NONADHERENCE AMONG KUWAITI NATIONALS WITH TYPE 2 DIABETES MELLITUS

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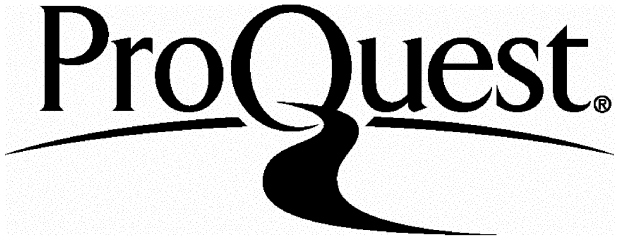

This thesis describes research conducted in the School of Pharmacy, University of London between October 2006 and June 2010 under the supervision of Prof. Nick Barber and Dr. Tina Brock. I certify that the research described is original and that any parts of the work that have been conducted by collaboration are clearly indicated. I also certify that I have written all the text herein and have clearly indicated by suitable citation any part of this dissertation that has already appeared in publication.

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ABSTRACT

Introduction: Nonadherence to medications and diabetes self-care behaviours among Kuwaitis with Type 2 Diabetes Mellitus (T2DM) is believed to be a major barrier to appropriate management of the disease. Published studies of nonadherence in T2DM suggest a Western bias which may not adequately describe the Kuwaiti experience.

Aims: (1) To explore barriers to adherence to medications and other diabetes self-care behaviours among Kuwaitis with T2DM. (2) To assess the prevalence of nonadherence to medications and other diabetes self-care behaviours, and identify predictors of medication nonadherence.

Methods: (1) A qualitative exploratory study, using in-depth interviews with 20 Kuwaiti T2DM patients. (2) A cross-sectional quantitative survey of 250 Kuwaiti T2DM patients, randomly selected from all the six districts of the country.

Results: Qualitative interviews revealed that many barriers to diabetes medications and other self-care behaviours among Kuwaitis appeared specific to the Kuwaiti culture, such as patients' beliefs about Western brands of medications, fatalism and submission to God's will in coping with illness, perceptions of social support, and difficulties related to access and organisation of the Kuwaiti healthcare system. However, some reported barriers were similar to the Western literature. The quantitative survey showed 43% of Kuwaiti T2DM patients were nonadherent to their diabetes medications, of which 45% had made a decision not to take their medications. Over half of nonadherers (52%) inadvertently did not take the medications as prescribed, mostly as a result of forgetting (42%). Nonadherence to medications was associated with poorer health outcomes. Beliefs about medicines and perceptions of healthcare provider support were issues of concern. Nonadherence to other diabetes self-care behaviours was high, 15%-68%, depending on the behaviour.

Conclusion: Diabetic nonadherence constitutes a significant proportion in Kuwait. Barriers to adherence were complex and often interlinked, suggesting that multiple, tailored interventions may be needed to improve diabetes adherence, care and outcomes.

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CHAPTER 1

INTRODUCTION

In Kuwait, type 2 diabetes mellitus (T2DM) is emerging as a major public health concern (Abdella et al., 1996). According to the last available estimate, the prevalence of the disease was about 14.8% among Kuwaitis above 20 years of age (Abdella et al., 1998), however this figure is likely to be an underestimate and the true prevalence may have increased over the past few years.

Apart from the fact that diabetes is a major public health concern in Kuwait, my interest in diabetes in particular started early during my childhood as both of my grandparents have passed away of diabetes-related complications. My grandfather suffered the loss of his sight several years before he was deceased, his kidney function deteriorated towards the final days of his life when he endured foot amputation as well. He later passed away due to a stroke secondary to his diabetes. A similar situation was repeated with my grandmother. Both my grandparents were on multiple medications, and it was very difficult for them to adhere to their medications given their lack of understanding of their disease process and the serious nature of its complications at the time. I believe that many of the complications they suffered could have been avoided and my grandparents could have enjoyed a life which is indeed longer and with better quality, that is, if they were appropriately managed and have taken their medications more effectively.

Factors influencing nonadherence to diabetes treatment has been the focus of many worldwide initiatives. A report by the World Health Organisations (WHO) highlighted that poor adherence to treatment of chronic disease is a worldwide problem of striking magnitude, averaging about 50% of patients in developed countries, and even lower proportion of patients in developing countries. The same report also highlighted the serious consequences of poor adherence, including poor health outcomes and increased healthcare costs (WHO, 2003).

In Kuwait, T2DM is becoming more prevalent and its complications are on the rise each year, suggesting that nonadherence to medications is a likely problem. The prevalence

of nonadherence to medications still unknown, obscuring the size of the problem. This problem is further complicated by a lack of studies investigating local and specific variations in believes and attitudes towards adherence to medication and other self-care behaviours in Kuwaiti T2DM patients, which is a major obstacle towards improving diabetes care in Kuwait. It is believed that Kuwaiti people may have specific cultural, religious and attitudinal variations that would influence their adherence to medications. If specific factors interfering with medication adherence are identified, then targeted interventions can be designed to improve adherence to medications, and thus improve the therapeutic outcomes for Kuwaiti patients with T2DM. This was the starting thought for this thesis.

In this chapter, I will introduce the extent of nonadherence, its consequences, definitions, types, measurements, determinants, and theories used to explain nonadherence to medications. This will be followed by a review of the current literature related to nonadherence to medications in T2DM, drawn from evidence from the Western and Middle Eastern literature to help understand the possible factors and barriers that would interfere with medication adherence in patients with T2DM, concluding with the specific aims of this thesis.

1.1 Extent of the problem of nonadherence

Nonadherence to health regimens is a common problem in all chronic diseases, with typical rates of about 50% and a range of 0-100% (Sackett, 1976b). As for medication adherence in particular, a report commissioned by the NHS National Coordinating Centre for Service Delivery and Organization (NCCSDO) highlighted that reviews from different countries and across different disease conditions have consistently estimated that 30-50% of prescribed medication is not taken as instructed (Horne et al., 2005). The same report emphasized that "There is no evidence that the problem of nonadherence has been solved by recent advances in the design and presentation of medicines or by the evolution of healthcare services that have tended to become more patient-centered".

1.2 Consequences of Nonadherence

Nonadherence to medication has been recognized as a major public health problem that imposes a considerable financial burden upon modern health care systems (Horne, 1997; WHO, 2003). In developed countries, most health care resources are directed at the

management of chronic diseases, and the prescription of medication is one of the most common medical interventions, and in many countries, one of the biggest sources of expenditures on health (Horne et al., 1999). Failure to take the medicines as intended is therefore likely to result in relative therapeutic failure, disease progression, and the need for more aggressive treatments, which might further increase the risk of drug-induced problems. Unnecessary suffering, loss in productivity, and even premature death can also result from nonadherence to medications (Grymonpre et al., 1998). Avoidable medical expenses may also follow, due to hospitalizations and the waste of expensive medicines that are misused or unused (Royal Pharmaceutical Society of Great Britain, 1997). A study conducted in the United States to evaluate the impact of medication adherence on healthcare utilization and costs for four chronic conditions (diabetes, hypertension, hypercholesterolemia and congestive heart failure) involving 137,277 patients, found that, a high level of medication adherence was associated with lower disease-related medical costs for patients with diabetes and hypercholesterolemia. Hospitalisation rates were significantly lower for patients with high medication adherence for all four conditions (Sokol et al., 2005).

