or leave home, do you sometimes forget to bring along your [diabetes] medication(s)?		
5. Did you take your [diabetes] medication(s) yesterday?		
6. When you feel like your [diabetes] is under control, do you sometimes stop taking your medication(s)?		
7. Taking medication(s) every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your [diabetes] treatment plan?		

8. How often do you have difficulty remembering to take all your medication(s)?

(**Please circle your answer below)**

Never/Rarely…………………………………...**4**

Once in a while…………………………………**3**

Sometimes………………………………………..**2**

Usually……………………………………………**1**

All the time…………………………………………**0**

Appendix 11: Beliefs about Medicines Questionnaire (BMQ-S)

**YOUR VIEWS ABOUT
MEDICINES PRESCRIBED FOR YOU**

- We would like to ask you about your personal views about medicines prescribed for you.

- These are statements other people have made about their medicines.

- Please show how much you agree or disagree with them by ticking the appropriate box.

**There are no right or wrong answers.
We are interested in your personal views**

	Views about MEDICINES PRESCRIBED FOR YOU:	Strongly Agree	Agree	Un-certain	Disagree	Strongly Disagree
N1	My health, at present, depends on these medicines					
C1	Having to take these medicines worries me					
N2	My life would be impossible without these medicines					
C2	I sometimes worry about long-term effects of these medicines					
N3	Without these medicines I would be very ill					
C3	These medicines are a mystery to me					
N4	My health in the future will depends on these medicines					
C4	These medicines disrupt my life					
C5	I sometimes worry about becoming too dependent on these medicines					
N5	These medicines protect me from becoming worse					
C6	These medicines give me unpleasant side effects					

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استبيان خاص باستخدام أدويتك الخاصة بداء السكري

يتبع العديد من الناس طريقة تناسبهم لأخذ أدويتهم الخاصة بداء السكري تختلف عن التعليمات المطبوعة أو الموصوفة من الطبيب المعالج. في الأسفل بعض الأسئلة التي تناقش طريقة استخدام المريض للدواء، ليس هناك إجابة صحيحة أو خاطئة، فقط ما يهمنا هو رأيك الشخصي.

1. هل تنسى أحيانا أخذ أدويتك الخاصة بالسكري؟ نعم   لا

2. خلال الأسبوعين الماضيين، هل تذكر أيام لم تأخذ فيها دوائك الخاص بالسكري؟ نعم   لا

3. هل توقفت عن أخذ دوائك بدون إخبار طبيبك المعالج بسبب تدهور حالتك؟ نعم   لا

4. عندما تغادر منزلك أو تسافر، هل تنسى أحيانا أخذ أدويتك الخاصة بالسكري؟ نعم   لا

5. هل أخذت أدويتك الخاصة بالسكري أمس؟ نعم   لا

6. عندما تشعر بأن مستوى السكر بالدم لديك جيد، هل تتوقف عن أخذ دوائك؟ نعم   لا

7. أخذ الأدوية يوميا غير ملائم لدى العديد من الناس، هل تشعر بأنك منزعج بسبب أخذك لعلاج السكري؟ نعم لا

8. إلى أي مدى تواجه صعوبة في تذكر أخذ علاجك الخاص بالسكري؟
أبدا/نادرا   نادر جدا   أحيانا   غالبا   دائما

</div>

© Morisky, School of Public Health

<div dir="rtl">

العبارات في الأسفل تتعلق بآرائك حول أدويتك الخاصة بداء السكري، اختر الجواب الأنسب:

	عبارات رددها الغير	أوافق بشدة	أوافق	غير واثق	أعترض	أعترض بشدة
N1*	تعتمد صحتي في الوقت الحالي على هذا الدواء					
C1*	وجوب تناول هذه الأدوية يشعرني بالقلق					
N2*	أدويتي تساعدني على ضبط مرض السكري					
C2*	أشعر بالقلق أحيانا من الآثار الجانبية لهذه الأدوية على المدى البعيد					
N3*	بدون هذا الدواء ستسوء حالتي الصحية كثيرا					
C3*	أدوية السكر شيء غامض بالنسبة لي					
N4*	تعتمد صحتي المستقبلية على هذا الدواء					
C4*	تعرقل هذه الأدوية نظام حياتي					
N5*	تمنع هذه الأدوية الارتفاع الشديد لمستوى السكر بدمي					
C5*	كثرة الاعتماد على هذه الأدوية تقلقني أحيانا					

</div>

© Rob Horne, School of Pharmacy

Appendix 12: The clinical information sheet

Completion form (to be completed by the interviewer)

Total interview time: -----------minutes

Was any person (other than patient) present at this interview: Yes No. **If yes,** comments on their participation:

Was the interview audio-recorded: Yes   No. **If no,** state the reasons:

*Latest HbA1c level(s): --------------------Date of measurement: --------------------

*Latest blood glucose level(s): -----------mmol/l. Date of measurement: -------------

*BMI=----------Kg/m^2

*Smoking status:

Smoker (------cigarettes/day)   Non-smoker   Ex-smoker

*Current anti-diabetic treatment:

Clinical data to be obtained from patient's medical notes

Appendix 13: UCL Research Ethics Committee Approval Letter

UCL RESEARCH ETHICS COMMITTEE
GRADUATE SCHOOL OFFICE

Professor Felicity Smith
Department of Practice and Policy
School of Pharmacy
UCL

9 January 2014

Dear Professor Smith

Notification of Ethical Approval
Project ID: 5328/001: Use of anti-diabetic medicines and devices by adults in the management of diabetes mellitus in Kuwait

I am pleased to confirm that in my capacity as Chair of the UCL Research Ethics Committee I have approved your study for the duration of the project i.e. until January 2015.

Approval is subject to the following conditions:

1. You must seek Chair's approval for proposed amendments to the research for which this approval has been given. Ethical approval is specific to this project and must not be treated as applicable to research of a similar nature. Each research project is reviewed separately and if there are significant changes to the research protocol you should seek confirmation of continued ethical approval by completing the 'Amendment Approval Request Form'.

The form identified above can be accessed by logging on to the ethics website homepage: http://www.grad.ucl.ac.uk/ethics/ and clicking on the button marked 'Key Responsibilities of the Researcher Following Approval'.

2. It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. Both non-serious and serious adverse events must be reported.

Reporting Non-Serious Adverse Events
For non-serious adverse events you will need to inform Helen Dougal, Ethics Committee Administrator (ethics@ucl.ac.uk), within ten days of an adverse incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Chair or Vice-Chair of the Ethics Committee will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.

Reporting Serious Adverse Events
The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator immediately the incident occurs. Where the adverse incident is unexpected and serious, the Chair or Vice-Chair will decide whether the study should be terminated pending the opinion of an independent expert. The adverse event will be considered at the next Committee meeting and a decision will be made on the need to change the information leaflet and/or study protocol.

On completion of the research you must submit a brief report (a maximum of two sides of A4) of your findings/concluding comments to the Committee, which includes in particular issues relating to the ethical implications of the research.
With best wishes for the research.

Yours sincerely

Professor John Foreman
Chair of the UCL Research Ethics Committee

Cc: Zahra Khalil Alsairafi, Applicant

Appendix 14: Ministry of Health Approval Letter

\o\o\۲

State Of Kuwait
Ministry Of Health
Asst. Undersecretary for Planning & Quality

دولة الكويت
وزارة الصحة
وكيل الوزارة المساعد لشئون التخطيط والجودة

مكتب الوكيل المساعد لشئون التخطيط والجودة

Reference : ۸۷۷

Date :

المرجع : و.م.ت.ج./ ١٦١ / ٢٠١٤

التاريخ : ..../..../....

السيد الفاضل / د. وكيل الوزارة المحترم

تحية طيبة وبعد ،،،،

الموضوع / تسهيل مهمة الباحثة/ زهرة خليل الصيرفي

رقم البحث (٢٠١٣/٩٣)لإجراء بحث تحت عنوان :

Use of anti-diabetic medicines and devices by adults in the management of diabetes mellitus in Kuwait

يرجى التفضل بالإحاطة بأن اللجنة الدائمة لتنسيق البحوث الطبية والصحية المشكلة بموجب القرار الوزاري رقم ٢٠٧ لسنة ٢٠١٢ قد أوصت باجتماعها الثامن (٢٠١٤/١) المنعقد يوم الثلاثاء بتاريخ ٢٠١٤/١/٢٨ بالموافقة على إجراء البحث رقم (٢٠١٣/٩٣) المقدم من الباحثة/ زهرة خليل الصيرفي بتاريخ ٢٩/ ١٢ /٢٠١٣ تحت عنوان :

Use of anti-diabetic medicines and devices by adults in the management of diabetes mellitus in Kuwait

وذلك بعد أن قامت اللجنة إستناداً للقرار الوزاري رقم ٢٠٧ لسنة ٢٠١٢ والتعميم الصادر من السيد / وكيل الوزارة برقم ١٥٦ لسنة ٢٠١٢ بإستطلاع آراء الجهات ذات العلاقة بموضوع البحث حيث ورد الرد من السيدة الدكتورة / رئيس مجلس أقسام الأمراض الباطنية (رقم الوارد ٧٥ بتاريخ ٢٠١٤/١/٢٣) والسيدة الدكتورة / مدير الإدارة المركزية للرعاية الصحية الأولية (رقم الوارد ٨٥ بتاريخ ٢٠١٤/١/٢٦) والسيد / الوكيل المساعد للشئون القانونية (رقم الوارد ٩٥ بتاريخ ٢٠١٤/١/٢٧) .

1

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<table>
<tr><td>State Of Kuwait
Ministry Of Health
Asst. Undersecretary for Planning & Quality</td><td></td><td>دولة الكويت
وزارة الـصـحـة
وكيل الوزارة المساعد لشئون التخطيط والجودة</td></tr>
</table>

Reference : ....   المـرجع : ....

Date   : ....   التاريخ : ....

ويتم البحث باستخدام استبيان لجمع البيانات من خلال المقابلة الشخصية مع مرضى السكر البالغين الذين يراجعون عيادات السكر بمراكز الرعاية الصحية الأولية والمستشفيات بعد أخذ الموافقة المستنيرة ممن يوافقون على المشاركة بالدراسة ولا يتضمن البحث إعطاء أي أدوية أو إجراء فحوصات إضافية أو التدخل في الخطط العلاجية الموضوعة للمرضى ولا يتضمن البحث أي مخاطر على المرضى .

برجاء التفضل بالإطلاع والتوجيه بما ترونه مناسباً نحو إعتماد توصية اللجنة والموافقة على مخاطبة الجهات ذات الصلة بموضوع البحث (**السيد / الوكيل المساعد للشئون الفنية : إدارة الرعاية الصحية الأولية والسادة / مدراء المناطق الصحية والمستشفيات**) بهذا الشأن للعمل على تسهيل مهمة الباحثة لإجراء البحث بمراكز الرعاية الصحية الأولية بالمناطق الصحية والمستشفيات .

مع مراعاة إلتزام الباحثة بالمحافظة على حقوق المرضى المشاركين بالبحث بالخصوصية وسرية المعلومات وعدم تداولها خارج إطار البحث ووفقاً للضوابط المنظمة لذلك والحصول على الموافقة المستنيرة من المشاركين في البحث باستخدام النموذج المعتمد لذلك Informed Consent .

وتفضلوا بقبول فائق الاحترام،،،

الدكتور/ وليد خالد الفلاح
الوكيل المساعد لشئون التخطيط والجودة
رئيس اللجنة الدائمة لتنسيق البحوث الطبية والصحية

د. خالد السهلاوي
وكيل وزارة الصحة

2

<table>
<tr><td>P.O. Box:(5) 13001 Safat, Kuwait
Tel : 24867159 - 24866724 Fax: 24877957 - 24866739</td><td>ص.ب: (٥) الرمز البريدي ١٣٠٠١ الصفاة، الكويت
تلفون: ٢٤٨٦٦٧٢٤ - ٢٤٨٦٧١٥٩ فاكس ٢٤٨٦٦٧٣٩ - ٢٤٨٧٧٩٥٧</td></tr>
</table>

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Appendix 15: An agreement form for the use of MMAS-8

MMAS-4 or 8 License Contract and Copyright Agreement

The license agreement is in effect for a one-year period or the duration of the study, whichever is shorter. If your study is longer than one year, a renewal of license is available based upon a brief status report prior to expiration of the waiver of license fee and copyright agreement.

If I am eligible for a waiver of license fee contractual agreement, I agree to provide Dr. Morisky a report of my findings upon completion of this study, cite the required references as noted on this waiver of license fee agreement and will comply with the copyright specification outlined above regarding the use of the Morisky Medication Adherence Scale, 8-Items, MMAS-8 and will abide with its requirements. Please scan and email to*: Donald E. Morisky, ScD, ScM, MSPH, Professor, Department of Community Health Sciences, UCLA Fielding School of Public Health, 650 Charles E. Young Drive South, Los Angeles, CA 90095-1772; email to dmorisky@ucla.edu.*

Please sign and return this contractual agreement in a Word.doc format, Pages 1 and 2 to Professor Morisky and he will provide you with the scale and coding criteria and signature authorizing use of this copyrighted scale. I agree to use only the English version of the MMAS-8 unless I purchase a validated translation of the MMAS-8 through Professor Morisky. I understand that it is a violation of international copyright laws to either use your own translation and call it the "MMAS-8" or use an existing MMAS-8 scale that has been translated and used for another study. The validated translation is non-transferrable and is linked to a specific license agreement and cannot be reproduced, copied, distributed, placed on the internet, published, or used by another individual.

Name and contact information of Licensee:

I'm Zahra Alsairafi, a PhD student from UCL, School of Pharmacy. I'm doing a research about the use of medicines by adults with type 2 diabetes in Kuwait, and aims to measure their adherence levels.

Title of Study: use of anti-diabetic medicines and devices by adults in the management of type 2 diabetes in Kuwait

Number of Anticipated Administrations of the MMAS-8:

Signature of Licensee: Zahra

Date: 02 /12 / 14

Signature of Developer/Owner: *Donald E. Morisky*

Date: December 15, 2014

1 **Participant No.: 40**

2 **Date: 12/06/2014**

3 **Place: Coffe Shop**

4 **Time: 11:10 a.m**

5 <u>General views and experiences</u>

6 **Interviewer: What do you know about the possible long-term effects of diabetes?**

7 **Interviewee:** What are the possible effects of diabetes? I am living all of these effects, I'll tell you now: Diabetes is the slow/silent death, it affects on my eyes, kidneys, and I'm always tired and feel that I don't have energy at all. I'm either hypo- or hyperglycaemic, this causes me to be nervous all the time, even because of hot weather I feel angry and tired.