Other consequences of nonadherence to treatment (and medications) include provider and patient frustration, anger and hopelessness (Bosworth et al., 2006) because of inability of healthcare providers to assess response to therapy. In the context of clinical trials, nonadherence to medications may lead to loss of time and resources and reaching false clinical conclusions whereby an effective medication may be disregarded.

In the report by the WHO (2003), it was highlighted that nonadherence is the single most important modifiable factor that compromises treatment outcome. In support, a large meta-analysis involving more than 19,000 patients in 63 studies found that, on average, 26% more patients experienced a good outcome by adhering to treatment than by not adhering (DiMatteo et al., 2002). However, it is worth noting that this percentage was calculated based on all studies included in the meta-analysis which involved adherence to different types of treatment (e.g., diet, exercise, medications, and weight loss) and not just medications.

Further, it is worth noting that the adherence-outcome relationship is not that straightforward and is not always positive. DiMatteo and others in 2002 highlighted that

factors such as treatment efficacy, genetic variations in response rates, and limitations in current understanding of disease can affect the relationship between adherence to treatment and outcomes. Further, although most studies highlight the negative consequences of nonadherence to medication, there are instances where adherence to medication can have negative consequences and nonadherence may be the rightful decision to make. Horne and others in 2005 gave examples where nonadherence may be rational, such as when the diagnosis or the prescription is inappropriate, or in case of adverse drug reactions. In support, a review of the literature highlighted that nonadherence to the medications can be rational in cases where patients don't adhere in an attempt to preserve their quality of life, achieve their personal goals and maintain their identities (DiMatteo, 2004b). Nevertheless, this only occurs in some situations, and with the current advances in the manufacturing and development of medications, together with the indisputable positive health outcomes consequent on the effective use of medications, it is established that adherence to medications would do more good than harm. Furthermore, it is argued that "increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments" (Haynes, 2001).

1.3 Definitions and operationalizations

There is great variation in the conceptual or operational definitions of treatment adherence. Closely related terms which have been used to refer to the concept are *compliance, concordance, cooperation, mutuality* and *therapeutic alliance.* These have often been used interchangeably which has resulted in some degree of confusion. Below is a differentiation of the three most commonly used definitions:

1.3.1 Compliance, concordance and adherence

The term "compliance" was defined by Sackett and Haynes to denote "the extent to which a person's behaviour (in terms of medication taking, following a diet, modifying habits, or attending clinics) coincides with medical or health advice" (Haynes et al., 1979; Sackett, 1976a). Compliance is probably the most useful term in searching the literature. However, it has received much criticism due its negative connotations, as some argue it implies a lack of patient involvement in the process (Becker, 1985; Vermeire et al., 2001). Compliance implies that patients have a passive role in their healthcare and that they should "submit" to their health care providers' orders in taking their medications or following other

treatment regimens (e.g., diet, exercise, weight loss, etc.). Failing to "comply" is usually associated with blame, whether this blame is placed on doctors or patients (WHO, 2003; Vermeire et al., 2001). Therefore, terms like "adherence" or "concordance" are now more preferred.

The term "concordance" is a UK-specific term which was introduced about a decade ago by the Royal Pharmaceutical Society of Great Britain. It focuses on the consultation process in which the doctor and patient agree on therapeutic decisions incorporating their respective views, and extends to involve supporting patients in medicine taking. It is argued the term "concordance" reflects the contemporary practice of medicine and healthcare provision, allowing greater responsibility for both doctors and patients to reach mutual agreement regarding therapeutic decisions (Royal Pharmaceutical Society of Great Britain, 1997). However, if agreement cannot be reached, the patients' view should prevail.

Although the term has gained much appeal because it respects patients' rights in deciding about taking their medications, it has been criticized for the moral and ethical issues it raise. Horne and others in 2005 highlighted some of these criticisms as follows:

- Concordance has a limited scope, dealing with prescribing-related consultations but not medication-taking behaviour.
- Concordance implies that achieving concordance will improve adherence. However, this is an assumption that requires empirical evidence.
- Concordance may raise ethical issues in circumstances where the patient, knowledgeably or unknowledgeably, refuses a life-saving treatment, or chooses a treatment which could result in self-harm or harm of others. This could occur when patients misinterpret likely risks or benefits of treatment, or when they have created false beliefs based on erroneous information.
- Concordance does not address the balance between individual rights and responsibilities.

The term "adherence" implies that the patient is free to decide whether to adhere to the doctor's recommendations and that there is no reason to blame patients should they wish not to follow the treatment (Horne et al., 2005). Unlike the term "compliance",

"adherence" is seen as more respectful of the role patients play in their own treatment plan. It is also the preferred term and therefore will be used throughout this thesis.

1.3.2 Operationalization of adherence/nonadherence definitions

One of the major problems in adherence research is probably the wide variation in operationalizations of adherence definitions across studies. Further, different researchers use different ways to define adherence in their studies (Becker, 1985), with each stressing what matters the most to them. Clinicians, for example tend to define nonadherence in terms of the point below in which the desired therapeutic result is unlikely to be achieved. However, behavioural scientists tend to define nonadherence as any deviation from the prescribed treatment, whether or not such deviation was associated with clinical effect. In contrast, some researchers paid little attention to both clinical and behavioural considerations and simply classified people as adherers and nonadherers based on statistical methods (e.g., people falling above or below the median or mean levels of adherence in the study group).

Yet, other researchers have used arbitrary cut-offs, either because this level of nonadherence seemed significant, or simply because that level was used in previous research (Becker, 1985). In medication adherence studies, researchers have commonly used 80% as a cut-off point below which a patient is considered to be nonadherent to medications (Shalansky et al., 2004). Even with the use of cut-offs, researchers varied in how to estimate patients' adherence level using these cut-offs, with some relying on patients' self-report of doses taken as prescribed during a specified period of time (Gao and Nau, 2000), while others relied on prescription refill records (Shalansky et al., 2004).

1.4 Types of nonadherence

When speaking of nonadherence to medications, many types have been described in the literature (Horne et al., 2005; Hilker, 2007). For example, nonadherence can be in not getting the prescription filled in the first place, filling the prescription irregularly, taking an incorrect dose of the medication (lower or higher), taking the medication at the wrong time, forgetting a dose, or discontinuing the treatment prematurely. The following offers a way of classifying these types of nonadherence:

1.4.1 Primary vs. secondary

Primary nonadherence is when patients do not fill the original prescription of the medication(s) for some reason (e.g., limited access to a pharmacy, high cost of medication(s), perceptions that the prescription is inappropriate or unnecessary, dissatisfaction with the diagnosis, etc.). Studies showed that the prevalence of primary nonadherence is between 2.4-20% (Rashid, 1982; Ekedahl and Mansson, 2004).

Secondary nonadherence occurs when the medicines are not taken as intended, such as taking an incorrect dose (which could be either taking less or more than the usual dose), taking the dose at the wrong time, forgetting the dose, or stopping the treatment prematurely, either due to an informed decision or due to failure in obtaining repeat prescriptions.