Beliefs about seriousness

8 **Interviewer: Diabetes is increasing nowadays in our country, why do you think this is the case?**

9 • *Some people think that God is important in determining who gets diabetes; others believe it is more to do with heredity/themselves, what do you think*

10 **Interviewee:** To talk about myself, fast/junk food is the reason of my diabetes, people now eat a lot, breakfast, lunch and dinner and are all from restaurants, which we don't know what type of oil they are using. I don't think that heredity may cause diabetes, I didn't have diabetes since I born.

Internal locus of control

11 • *Some patients try to forget that they have diabetes, because they think it 'll get worse if they worried about it, what do you think*

12 **Interviewee:** Look, my grandmother was thinking like that, she was saying I'd forget diabetes because if I put it in my mind, I'll get it. She refused to take any medicine until her health deteriorated and needed to take insulin injections and not tablets.

13 • *How do you think we should address the problem in Kuwait*

14 **Interviewee:** People need to know more about healthy eating.

15 <u>Day-to-day life</u>

16 **Interviewer: What effect has having diabetes had on your life?**

17 • *Tell me about any changes you have made in your diet (e.g., the way you buy, cook and eat your food)*

18 **Interviewee:** Before I know that I have diabetes, I was eating white bread/rice all the time, putting sugar in the tea and eating lots of chocolate everyday. After diabetes, I switched to brown bread, drink tea without sugar and eat only one chocolate per day.

Nutritional awareness

19 • *Can you describe changes you have made in your physical activity, if any*

20 **Interviewee:** I tried to practise sport but I failed.

21 • *If you are a smoker, do you still smoke, have you attempted to stop, if you have quit, why*

22 **Interviewee:** I don't smoke.

23 • *Have you made any other changes*

24 **Interviewee:** No.

25 • *How does these changes fit within your daily routine*

26 **Interviewee:** At the beginning, I felt that I was forced to apply diet and to change my habits but then I get used to it.

27 • *For all the changes that you have attempted, what has helped you to make them*

Perceived benefits

28 **Interviewee:** The disease and its effects forced me to apply such changes.

29 • *For all the changes that you have attempted, what has been the easiest/most difficult thing to apply*

30 • *In what ways it was easy/difficult*

31 **Interviewee:** The most difficult thing to me is the sport; I always feel tired and become hypoglycaemic easily.

Perceived barriers

32 • *For the changes that you couldn't apply, what are the barriers to making these changes (e.g., barriers to: following healthy diet, practising exercise or stop smoking)*

33 **Interviewee:** Tiredness and Hypoglycaemia.

34 • *To what extent do you think that your lifestyle modifications will help you managing your diabetes*

35 **Interviewee:** Yes off course, diet and sport are very important to patients with diabetes.

36 <u>Therapeutic regimen</u>

37 **Intrerviewer: For your diabetes, what medicines/device are you using currently?**

38 • *How do you use them*

39 • *How long have you been using this device*

40 **Interviewee:** I'm using the pump since last year.

41 • *Before using this device, how were you managing your diabetes*

42 **Interviewee:** I was using insulin pens.

43 • *Tell me in what ways have you found your medicines helpful*

Glycaemic control
Beliefs about efficacy

Satisfaction with pump use

44 **Interviewee:** Look, the most beautiful thing in this world that controls diabetes is the pump. I tried to remove it for one day, I tried to live without any device in my live and use injections instead. You can't imagine, my health deteriorated and my blood glucose level became high and low, and it was only one day. Then, I returned to the pump and said *"live with the pump or not",* it becomes like the oxygen to me.

45 • *Are there any problems with taking your medicines, what are these*

46 **Interviewee:** No.

47 • *How do you feel about taking your medicines for a long period*

Beliefs in need
Beliefs about efficacy

48 **Interviewee:** I feel really bad especially when I remember that my body is completely depends on the pump. I always worry if I want to go somewhere/travel, I don't know what will happen if the pump suddenly stop, I'll be tired and lost.

49 • *Have you had a time when you get a different brand of your medicines? How did you feel about it?*

Beliefs about brands

50 **Interviewee:** I haven't tried but I feel that if the medicine gives me the same action and have no bad reactions on my body, it's ok.

51 • *Have you experienced any problem while using your device (e.g., pain, skin infection, irritation, bruising, mechanical problems, others)*

Problems of pump

52 **Interviewee:** Any one who looks at the injection sites in my body thinks that I'm burned, my skin becomes dark and black. Also, I have another problem is that when I want to take a shower or go to swimming for a long time (1-2 hours), I removed the pump but when I re-put it, I feel that it's not working properly. I knew that when I had my lunch/dinner and then measured my blood glucose level, I found it high.
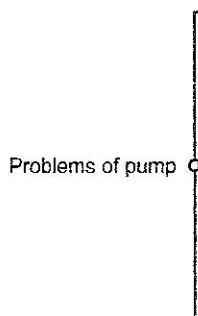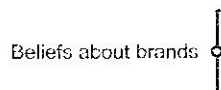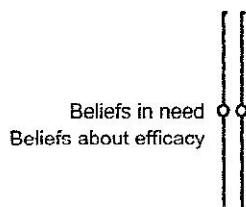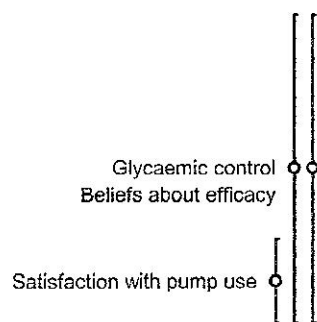
Managing problems

53 • *What did you do to solve these problems*

54 **Interviewee:** For the skin colours, I keep changing the site of needle all the time. For the other problem, I tried to remove the pump and re-put it again.

55 **Interviewer: How easy or difficult do you find using your device?**

56 • *Was it easy/difficult to learn how to use it*

Operating of the pump

57 **Interviewee:** Yes, it was easy to learn, although I still don't know how to count the calories.

58 • *Any difficulty in measuring insulin dose correctly/other difficulties*

Operating of the pump

59 **Interviewee:** You only put your calories and leave everything for the pump; it measures and gives you the dose precisely.

60 • *Are there things you find easier/harder to do now, compared to your previous therapy*

61 • *What are these and how are they easier/harder*

Comparison with previous

62 **Interviewee:** Insulin pens were small, easy to carry (I put them in my bag) and could take them anytime at any meal (breakfast/ lunch) and anywhere. On the other hand, they don't measure the dose for you and you couldn't administer the correct dose all the time. My blood glucose level was uncontrolled. The pump measures the correct dose for you according to your calories and delivers the dose for you, but it looks unacceptable, it's something attached to your body. Also, nowadays in the summer, when I go to swimming, I need to stop and remove it and then re-put it, which is annoying.

63 **Interviewer: How can you describe your life while using this device?**

64 • *Is it easy/normal life, you can do what you want*

65 • *Do you feel stressed and overwhelmed because of using this device*

Self-efficacy

Beliefs about disease

66 **Interviewee:** All what I can say is thanks God; you have to accept what is in your life and body whether it's good or bad. Diabetes is in my body and will not go by any injection/device, so I have to accept it. Whenever you accept everything in your life and feel satisfied, you'll get what you want. I know many patients who tried to transplant pancreas but all failed. I accept the disease and so the pump in my life.