1.4.2 Intentional vs. unintentional

Intentional nonadherence is when patients deliberately alter or stop the use of the medicine due to rejection of the treatment or the diagnosis altogether. It arises from patients' beliefs, attitudes, and expectations which influence motivation to commence and persist with the treatment (Horne et al., 2005).

Unintentional nonadherence is when the patient fails to take the medicines as intended due to individual constraints (e.g., limitations in memory, manual dexterity problems) or other environmental barriers (limited access to healthcare, cost, competing demands) (Horne et al., 2005).

Studies have found that 9-46% of patients are intentionally nonadherent to their medications, whereas 31-55% of patients are unintentionally nonadherent (Lowry et al., 2005; Wroe and Thomas, 2003; Clifford, 2004). It is argued that considering intentional and unintentional nonadherence separately is essential when designing interventions to improve patients' adherence to medications (Wroe, 2002). For example, patients who fail to adhere to their medications due to memory impairment (i.e., unintentional nonadherence) may benefit from special reminder packaging systems, whereas those who do not adhere due to a cognitive decision (i.e., intentional nonadherence) may be less likely to benefit from such intervention and may require interventions aimed at increasing their motivation and awareness to adhere to their medications. However, it is important to note that this

classification is not exclusive, as there is an overlap between the different types of nonadherence. For example, secondary nonadherence (not taking the medication as intended) may be due to a limitation in memory which leads the patient to forget taking the medication (unintentional nonadherence).

1.5 Methods for assessment of adherence/nonadherence to medication

Adherence to medication has been estimated using various methods, which fall under two main categories; direct and indirect measures. Direct methods provide evidence that the medication has been taken by the patient, whereas indirect methods only imply that the medication has been taken by the patient, although this cannot be ascertained. In this way, they can act as proxy measures for adherence. Advantages and limitations of the various methods for assessing adherence are discussed below.

1.5.1 Direct Measures

As the name suggests, these methods can directly assess the extent of adherence:

1.5.1.1 Direct observation

This method involves direct observation of the patient taking the medication. However, there are some drawbacks which might limit the usefulness of this method. For example, it is intrusive, time consuming and labour intensive, which makes it far from ideal for daily practice. Furthermore, it is impractical for outpatient settings, and may encourage reactivity (i.e. patients improving their adherence to medications as a result of being observed). Despite its impracticality, it can be useful in certain situations (for example in direct observation therapy [DOT] for patients who are at high risk of being nonadherent to their tuberculosis medications to avoid the spread of the infection).

1.5.1.2 Physiologic measures (e.g., drug concentrations in body fluids)

In this method, direct assays of the drug or its metabolite in the blood, urine, or saliva are compared with what is expected from strict adherence to a given medication regimen. It may involve the use of drug markers with the target medication. This method has limitations, as individual differences in metabolism and volume of distribution may lead to variations in drug levels even if two patients had the same level of adherence (Farmer, 1999). Further, accuracy of the method is highly dependent on dose and timing, which can be misleading if patients take the medicine only just before clinic visits. In

addition, drug levels are not often routinely available for most medications (Haynes et al., 2002) which limits the usefulness of this method. The high cost and invasiveness of the method present further limitations for its use in everyday practice.

1.5.2 Indirect Measures

Indirect methods provide an estimation of nonadherence using proxy measures, for example:

1.5.2.1 Pill count

Adherence can be estimated by counting pills, and comparing the number of doses remaining in a pack with what is expected if the patient had fully adhered over a specified period of time. In this regard, some researchers have used the medication possession ratio (MPR) to assess patients' adherence to medications (Lee et al., 2006), which is the proportion of days during which the patient possessed a supply of the medication relative to how much medication supply the patient should ideally have over a given period of time. Although assessment of adherence using pill counts is cheap and useful for everyday practice, it has a number of problems. For example, patients do not always keep their medications in their original containers, and they may not always return these containers on request. Further, if frankly acknowledged, pill counting may encourage "dose dumping", whereby patients discard some pills to trick healthcare providers with a false optimal adherence to treatment (Becker, 1985).

1.5.2.2 Self-report

In this method, adherence can be measured simply by asking patients through interviews, patient-kept diaries or by using questionnaires that are self-completed by patients or their healthcare providers (Farmer, 1999). This is a relatively inexpensive method that can be used in naturalistic studies and clinical practice. Nevertheless, it is subject to patients recall and memory, and it is limited by several other problems which were highlighted by Horne and others in 2005, as the following:

- Patients may exaggerate their adherence if they believe that reports of nonadherence will affect the delivery of their healthcare by clinicians.
- The wording of self-report questionnaire items may present problems. For example one item in a questionnaire developed by Morisky et al. in 1986

described nonadherence as "careless" behaviour. Patients may perceive this as judgmental and may be more reluctant to admit nonadherence behaviour. Further, if questionnaire items combine reports of nonadherence with reasons for nonadherence, it might present confusion for patients (e.g., an item like "I take less medication if I'm feeling better" is difficult for patients to respond to if they take less medication but not because they feel better).

Despite its limitations, self-report was found to compare well with other methods used to assess adherence (Garber et al., 2004; Butler et al., 2004a). In addition, although self-report may overestimate levels of adherence, it is believed that patients who report poor adherence to treatment are more likely to be correct (Farmer, 1999; Haynes et al., 2002). This suggests that self-report might be helpful in detecting nonadherence.

1.5.2.3 Electronic monitoring

This method involves the use of devices (e.g., Medication Event Monitoring Systems [MEMS]) that electronically record the opening of the container, such that the number of times the container is opened, and the exact times of the day where it happened can be precisely known. This technique has the advantage of providing an overall picture of drug use, highlighting the extent and pattern of "drug holidays" (when patients stop taking their medication for a certain period of time) and "white coat adherence" (when the patient deliberately switches to optimal medication use in the days immediately preceding an appointment with the doctor) (Feinstein, 1990). Nevertheless, the method is not free of limitations. Horne et al. (2005) highlighted some of these:

- High cost of the devices, limiting its usefulness to clinical trials more than naturalistic studies and clinical practice.
- The opening of the container does not guarantee the ingestion of the medication (doses may be discarded).
- Ethical considerations in the use of these devices entail that patients must be informed that their adherence behaviour is being monitored; this may lead to temporary improvements in their adherence as they strive to meet the observer's expectations.
- The devices cannot be fitted to many of the dosage forms and packages used in routine care.

- The devices do not provide information about the type of nonadherence (intentional or unintentional).

1.5.1.4 Use of pharmacy records (e.g., prescription refill rates)

Pharmacy records (e.g., prescription refill rates) can be used to estimate patients' adherence to medications, if they use one particular pharmacy to refill their prescriptions and they do not stockpile their medications or give them to others. The method involves assessing whether patients refill their prescriptions in a timely manner which may indicate that they are using their medications appropriately. Conversely, if patients refill their medication(s) irregularly, nonadherence is suspected. The number of days the patient remained without medication supply can be calculated and nonadherence can be estimated. Assessing patients' adherence using this method has some limitations. Unlike electronic monitoring, the method does not provide information on the pattern of medication use. Furthermore, it is of limited value if patients use more than one pharmacy for refills, or if the pharmacy records or database are incomplete.

1.5.1.5 Health outcome measures

Adherence is sometimes measured in terms of achievement of the treatment goal (e.g., in case of diabetes, when glycosylated haemoglobin [HbA1c] <7%). However, this method is also limited because there is no straightforward link between adherence and health outcome (DiMatteo et al., 2002). Patients may improve for reasons other than following the prescribed regimen and they may deteriorate or remain stable despite taking their medications as prescribed (Vermeire et al., 2001). For example, Becker (1985) explained that a nonadherent hypertensive patient may have optimal blood pressure because of weight loss, exercise or even reassurance from the doctor, and not necessarily from adhering to medications.

In summary, there is no "gold standard" measure of adherence as no method is completely without flaws. Despite three decades of research on adherence, one of the most challenging issues is that the act of measuring adherence introduces an effect on behaviour; i.e., patients may change their adherence as a result of being monitored. Therefore, Horne and others in 2005 highlighted that "the choice of adherence measures represents a compromise in which accuracy and comprehensiveness of the measure is balanced against reactivity and the practical, ethical and cost limitations". Furthermore, researchers

recommend using a combination of methods rather than a single method for assessing adherence to medications, as this is likely to provide a more valid estimation of patients' adherence behaviour (Farmer, 1999; Cummings et al., 1984; DiMatteo and Haskard, 2006).

1.6 Determinants of adherence

Many factors were linked to nonadherence to medical regimens (including medication). Earlier reviews suggested that more than 200 variables have been studied in relation to adherence, although none of them consistently predicted nonadherence (Haynes, 1976b). These variables will be categorized into patient-related factors, treatment-related factors, healthcare provider related factors and health system-related factors and discussed in the following sections.

1.6.1 Patient-related factors

1.6.1.1 Demographics

The search for demographic factors that identify the "nonadherent patient" has met with little success (Meichenbaum and Turk, 1987). Many studies have attempted to find correlations between age, sex, socioeconomic status, education, ethnicity and nonadherence to treatment. However, findings are too inconsistent to allow for accurate conclusions to be drawn. One large review concluded that there was no association between demographic variables and adherence to treatment (Haynes, 1976a).

1.6.1.2 Economic factors

Poverty, poor socioeconomic status and high medical costs are frequently linked to patients' nonadherence to medications. These factors are particularly prominent in countries where patients pay or share some of the cost of their medication prescriptions. In the United States, small increases in copayments (less than $2) were associated with a significant decrease in drug utilization rates (Harris et al., 1990). However, it is argued that the relationship between patients' out-of-pocket medication costs and adherence is complex, and individuals' response to cost pressures cannot be predicted solely based on their level of financial burden (Piette et al., 2006). Previous research by the same authors found that patients with diabetes reported cost-related underuse of their medications despite their apparent ability to afford treatment (Piette et al., 2004). Therefore, they proposed that

non-cost factors may modify patients' likelihood of cutting back on medication use in response to financial pressures.

1.6.1.3 Medical condition

Medical condition-related factors that have been studied in relation to adherence include: diagnosis, severity, duration, previous bouts, recency of last attack, previous hospitalization, length of stay in hospital, previous therapy, degree of disability, and symptoms. Findings of studies focusing on these variables were inconclusive (Haynes, 1976a). However, there were two exceptions: disease severity and diagnosis. It was found that patients' adherence to treatment is decreased when the condition is mild, or asymptomatic. This is specifically important in diseases such as hypertension where patients often do not feel a physical response to their medications. As for diagnosis, nonadherence to treatment was more common in patients with a psychiatric diagnosis compared to those with a somatic diagnosis (Haynes, 1976a; Vermeire et al., 2001). A large meta-analysis assessing the effect of depression on patients' adherence to medications for conditions other than depression found that depressed patients were three times more likely to be nonadherent to medications compared with patients without depression (DiMatteo et al., 2000).

1.6.1.4 Social factors

Social support, which includes the assistance and support patients receive from friends, family, and other significant people, has an established role in improving patients' adherence to treatment. Haynes (1976a) reviewed six studies exploring the relationship between social support provided by family and patients' adherence to treatment. In five of these six studies, social support provided by family was significantly associated with improved patients' adherence to treatment (Haynes, 1976a). Results of a meta-analysis provided stronger quantitative evidence that social support had substantial effects on patients adherence to medical treatment, with functional support (e.g., family cohesion, practical/instrumental, and emotional support) showing a greater impact than structural support (e.g., marital status, living arrangement) (DiMatteo, 2004a). This highlighted that the quality of relationships between patients and significant people in their lives are more important than the mere presence of such people.

Despite the evidence of positive impact of social support on patients' adherence to treatment, the exact mechanism by which this occurs is still unclear. DiMatteo (2004) highlighted that research suggests it could be through encouraging optimism, boosting self-esteem, neutralizing stresses resulting from illness, improving depression, or providing practical assistance (DiMatteo, 2004a).

1.6.2 Treatment-related factors

Type of medication, degree of behavioural change required, complexity, duration, adverse effects, dosage, use of safety dispensers, and intrusiveness are features of treatment regimen that have been studied in relation to nonadherence (Haynes, 1976a; Meichenbaum and Turk, 1987), with complexity, duration of treatment and the degree of the behavioural change required being the most widely assessed. These will be discussed in the following section.

1.6.2.1 Complexity of regimen

Complexity of the treatment regimen was found to have a negative association with adherence (Haynes, 1976a; Meichenbaum and Turk, 1987; Vermeire et al., 2001). This is unsurprising as one would expect that the more complex the regimen, the more difficult it is for the patient to adhere to it. In the review by Haynes (1976a), twelve of sixteen studies have found a negative association between complexity of regimen and treatment adherence. In support of this review, a study by Stone (1979) found that the rate of nonadherence to medication was 15% when patients were taking one medication only, 25% when they were taking two or three medications, and 35% when they were taking more than five medications (Stone, 1979) . In addition to the number of medications, the number of doses per day was also associated with an increased rate of nonadherence (Meichenbaum and Turk, 1987).

1.6.2.2 Duration of therapy

There were inconsistencies in findings of different studies regarding the impact of duration of therapy. In Haynes review (Haynes, 1976a), six of eleven studies found a negative association between duration of treatment and treatment adherence. The other five studies found no such association. However, Haynes argued that lack of association in the latter studies could be due to a bias in the sampling strategies because only patients with ongoing treatment were sampled.

1.6.2.3 Degree of behavioural change required

The more behavioural change the treatment requires on part of the patient, the greater the challenge to adherence. For example, in the treatment regimen for diabetes, adherence to exercise and diet was found more difficult than adherence to medication (Vermeire et al., 2003).

1.6.3 Healthcare provider-related factors

Many studies have linked aspects of the patient-healthcare provider interactions and patients' adherence to treatment (including medications). Coleman (1985) argued that four major aspects of physicians' behaviour may impact on patients' adherence to treatment: compassion, communication, activating patient self-motivation and shared responsibility with the patient (Coleman, 1985). However, communication appears to be the most widely studied in relation to patients' adherence to medication. A systematic review of the research on communication between patients and health care professionals emphasized that health care professionals' behaviour can impede as well as enhance patient involvement (Stevenson et al., 2004).