67 **Interviewer: Does your device interfere with your normal life activities?**

Wearing clothes ⊙

Eating ⊙

Glycaemic control ⊙

Sleeping ⊙

Comparison with previous ⊙

Practicability and flexibility of ⊙

68 • *Wear the clothes*

69 **Interviewee:** When I want to go to usual places (work, family's homes), it's ok, as I wear my *"abaya; women gulf dress"*, it covers the pump very well. But I feel upset if I want to wear a nightdress or jeans and t-shirt, it looks unacceptable, you can see it even from a far distance. I feel that people say something about me; you can feel that I carry something in my body.

70 • *Eating*

71 **Interviewee:** I feel that with pump, I am eating more.

72 • *Exercise*

73 • *Practising hobbies*

74 **Interviewee:** With the pump, I feel more fresh, especially if I set it for a double-dose, it's like the oxygen to me.

75 • *Sleep*

76 **Interviewee:** You hurt me, yes; sleeping with the pump is bad. At the beginning, I was pregnant and move a lot during sleeping and the wire gets around my body, which annoyed me. Now, I used to move the pump with me either to the right/left even when I am sleeping, it becomes something that I used to.

77 • *How does this compared to your previous therapy*

78 **Interviewee:** With insulin pens, I have no problems with wearing clothes or sleeping but as I said I was eating less but tired and sick all the time.

79 **Interviewer: How do you fit taking your medicines into your daily routine?**

80 • *Tell me how did you use your medicines yesterday*

81 **Interviewee:** Yes, the pump doesn't bother me.

82 **Interviewer: In order to make life easier, patients sometimes use their medicines in their own ways. Do you remember a time when you have not used your medicines as prescribed, please tell me why did this happen?**

83 • *Do you change the way you take your medicines when you travel/at weekends*

84 **Interviewee:** The doctor set the pump for me, and I don't change anything.

Only if I want to have some sweet or eat a lot, I put an extra dose. I tried the pump several times during travelling and it was ok, thanks God. Even when I've been to an island, and swam a lot, I just remove it and then re-put it.

Practising sport with pump

85 **Interviewer: Tell me about changes you make in taking your medicines during the holy month of Ramadan.**

86 *• Why are you making these changes*

87 **Interviewee:** I haven't experienced Ramadan with the pump, last Ramadan I was using pens but I didn't fast.

88 **Interviewer: What do you think about the role of herbal medicines in the treatment of diabetes?**

89 *• Have you ever used them, what do you use*

90 *• When did you start using it*

91 *• How often do you use it, instead of/with your regular medicines*

92 **Interviewee:** I've heard about a mix of herbs from a dietician (green beans to be soaked in water), I used it during my pregnancy when I firstly diagnosed with diabetes but only for 2-3 times, because I was always worry from its effects. I used along with insulin pens.

Use of herbals

93 *• How helpful do you think they are*

94 **Interviewee:** It was good with me as I used it each time I got high blood glucose level and it reduced it, but I dot' think about the efficacy of herbals, some of them have no effect.

Beliefs in the efficacy of

95 Blood glucose monitoring & glycaemic control

96 **Interviewer: Tell me about monitoring your blood glucose level.**

97 *• How often do you monitor your blood glucose level and when*

98 **Interviewee:** Everyday, every time, before meal, after meal until my fingers become stiff.

Regular SMBG

99 *• What result are you aiming for, and what you consider bad result*

100 *• How often do you achieve your target, and what helps you achieving it*

101 **Interviewee:** I think if I get 8-9 mmol/l, it's good and above 26-27 mmol/l is high. I wish to see number 5 mmol/l, but I never get it. I often get 6-6.5 mmol/l, and this is even if I tried my best in eating healthy and staying away

Awareness about good

from sweet and fat, even if I didn't eat for a long period, I don't get below 6-6.5 mmol/l. When I got high blood glucose level, I don't know why this happened. I am not aware about the things that leaded to this.

102 • *What do you do if you have not achieved your target*

103 **Interviewee:** Nothing.

104 • *What hinders you from regularly monitoring your blood glucose level (e.g., lack of time, forgetfulness, impaired manual/visual dexterities, too complicated, too painful, stress, lack of awareness)*

Barriers

105 **Interviewee:** None.

106 • *Do you feel that your device requires you to monitor your blood glucose level more often than you would like*

SBGM

107 **Interviewee:** Yes, with the pump I am monitoring my blood glucose level more than before. This is because that I feel the pump is connected to the measurement that you get. So, if I don't know my measurement, I feel that I'll be lost.

108 • *How does this compared to your previous therapy*

Comparison with previous

109 **Interviewee:** With insulin pens, I only monitored my blood glucose level when I was feeling tired. If I felt fine, I didn't monitor it.

110 **Interviewer: Describe how does your device help you in controlling your diabetes?**

111 • *Achieving good blood glucose control*

Glycaemic control

112 **Interviewee:** Yes, I feel with the pump I am more controlled and fresh.

113 • *Having hyper/hypoglycaemia*

Hypoglycaemia

114 **Interviewee:** With insulin pens, I got more hypoglycaemia (it goes down to 1 or no number). With the pump it's fine, and goes up.

115 • *Improving awareness of hypoglycaemia*

Awareness about hypo-

116 **Interviewee:** Sometimes I got hypoglycaemia but I don't know until I monitor my blood glucose level.

117 • *Avoiding weight gain*

weight gain

118 **Interviewee:** I feel that I put extra kilograms since I used the pump, and I eat more than before.

119 • *Having hospital admissions due to poor control*

Hospital admissions

120 **Interviewee:** Before the pump, you couldn't count how many times I

Hospital admissions

entered the hospital but now *"thanks God"* I don't need that.

121 <u>Social support</u>

122 **Interviewer: Can you tell me how do your family and friends support you in managing your diabetes?**

123 • *Calculating doses*

124 • *Administering doses*

125 • *Checking site of injection*

126 • *Monitoring blood glucose level*

127 • *Eating special food*

128 • *Exercising*

Independency

129 **Interviewee:** No one is helping me with any of these activities. For the pump, I'm doing everything from A-Z, my husband doesn't know how to use it, I haven't learned him about its use. But he is helping me in detecting hypoglycaemia when I am sleeping, he looks if I am sweating or when I remove the throw from my body, he wakes me up and gives me a juice or something.

130 • *How does this compared to your previous therapy*

Comparison with previous

131 **Interviewee:** Even when I was using insulin pens, no one was helping.

132 **Interviewer: How do you feel about talking with others regarding your disease or administering your medicines/using your device in front of others?**

133 • *Embarrassed*

134 • *Different from others*

135 • *Diabetes interfere with your social life (e.g., social gatherings)*

Embarrassment
Confidnce

136 **Interviewee:** At the beginning, it was affecting me very much and I was feeling embarrassed to say that I am a patient with diabetes. But now it's ok, diabetes becomes my friend, and I talk about it very comfortably, it doesn't interfere with my social life.

137 **Interviewer: Does using your device have an effect on other family members?**

138 • *How much they help*

139 • *How much they are worrying about you*

140 • *How does this compared to your previous therapy*

141 **Interviewee:** Using the pump didn't affect on my family members, they only ask me between time and another *"how is the pump with you? Do you feel comfortable?"*. When I was using insulin pens, they were worrying more than now because tiredness and fatigue were very obvious on my face and body.