Adopting a patient-centered communication style appears to improve the patients' adherence to treatment. According to Henbert and Stewart (1990), this style of communication was introduced into the literature in 1970 and was defined in terms of doctors' responses which enabled patients to express all of their reasons for coming, including symptoms, thoughts, feelings and expectations. It involves a shift from thinking about patient care in terms of disease and pathology towards thinking in terms of people and their problems (Henbest and Stewart, 1990).

Various studies support the role of a patient-centred approach in communication and adherence to treatment. In one review, eleven of 15 studies using adherence as an outcome found a positive association between a patient-centered approach in consultation and adherence to treatment (Michie et al., 2003). In terms of adherence to medication, it was found that patient-centred advice delivered by pharmacists to patients starting a new medicine for a chronic condition was associated with significant improvement in patient adherence to that medicine ($p=0.032$) (Clifford et al., 2006). It is likely that the positive impact of improved communication on patient adherence may be due to increasing patients knowledge and understanding, changing patient beliefs and attitudes, and increasing

patients' motivation by encouraging them to actively participate in their healthcare (Alexander et al., 2006).

1.6.4 Health system-related factors

Organizational factors related to the healthcare system such as continuity of care, assignment of regular physicians to patients, clinic convenience and clinic waiting times were all associated with adherence to treatment (and medications). However, studies have yielded mixed findings.

In the review by Haynes (1976a), adherence was not related to assigning patients to a specific physician within clinics, and was not affected by the type of clinic (private vs. public clinics). However, convenience of the clinic in terms of timing and scheduling appointments was positively related to adherence to appointment-keeping, but there were no studies linking it to adherence to medication. Similarly, waiting times (whether waiting for referrals, waiting during clinic appointments, or at the pharmacy) were associated with patients adherence to clinic appointments such that the longer the waiting times, the less the chances patients were able to keep their appointments. However, no studies reported the impact of waiting times on patients' adherence to medications.

1.7 Explanatory models applied to nonadherence

Theories of social psychology have been widely used to explain and predict patients' adherence behaviours. This section will describe briefly some of these theories, with special emphasis on their applications to patients' adherence to medications.

1.7.1 Social learning (cognition) models (SCMs)

Social cognitive models commonly assume that attitudes and beliefs are major determinants of adherence. According to these models, behaviour is a function of an individual's beliefs or expectancy that the behaviour will lead to a particular reinforcement and the extent to which that reinforcement is valued (Rotter, 1982). Therefore, patients are more likely to adhere to their medications if they believed that this will lead to a particular outcome (e.g. improved health, saving their life), and if that outcome was important to them (Horne and Weinman, 1998).

Social cognitive models were originally derived from the Social Learning Theory (Rotter, 1954), which was later termed the Social Cognitive Theory (Bosworth and Voils,

2006). The theory suggests that before people can engage in a particular behaviour, they must undergo processes of reasoning, decision-making and problem solving. There are a number of social cognitive models that are based on the social learning theory; some were specifically designed to explain health-related behaviours such as the Health Belief Model (Rosenstock, 1974) ,while others were designed to explain general behaviours such as the Theory of Planned Behaviour (Ajzen, 1991). In addition, two competing views emerging from Social Learning Theory are Locus of Control and Self Efficacy. These will be discussed in the following sections.

1.7.1.1 Locus of control (LC)

Locus of control theory was developed by Rotter (1966) to denote the extent to which the person feels that they have control over a situation or that the situation is being controlled by external factors such as fate, luck or chance. In this respect, Rotter suggested that people can either have an internal or an external locus of control. The theory assumes that internals will be more likely to engage in reinforcing behaviours because they believe that reinforcement is dependent on their own behaviour (Horne and Weinman, 1998). For example, if patients believe that taking medications is within their control, they are more likely to adhere to their medications.

The concept of locus of control was later applied to health by Wallston et al. (1976) adapting the health locus of control (HLC) which was unidimensional (i.e., external vs. internal), as the original LC (Wallston et al., 1976). Later, it was further extended to adapt the multidimentional health locus of control scale (MHLC) (Wallston and Wallston, 1978), which divided control beliefs into three separate scales: an internal scale, and two external scales i.e. *chance* and *powerful others* (Levenson, 1973b; Levenson, 1973a). As the general HLC was found a weak predictor of health behaviour, Wallston et al. (1994) developed a condition-specific version of MHLC which further divides powerful others into two independent scales: *doctors* and *powerful others*. Similar to the LC, both the general and condition-specific HLC assume that internals are more likely to engage in health-promoting activities. Many studies have utilized the HLC theory to explain individual differences in the likelihood of engaging in medication adherence behaviour. Some studies found that individuals high in internal locus of control were more likely to adhere to HIV (Molassiotis et al., 2002), hypertension (Kirscht and Rosenstock, 1977), and

diabetes medication regimens (O'Hea et al., 2005). Overall, it has been found that the HLC is relatively weak in predicting health behaviour (including adherence to medication), accounting for only small amounts of the variance in patients behaviours (Conner and Norman, 2005). Therefore, there is currently little research interest in the HLC as a predictor of adherence to medication.

1.7.1.2 Self-efficacy (SE)

In 1977, Albert Bandura introduced the concept of perceived "self-efficacy" in his social cognitive theory denoting an individual's belief that he/she is able to perform a particular behaviour that will lead to a desired outcome (Bandura, 1977). In this way, LC refers to one's beliefs about the degree of control one has over a behaviour, whereas SE refers to one's confidence in the ability to perform that behaviour (Horne and Weinman, 1998). Another principal component of the social cognitive theory of Bandura is "outcome efficacy", which refers to one's belief that his/her action will lead to a particular consequence. Bandura's theory suggests that both self-efficacy and outcome-efficacy beliefs are important in modifying health behaviours, such that people with high self-efficacy and high outcome efficacy are more likely to perform health-related behaviours. For example, patients are more likely to take their medications if they believe that they are capable of doing that and that this will lead to the desired outcome (e.g., good health).

Many studies have utilised the concepts of self-efficacy and/or outcome efficacy to understand and predict patients' adherence to medication regimens. Studies found that greater self-efficacy predicted better adherence to medication in diabetes (Aljasem et al., 2001; Skelly et al., 1995; Nelson et al., 2007), hypertension (Roh, 2005), asthma (van Es et al., 2002) and HIV (Molassiotis et al., 2002; Murphy et al., 2002), although some studies found no association between self-efficacy and adherence to medication (Chlebowy and Garvin, 2006). Although self-efficacy was originally developed within Bandura's social cognitive theory, it became highly appealing to health psychologists and was incorporated into most theories of health behaviour like the health belief model, theory of reasoned action, and protection motivation theory (Schwarzer and Fuchs, 1996).

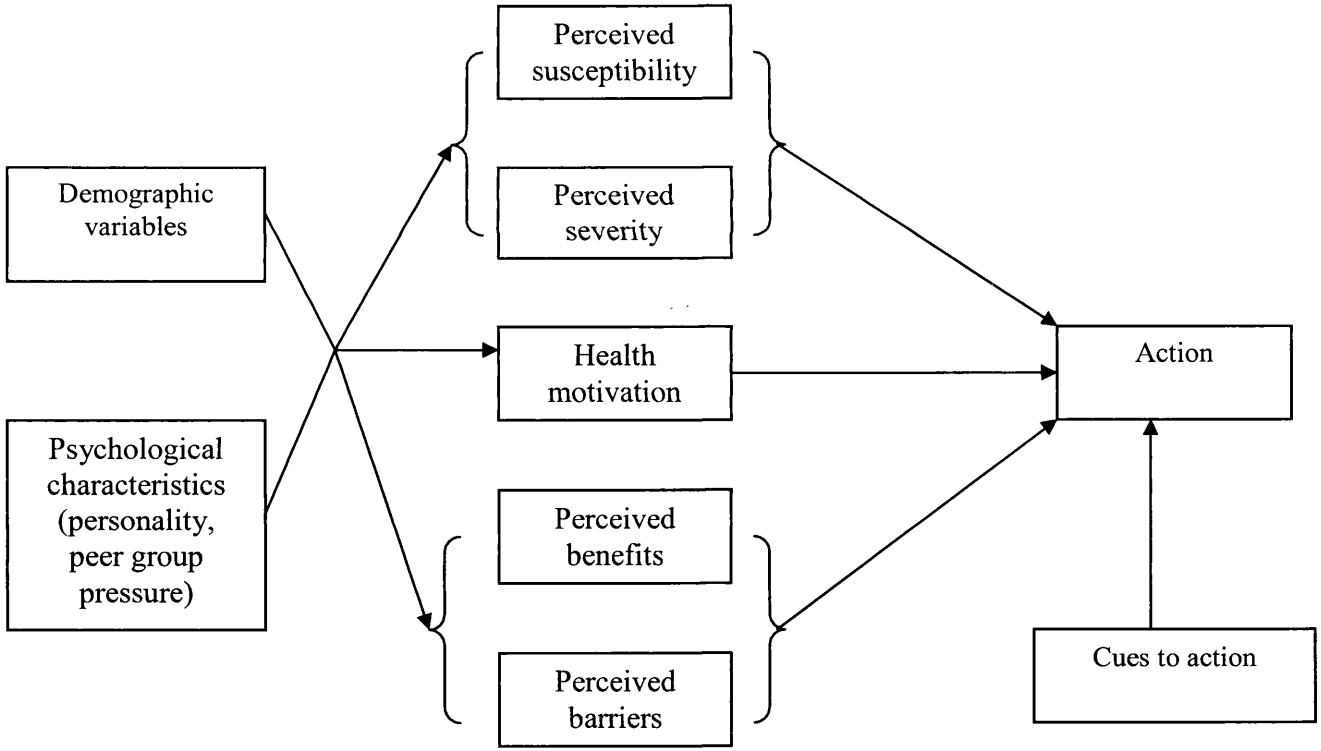
1.7.1.3 Health belief model (HBM)

This model is probably the most commonly used model in studies of adherence and health behaviour (Bosworth and Voils, 2006). It was originally developed to explain why

people fail to participate in disease prevention programmes or screening tests (Rosenstock, 1974). A diagram of the model is illustrated in Figure 1.1. The original model proposed that the likelihood of individuals engaging in a particular behaviour (e.g., taking medications) was a function of their beliefs about the *perceived threat* of the disease and an evaluation of the *risk/benefit* of the recommended course of action. In turn, perceived threats included two distinct dimensions: perceived *seriousness or severity* of the threat, and the individual's perceived *susceptibility* to it. Becker and Maiman (1975) further modified the model by incorporating *cues to action*, which they argued a necessary component to trigger the behaviour (e.g., symptoms, social influence and health education campaigns). Furthermore, an individual's health motivation was incorporated in later versions of the model (Horne and Weinman, 1998; Becker et al., 1977).

To simplify this with the example of medication adherence behaviour, the health belief model proposes that patients will be more likely to adhere to their medication if they perceive their illness to be severe or serious, themselves as susceptible to the complications of the disease if left untreated, and that the benefits of adhering to their medications (e.g., symptom relief, preventing complications) outweigh the risks or barriers of taking it (e.g. side effects, complexity, interference with life routine, etc.). In addition, certain stimuli must occur to trigger adherence to medications (e.g., symptoms, health professional's advice, social pressure). The HBM has been widely applied to predict adherence to medication across a broad range of conditions including hypertension (Kirscht and Rosenstock, 1977; Hershey et al., 1980), diabetes (Polly, 1992; Daniel and Messer, 2002), renal diseases (Cummings et al., 1982) and psychiatric diseases (Kelly et al., 1987). Although several studies have demonstrated the value of the HBM in predicting adherence to medication, there have been several criticisms to the model (Horne and Weinman, 1998; Abraham and Sheeran, 2005). The HBM simplifies health-related cognitions into broad constructs such as "barriers" and "benefits" without specifying the beliefs underlying these constructs and implying that behaviour is a direct result of cognitions. The model also does not incorporate social factors and fails to include an intention stage, which has been found by many researchers to mediate between cognitions and behaviour. In addition, the definitions of the main constructs of the model were left open to debate, leading to large inconsistencies in the conceptualization and operationalization of the model across different studies.

Figure 1.1: The Health Belief Model



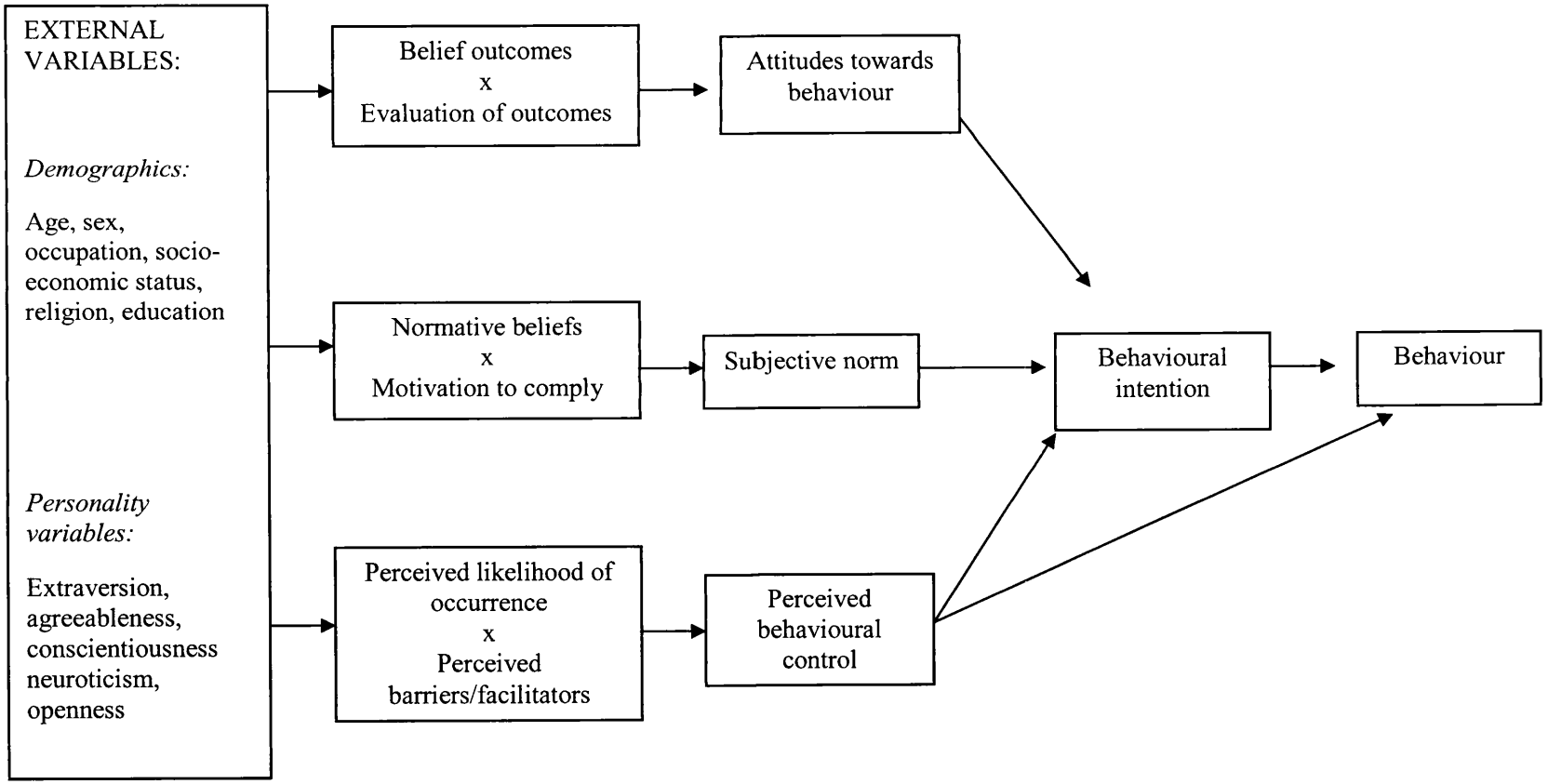
1.7.1.4 Theory of reasoned action/Theory of planned behaviour (TRA/TPB)