Initial worries
Comparison with previous

142 Healthcare providers

143 **Interviewer: Describe your experience with healthcare providers (e.g., physicians, pharmacists, nurses, dieticians).**

144 • *Who have you spoken with, and how regularly you see them*

145 • *What information have you been given (e.g., education about diabetes, complications, medicines use, carbohydrate counting, lifestyle modifications and check-ups)*

Good HCP

146 **Interviwee:** The physician is the most helpful person in the world, without him, I won't be alive. He is responsible for providing adequate information about the disease, prescribes correct medicines with accurate doses and he knows what I am complaining from exactly, and tells me what I need to do. I see my doctor every 3-4 months.

Defect in HCS

147 I haven't seen the dietician, *"who could see the dietician in this hospital?"*. I tried to put an appointment but the staff were not cooperative and appointments are inflexible.

148 • *Have you received sufficient training for the use of device*

Good service

149 **Interviewee:** Yes, I received the sufficient education from the *Medtronic* Company (for two days).

150 • *Do you think that healthcare providers are helpful, in what ways*

151 **Interviewee:** My doctor is the most important part in my life that I don't want to lose, without him; my blood glucose level wouldn't be controlled.

152 • *Does your physician discuss with you your treatment plan, how do you feel about it*

Good HCP

153 **Interviewee:** Yes, I trust my doctor's recommendations and I go with him.

154 • *Have you experienced a time when HCPs were unhelpful, in what ways*

155 **Interviewee:** Nurses are silly persons; they don't have any role in my life.

Defects in HCS

156 Pharmacists are like *"parrots"*; they only repeat the same sentences all the

Defects in HCS

time for every patient. Only dispense the medicines and say *"Umm, umm, ..."*

157 Also, I faced all the problems in the life when I was visiting the primary care unit. Physicians and nurses there are all losers, they have no information. They don't tell you what you need to do exactly and makes my diabetes a nightmare.

158 <u>Healthcare system</u>

159 **Interviewer: Tell me about healthcare services that you have receieved**

160 • *Are there any services that you would like to get all the time*

161 • *What other services you would like to have (e.g., receiving reminder phone calls for your appointment)*

Required service

162 **Interviewee:** Yes, I need someone to remind me about my appointments, also all what we need from medical and non-medical staff, as patients with diabetes is to take care of us. Patients with diabetes can't control their moods (whether they are old or young), and they are not crazy people.

Required service

163 Also, I suggest that they provide us with a special ID, so that any person can recognise us as diabetics, because we may suddenly lose our consciousness or get hyperglycaemia.

defects in HCS

164 Also, we miss the connections between different healthcare professionals at the same hospital. Patients with diabetes need care for their eyes, feet, kidneys, and all these professionals must deal with us as patients with diabetes and not like any other patient who hasn't got diabetes.

165 • *Have you experienced any problems, what are these (e.g. unavailability of medicines, inflexibility of appointments, discontinuity of care)*

defects in HCS

166 **Interviewee:** Please help patients using pumps, and put two lines under this: in dispensing extra items. For example, they always dispense to me for two months but why not they dispense for two months and a half. As I've told you, when I go to swimming, I need to remove the pump and to put something rounded like *"a plaster"* to cover the site of the needle, I need more from this item, sometimes it doesn't stick very well or I lose it in the swimming pool.

167 <u>Final questions</u>

168 **Interviewer: In general, are you happy with your current device?**

169   • *Do you think that you may change it at any time*

170   • *Would you recommend your current device to other patients*

171   As in question 4.

172   **Interviewer: Finally, would you like to add anything about your disease, medicines/device, healthcare providers or system that we have not discussed?**

173   • *Any other good things*

174   • *Any other concerns/problems*

175   **Interviewee:** None.

سؤال 1:

ما هي الأضرار التي يسببها مرض السكر على الجسم أنا أقولج أن عاشيتها الأضرار ، السكر هو الموت البطيء / الموت الصامت .

السكر أثر على عيوني / كلاي / دايماً تعبانه وما في طاقة / دائماً إجهاد . الوعي بخطرة المرض

هبوط وارتفاع دائم ، وسبب اختلال في جهازي العصبي ، صرت لا أتحكم بأعصابي ، حتى الجو الحار يؤثر على – بسرعة أطيح .

سؤال 2:

• أنا عن نفسي أرى بأن السكر يأتي بسبب الأكل / الوجبات السريعة ، أصبح الناس يأكلون ريوق / غذا / عشا كله من المطاعم اللي ما تدرين شنو تستخدم من زيوت . الإيمان بالقدرة الذاتيه
لا أعتقد للوراثة دور حيث أني لم أصب بالسكر منذ الولادة .

• جدتي كانت تقول ما بي أذكر المرض وكانت لا تأخذ لا حبوب ولا إبر الى ان أحتاجت ان تأخذ الإبر على طول . نسته لمدة 10 سنين كانت تقول إن ذكرته جاني .

• توعية الناس على الأكل الصحي . مقترح

سؤال 3 :

• قبل كنت 24 ساعة خبز أبيض حولته الى اسمر ، قبل على طول سكر بالشاي الحين ما أحط . أنا أحب الكاكاو وأريد الآن قللت فيه يعني كاكاو مرة باليوم . تغيير الأكل..

• حاولت أن أمارس الرياضة لكن لم أنجح .

• لا أدخن .

• أنفرض على هذا الرجيم وهو إذا تعودتي عليه صار عادة .

• أصعب شيء عندي هو ممارسة الرياضة أكبر عائق هو التعب الشديد / الهبوط يمنعني من مزاولة أي رياضة . صعوبات في التغيير..

• نعم الرياضة والرجيم يساعدان مريض السكر . الوعي بأهمية التغيير..

سؤال 4:

323

- صار لي سنة أستخدم المضخة . 18

- قبل كنت أستخدم أقلام الانسولين . 19

- نعم الأدوية تساعدني في تنظيم السكر ، أحلى شيء بها الكون هو المضخمة فيه 20
الشفا .جربت أتخلى عنها يوم واحد بالأسبوع ، قلت أبي أريح جسمي من الجهاز
وأرجع للإبر ، هو يوم واحد لكن أعتس يومي فوق / تحت ورجعت مجرة التعب لي
مرة ثانية صار السكر يرتفع فجأة وينزل – تخريطت فوق / تحت وهو مجرد يوم ،
رحت على طول ركبتها ما قدرت – صارت مثل الاكسجين بالنسبة لي – يا مضخة
يالا.

- إذا كان جسمج يعتمد على شيء فهذا متعب خصوصاً إذا أردت الخروج الى مكان / 21
أو عند السفر – أحاتي أن تتعطل المضخة بالطيارة أو أي مكان فأحس بأني راح
أضيع / أتعب .

- إذا كان الدواء متماشي مع جسمي فأتقبله عادي لو من أي شركة . 22

- اللي يشوف جسمي الحين يتوقع أني محروقة يصير مكان الإبر أسود – أغير مكان 23
الإبرة . لم تتعطل معي ، الله لا يقولها .

- ،المشاكل الثانية إني لما أوقف الجهاز عشان أسبح وأطول شوي (ساعة–ساعتين) 24
وأرجع أركبها، أحس إن الدوا ما يضخ عدل. أقول يمكن صار داخله ماي أو تكون
الإبرة متحركة داخل جسمي أو شي فأضطر إني أشيلها (الإبرة والجهاز) وأركبها مرة
ثانية عشان الدوا يسري مفعوله.

- ،أعرف إنها مو مضبوطة لأني لما أتغدا أو أتعشى وأحلل ألقى السكر مرتفع وهذا 25
دليل إن المضخة ما ضخت.

سؤال 5 : 26

- نعم كان التعلم على استخدام المضخة سهل مع أني الى الآن لا أحسب الكالوري 27
صح .

- نعم تقيس الجرعة مضبوط . 28

- الأقلام سهلة من ناحية أنها صغيرة – تنحط بالجنطه وتقديرن تقزين الإبرة بأي وقت 29
(ريوق / غدا) .

الإعتقاد بأهمية العلاج

الإعتقاد بفعالية الدواء

مشاكل المضخة

سهولة التعلم على استخدامه..

ضبط قياس الجرعة..

30	سلبياتها : ما تحسب الجرعات عدل ، ما كان سكري مضبوط معاها .
31 مقارنة بالعلاج السابق	المضخة : تحسب الكالوري والجرعة وتقزز وترتحين ويا سلام سلم عليها وأعطيها تحية .
32 عيوب المضخة	سلبياتها : موجودة بجسمج – شكلها مو مقبول . مثلاً أحنا الحين بالصيف لما أروح المسبح – لازم تشيلينهاوتسوين ايقاف وعباله .

سؤال 6:

33

34

القناعه والثقة على التحكم

• الحمدلله متى ما أقتنعتي داخليا أن هذا المرض موجود فيج وشرا أو خيرا بد منه – تتقبلينه بحلوه وشينه ، القناعة ما هو كلام يكتب / ينقال إذا كانت موجودة بالقلب راح تحصلين الي تبينه وتحسين برضا بغض النظر عن المرض فهو موجود موجود فيني يعني ما راح يشيلة مني لإجهاز ولا ابر إلا إذا الله أراد . حتى المرضى اللي قبلي حاولوا يزرعون بنكرياس وماتوا ومادري شنو هذي كلها أجتهادات بس هو المرض موجود لكن متى ما حسيتي بقناعه ورضا إن هذا امرض موجود معاج ترضين بالمضخة والحمد لله.

35

سؤال 7 :

36

تعارض المضخة مع اللبس

• نعم المضخة تتعارض مع لبس الملابس – تحتاج الى لبس خاص مثلاً إذا بلبس فستان كامل فشكلي مو حلو / تعيس تقولين بأن هذه الإنسانة فيها شيء غلط / جهاز / شيء حتى من بعيد . فمثلاً أن انحرج بالسهرات أما بالزيارات العادية لما ألبس العباءة عادي ما تبين .أما بلبس السهرات والجنزات فشكلها مو حلو .

37

تحكم أكثر مع المضخة

• مع المضخة ولما أضبطها أحس بانتعاش أكثر مثل جهاز الاوكسجين بالذات إذا حطيت جرعة مزدوجة .

38

تعارض المضخة مع النوم

• جيتي عالجرج فعلاً انا وايد أتقلب بنومي والواير يلف معاي يمين / يسار هذا أول أيامي كنت حيل مضايقة / حامل / يتعبني. الحين صرت دايركت من العقل الباطن صرت وأن نايمة الفها يمين / يسار معاي وأشيل الواير – صار شيء تلقائي.

39

سؤال 8 :

40

• نعم ، المضخة متماشية مع روتيني اليومي .

41

سؤال 9 :

42

- المضخة يضبطها الطبيب – إذا بأكل زيادة ، أزيد فوق جرعة الطبيب على حسب الكالوري اللي ماكلته .

43

- مع السفر جريتها كذا سفرة ، الحمد لله ماشية معاي حتى كنت رايحه جزيرة كله ماي، والحمد لله تأقلمت معاها – إذا بسبح أشيل الجهاز بعدين أحطه مرة ثانية .

44

سؤال 10 :

45

- لم يمر علي رمضان مع المضخة ولقد تناقشت مع الدكتور على كيفية استخدامها. السنة الفائتة كنت على الأقلام وما صمت.

46

سؤال 11:

47

- لقد أستخدمت خلطة من الأعشاب مرتين أو ثلاثة ، وكانت فترة حملي الأول . هذي الخلطة قالت لي عليها دكتورة تغذية ، عبارة عن بزاليا الخضراء الطويلة – أحطها بقرشة ماي وأشرب ومشت معاي بحملي ، متى ما أرتفع شربت وكانت فعلاً تنزل السكر لأنها مرة وكنت أستخدم الإبر وقتها. ما كثرت منها لأني خوافة كنت أخاف منها.

48

- لا أعتقد بالأعشاب ، فبعضها لا ينفع كلش.

49

سؤال 12 :

50

- كل شوي أقيس السكر قبل الأكل / بعد الأكل – قبل / بعد ، أحاتي لما أيدي راحت.

51

- يعني إذا صار القياس 8 – 9 مل مول / لتر يكون زين بالنسبة الى 26– 27 فهذا مرتفع .

52

- ودي يطلعلي رقم 5 بس عمره ما طلعلي 5 . غالباً يطلعلي 6 – 6.5 إذا كلش مجتهدة وسنعة وما كليت شيء ، أنا لو أصوم هم يرتفع معاي.

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- لا أدري لماذا يرتفع عندي السكر أو لا يطلع طبيعي يختلط الحابل بالنابل .

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- قياس السكر تعب أصابعي .

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- نعم أحس بأن مع المضخة فعلاً زاد احتياجي لقياس السكر أصلاً المضخة مرتبطة بجهاز القياس إذا ما حللت ما أعرف قراءتي وراح أضيع بدون القياس .

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- مع الإبر مو دايماً كنت أحلل متى ما حسيت إني زينة ما أحلل وإذا حسيت موزيه

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حللت .

سؤال 13 :

- نعم أحس مع المضخة ، السكر انتظم .

- مع الإبر كان السكري يهبط كثيراً يوصل لي 1 أو بدون رقم ، مع المضخة ، الحمد لله لا يوجد هبوط إنما كله أرتفاع .

- لا بعض المرات لا أعي بنوبات الهبوط .

- نعم مع المضخة زاد وزني ، صرت آكل كثيراً .

- هالفترة لم أدخل المستشفى لكن قبل دخلت وايد عدي وأغلطي .

سؤال 14 :

- المضخة لا أحد يساعدني فيها ، زوجي مو عارفها ما علمته عليها عدل ، أمور المضخة كله انا من الآلف الى الياء .

- لكن يساعدني في حالات الهبوط – يهتم إذا كنت نائمة يحس بجسمي إذا يعرق أو لما أقط البطانية فعلى طول ينتبه يكون يمي ويعطيني عصير أو شيء .

سؤال 15 :

السكر صار صديقي ، أسولف عنه بارتياح الحين ، لا يعرقل حياتي. أول صراحة كنت أنحرج أقول إني مريضة سكر ما كنت أحب أني أتكلم نهائياً كان يؤثر على بشكل مو طبيعي ، الحين خلاص .