The theory of reasoned action was first developed by Fishbein and Ajzen in 1975. Figure 1.2 illustrates a diagram of the TPB. According to this theory, behaviour is mainly dependent on the individual's intention to engage in that behaviour. Intention, in turn, is determined by *attitudes* towards the behaviour and *subjective norms* concerning the behaviour (Fishbein and Ajzen, 1975). Attitude towards the behaviour is a function of the individual's beliefs about the likely outcome (e.g., "taking my medication will control my diabetes") and the perceived value of the outcome (e.g., "keeping my diabetes under control is important to me"). Subjective norms are a function of an individual's perceptions of others beliefs about the behaviour (e.g., "my family want me to take my medications") and the motivation to comply with these beliefs (e.g., "I wish to please my family by taking my medications"). The theory was later modified and re-named the theory of planned behaviour (TPB) after incorporating another predictor of behaviour, which is the *perceived behavioural control (PBC)* (Ajzen, 1991). This refers to the extent to which one believes he/she has control over performing the behaviour, or the ease or difficulty of performing the behaviour. In the TPB, attitudes and subjective norms and perceived behavioural control all indirectly influence behaviour through their effect on intentions. However, PBC can also influence behaviour directly.

In summary, the theory of planned behaviour assumes that the more positive people's attitudes and subjective norms regarding the behaviour, and the greater their perceived behavioural control, the stronger their intentions to perform the behaviour. Also, the stronger people's intentions are, and the greater their perceived behavioural control is, the more likely it is that they will perform that behaviour.

Many studies have used the theory of reasoned action/planned behaviour to predict adherence to medication. Studies have proven that components of the theory were useful in predicting adherence to medication prescribed for urinary tract infections (Ried and Christensen, 1988), malaria (Abraham et al., 1999), bipolar affective disorders (Cochran and Gitlin, 1988), and hypertension (Miller et al., 1992). Although TRA/TPB has the advantage of incorporating an intention stage between behaviour and cognitions and accounting for social factors role in predicting behaviour, it has been faced with many criticisms. One of the major criticisms is that the theory can account only for rational behaviours and fails to

Figure 1.2: The Theory of Planned Behaviour



explain non-cognitive irrational behaviours (Conner and Sparks, 2005). In addition, the theory does not incorporate the influence of past behaviour on future behaviour, a predictor that has been shown to largely impact the performance of behaviour (Conner and Armitage, 1998).

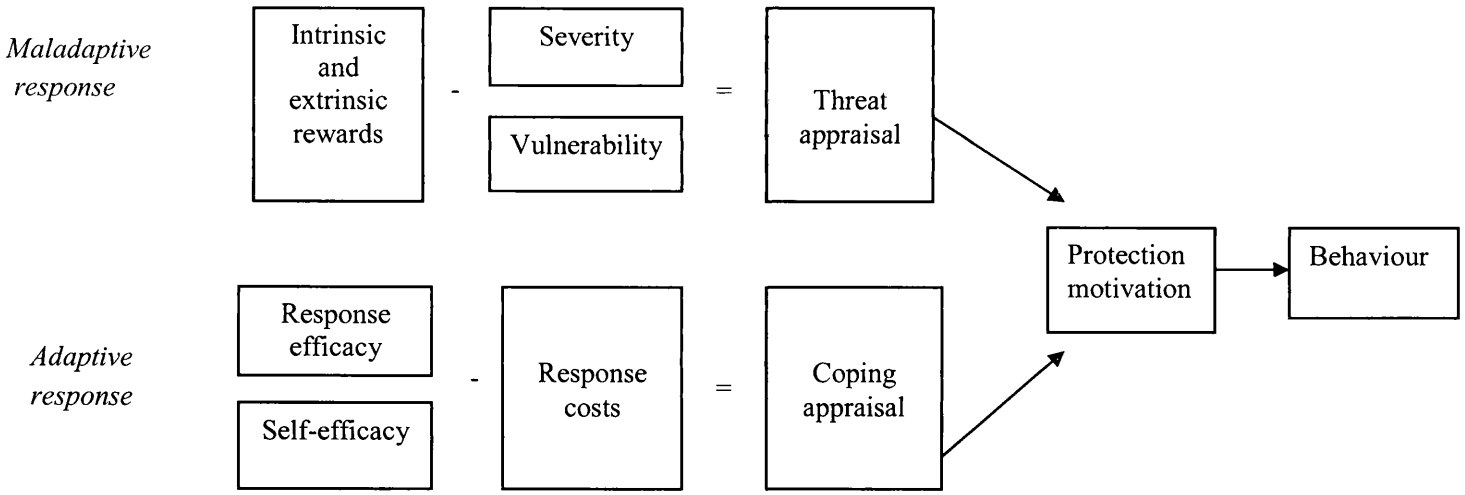
1.7.1.5 Protection motivation theory (PMT)

Protection motivation theory was originally developed by Rogers in 1975 as a framework to understand the impact of fear appeals (messages that use fear to persuade) on behaviour (Rogers, 1975). Figure 1.3 illustrates a diagram of the model. The theory can be seen as a hybrid theory in which three components originate from the health belief model (i.e., vulnerability, severity and response efficacy), while other components originate from the social learning theory (i.e., self efficacy, outcome efficacy). Further, as in the TPB, PMT also incorporates and stipulates that intentions, which are labelled "protection motivation", are the main and most immediate predictor of behaviour. However, these intentions are influenced by constructs other than those proposed by the TPB; these are *threat* and *coping appraisal* (as in the HBM).