سؤال 16 :

عادي لم يؤثر استخدام المضخة على أهلي، مرات يسألوني ها مرتاحه مع الجهاز – شلونه معاج ، شلونه معاج ، فكنت أسولفلهم . الحين أشوة أول الوضع مع الإبر أكثر يحاتون لأن كان التعب الجسماني واضح علي .

سؤال 17 :

- طبيب السكر هو الإنسان المساعد لولاه لكنت في تعب له دور كبير في حياتي – يعطيني المعلومات الكافية عن المرض / يعطي الأدوية الصحية / الجرعات

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زاد الحاجة للقياس..

ساعد في تنظيمه..

قلل من الهبوط/الإرتفاع..

زاد الوزن..

مساعدات أخرى..

تأثير المضخة عالحياة

مساعد..

سؤال 19 :

أحلى شيء بها الكون هو المضخة فيه الشفا. جربت أتخلى عنها يوم واحد بالأسبوع ، قلت أبي أريح جسمي من الجهاز وأرجع للإبر، هو يوم واحد لكن أعتقس يومي فوق / تحت ورجعت مجرة التعب لي مرة ثانية صار السكر يرتفع فجأة وينزل – تخربطت فوق / تحت وهو مجرد يوم ، رحت على طول ركبتها ما قدرت – صارت مثل الاكسجين بالنسبة لي – يا مضخة يالا.

الإرتياح من استخدام الجهاز..

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Appendix 17: The patients' responses to individual items of MMAS-8

Responses to items 1 to 7
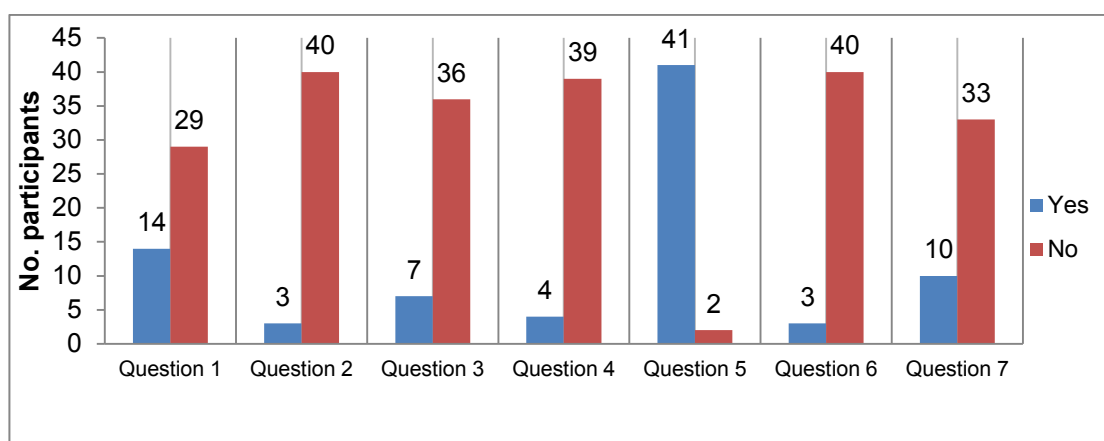
1. Do you sometimes forget to take your diabetes medicines?
2. People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your diabetes medicines?
3. Have you ever cut back or stopped taking you diabetes medicines without telling your doctor, because you felt worse when you took it?
4. When you travel or leave home, do you sometimes forget to bring along your diabetes medicines?
5. Did you take your diabetes medicines yesterday?
6. When you feel like your diabetes is under control, do you sometimes stop taking your medicines?
7. Taking medicines everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your diabetes treatment plan?

Responses to item 8
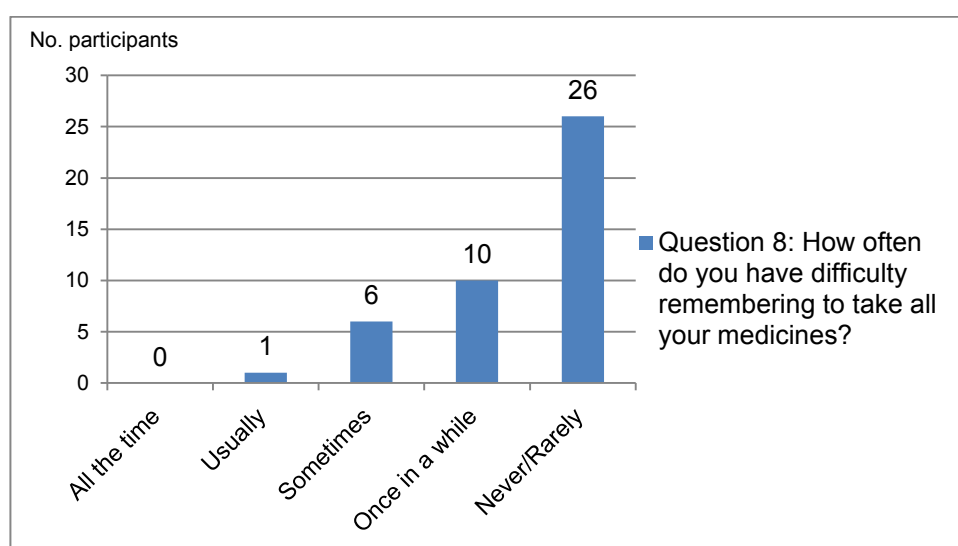
Appendix 18: The patients' total MMAS scores and adherence level

Participant	Total MMAS score	Adherence level*
1	4.5	Low
2	7	Medium
3	8	High
4	8	High
5	8	High
6	8	High
7	7	Medium
8	5.5	Low
9	8	High
10	4.5	Low
11	8	High
12	7	Medium
13	6	Medium
14	8	High
15	7.75	Medium
16	5	Low
17	5.5	Low
18	8	High
19	8	High
20	6.75	Medium
21	8	High
22	7	Medium
23	6.75	Medium
24	8	High
25	8	High
26	5.75	Low
27	7	Medium
28	5.5	Low
29	6.75	Medium
30	8	High
31	3.5	Low
32	8	High
33	6.75	Medium
34	8	High
35	4.25	Low
36	8	High
37	6.75	Medium
38	6.75	Medium
39	5.75	Low
40	7	Medium
41	7	Medium
42	8	High
43	5.75	Low

*MMAS=8, 6 to <8, <6 indicates high, medium and low adherence level respectively

Appendix 19: The patients' responses to individual items of BMQ-subscales

BMQ-necessity	Strongly agree	Agree	Un-certain	Disagree	Strongly disagree
(1) My health at present depends on this medicine	31	9	2	0	1
(2) My medicine controls my diabetes	32	8	2	1	0
(3) Without this medicine I would be very ill	29	9	4	1	0
(4) My health in the future depends on this medicine	19	15	7	1	1
(5) My medicines prevent my blood sugar from becoming too high	22	17	3	0	1
BMQ-concern					
(1) Having to take these medicines worries me	5	6	2	9	21
(2) I sometimes worry about the long-term effects of these medicines	10	13	3	7	10
(3) Diabetes medicines are a mystery to me	5	6	6	9	17
(4) These medicines disrupt my life	2	5	0	12	24
(5) I sometimes worry about becoming too dependent on these medicines	11	6	2	7	17

Appendix 20: The patients' BMQ-S necessity, concern and differential necessity-concern scores

Participant	Total necessity (25)	Total concern (25)	Necessity-concern (-20-20)
1	24	19	5
2	25	15	10
3	23	21	2
4	24	8	16
5	13	5	8
6	20	9	11
7	25	11	14
8	20	18	2
9	20	8	12
10	23	20	3
11	25	5	20
12	21	12	9
13	24	11	13
14	25	5	20
15	21	14	7
16	22	23	-1
17	19	19	0
18	23	17	6
19	24	10	14
20	23	13	10
21	23	5	18
22	21	25	-4
23	22	8	14
24	19	14	5
25	25	5	20
26	23	14	9
27	20	14	6
28	24	7	17
29	24	16	8
30	24	9	15
31	20	18	2
32	21	6	15
33	19	12	7
34	25	11	14
35	25	14	11
36	24	14	10
37	25	13	12
38	25	11	14
39	22	13	9
40	23	6	17
41	24	6	18
42	19	7	12
43	23	15	8

Appendix 21: The perspectives of HCPs on the identified issues and their evaluation in terms of agreement and importance

Statement	Agreement				Importance of consideration			
	1= Agree	2= Agree to a certain extent	3= Dis-agree	4= Un-certain	1= Most import-ant	2= Very important	3= Important	4= Least important
1. Non-adherence to treatment and healthy lifestyle is due to specific beliefs about the normality of the disease and lack of awareness about its seriousness and complications.	7	2	1	-	8	1	1	-
2. Non-adherence to treatment and healthy lifestyle is due to cultural factors, e.g. fasting in Ramadan, use of herbals and social gatherings.	6	2	1	1	5	3	-	2
3. Non-adherence to treatment is due to personal factors, such as forgetfulness, laziness, fear of or perceived side effects.	6	4	-	-	5	5	-	-
4. Non-adherence to diet is due to lack of individualised diet plans, which conform to patient's social and educational requirements.	1	5	4	-	7	3	-	-
5. Delivery of healthcare services is delayed, especially when referrals are needed.	2	2	3	3	4	5	1	-
6. Pen devices are not prescribed/dispensed for all insulin-dependent patients with type 2 diabetes in hospitals.	3	1	5	1	7	2	1	-
7. Certain items, such as small-sized pen needles are mostly unavailable in the pharmacy.	2	3	3	2	6	2	2	-
8. Although it is available in Medical Stores, Victoza^R pen is not dispensed to patients treated in the MOH.	6	-	1	3	4	-	5	1
9. Patients using insulin pumps gain weight due to different reasons, e.g. non-adherence to diet and exercise due to belief in the control provided by the pump, lack of awareness about carbohydrate counting, and not using the pump properly.	1	2	4	3	7	3	-	-
10. Consultation time is not enough to discuss all pump-related issues with the doctor.	1	4	3	2	8	2	-	-

Appendix 22: The HCPs' responses to the provided recommendations, in terms of importance and feasibility

Recommendation	Importance				Feasibility			
	1= Most	2= More	3= Less	4= Least	1= Yes, now	2= Yes, within a year	3= Yes, within 5-10 years	4=No
1. Health awareness of patients, e.g. awareness about short and long-term diabetes-related complications needs to be improved continuously through campaigns, group sessions or lecture courses at hospital clinics, primary-care units, KDS, or via audio-visual aids, e.g., educational programmes in radio and television.	10	-	-	-	5	3	2	-
2. Social and cultural beliefs and lifestyle concerns should be addressed and included in patients' medical notes.	8	1	1	-	5	2	3	-
3. HCPs should undergo Pre-Ramadan training programme, and cooperate together, in order to optimise care provided to patients during this month.	6	4	-	-	4	4	2	-
4. Educational and motivational advices regarding adherence to treatments should be provided verbally and in writing (e.g. brochures/leaflets), and reinforced with each clinical visit/prescription of medicines.	7	3	-	-	4	3	3	-
5. Dieticians need to be educated about the educational and social differences when dealing with patients, and how those differences could impact self-management behaviour of patients. Also, they need to be aware about how to individualise care plans that conform to each patient's needs and life.	6	-	4	-	4	1	5	-
6. Family members should be involved when constructing care plans and lifestyle modifications.	5	4	1	-	3	2	4	1
7. The delivery of healthcare services should be further coordinated particularly, when patients needed referrals to different HCPs/department.	8	2	-	-	1	3	6	-
8. Patients initiated on insulin should be informed about the different methods that are available for insulin delivery, e.g. pens and pumps. Also, they should be involved in making decisions related to the selection of the device.	4	3	2	1	4	3	-	3
9. Services, such as pharmacist/nurse-led diabetes clinics, or psychological interventions that take care of this group of patients by incorporating different HCPs in the management process should be implemented.	7	3	-	-	4	1	5	-
10. A 24-hours help-line service managed by diabetes specialists for urgent and between appointments enquiries should be considered.	6	2	2	-	1	3	3	3

Appendix 23: The structure, process and outcomes of the recommended healthcare services

Behavioural intervention

Structure	Process	Outcome
-Interventionist -Questionnaire + phone calls	-Baseline assessments (Including Demographic/Profile Questionnaire, The Summary of Diabetes Self-Care Activities Questionnaire, The Kristal Food Habits Questionnaire, The Gormally Binge Eating Scale, The Physical Activity Scale for the Elderly Questionnaire, and Rosenberg Self-Esteem Scale). -Meeting with the interventionist (Patient participation in goal setting, and selecting personalised strategies to overcome barriers). -Ten minutes follow-up phone calls at 1, 3 and 7 weeks post assessment (Concentrating on the extent to which patients have achieved their goals since last contact, and reinforcing or helping patients in problem-solving strategies, if needed). -12, 24 and 52 week assessment visits (Reviewing what has worked, setting further goals, and receiving written materials concentrating on lapse and relapse, key targets for changing eating and physical activity habits, and the importance of these changes in the management of the disease).	-Patients were able to remember and achieve the specific goals (e.g. eating/physical activity) that they established at the beginning of the intervention.

Clark and Hampson, 2001

Nurse-led clinic

Structure	Process	Outcome
-Two nurses. -Nurse-led protocol and education system.	-18-months follow-up programme (Education, drug type/dosage change).	-Glycaemic control (HbA1c reduction 11.6% vs. 7.7%). -Self-reported hypoglycaemia did not increase.

Gill et al., 2008

Pharmaceutical care programme

Structure	Process	Outcome
-One clinical pharmacist. -Follow-up care programme (12-month period), on monthly basis.	-A 20 minutes face-to-face interview with patients (Obtaining demographic and clinical details, assessing medication knowledge and adherence, completing QoL questionnaire). -A discussion with patients' physicians (Recommending intensive management to hypertension, reviewing the latest diabetes guidelines, and recommending simplification of dosage regimen, where appropriate). -A structured patient education (Including diabetes complications, proper dosage, side effects, healthy lifestyle, management of symptoms, self-monitoring). -Supplementary leaflets (Containing information about hypertension and hyperlipidaemia). -Behavioural modifications (Regarding monitoring of glycaemic control and recording levels in a record book, initiation of an exercise plan, improving understanding of food choices, discussing barriers to medication adherence, advising on stopping smoking).	-HbA1c reduction (8.5% vs. 6.9%). -BP reduction (131.4/85.2 mmHg vs. 127.2/76.3 mmHg). -Framingham risk prediction score (10-year coronary heart disease risk score) reduction (10.56% vs. 7.7%).

Al Mazroui et al., 2009