Threat appraisal involves the evaluation of a fear appeal to determine the perceived vulnerability, severity and fear of the threat. Therefore, one is more likely to have intentions to perform the behaviour if one believes one is vulnerable to the threat, the threat is severe, and one is fearful of the threat (Bosworth and Voils, 2006). Coping appraisal comprises three constructs: self-efficacy, response efficacy, and response costs. The first two constructs have been explained previously, and the latter refers to one's beliefs about how costly the recommended response will be. According to the theory, one is more likely to perform the behaviour if one believes one is capable of performing the behaviour, the behaviour will effectively reduce the threat, and the recommended response is not costly (Bosworth and Voils, 2006).

In summary, PMT postulates that threat and coping appraisal both influence intentions to perform the behaviour. However, they may also lead to maladaptive coping responses (e.g., avoidance, denial, fatalism, wishful thinking and hopelessness) which may influence behavioural intentions. These responses occur when following the recommended behaviour does not reduce fear, or when the individual receives a fear-arousing message but no recommended behaviour is suggested to reduce this fear (Norman et al., 2005).

Figure 1.3: The Protection Motivation Theory



The PMT has been applied to a number of health related behaviours, including exercise, condom use, breast self-exam, smoking, substance use and dietary fat consumption (Bosworth and Voils, 2006). Applications of the theory to adherence to medications are limited; nevertheless, it has been utilized to predict adherence to medication in diabetes (Palardy et al., 1998) and asthma (Bennett et al., 1998).

1.7.2 Transtheoretical model of change (TMC)

This model is one of the stage models of health behaviour, which assume that the initiation and maintenance of health behaviours may involve different stages, and is not a result of a one-off decision (Conner and Norman, 2005). Following that assumption, different cognitions may be more salient at different stages in promoting health behaviours. The transtheoretical model of change (TMC) was developed by Prochaska and DiClemente in 1984 and was widely used to understand the processes of change in alcoholism and smoking cessation. The most widely used version of the model identifies five distinct stages through which individuals are thought to progress in order to initiate and maintain a new behaviour (Conner and Norman, 2005). These stages are:

1- Pre-contemplation: where an individual is unaware that his/her current behaviour (e.g., smoking) constitutes a problem and has no intention to change it.

2- Contemplation: the individual is thinking about changing the risky behaviour but is not committed yet.

3- Preparation: the individual has an intention to change the behaviour and is starting to make plans about how to change it.

4- Action: the individual is actually attempting to change the behaviour.

5- Maintenance: the individual is six months abstinent from the risky behaviour and is attempting to prevent relapse.

Individuals are thought to move through these stages in order, although they may cycle through the stages several times before achieving long-term behaviour change (Conner and Norman, 2005). Currently, the evidence supporting the role of TMC in adherence to medications is limited.

1.7.3 The self-regulatory model of illness (SRM)

The fundamental principle of the SRM is a view of the patient as an active problem solver who undergoes a process of self-regulation in response to a health threat (Horne and Weinman, 1998). The SRM is shown in Figure 1.4. Like social cognitive models, the SRM assumes that patients' cognitive representations of a health threat affect their coping responses and self-management behaviours (Leventhal et al., 1992). The term "self-regulation" denotes the process by which patients attempt to shift from a current status (i.e. ill) to a future goal (i.e., less ill, or not ill) (Bosworth and Voils, 2006). Therefore, adherence to medication may offer a coping response by which patients can achieve this goal. However, SRM proposes three stages that patients must pass through:

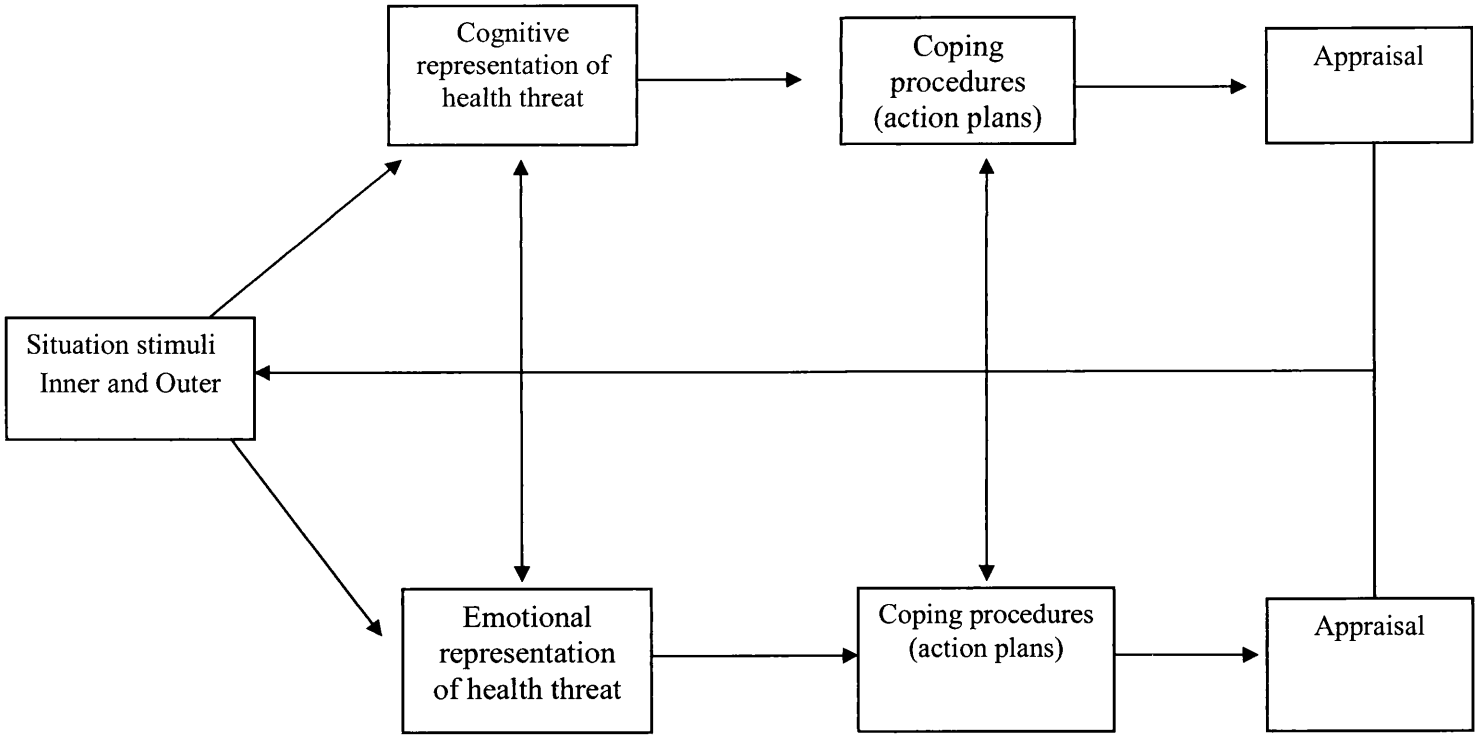
1- Representation of illness, which can be activated by internal or external cues (e.g., symptoms, information, etc.)

2- Development and execution of a plan to cope with the illness

3- Evaluation of the coping strategy

Key features of these stages have been identified (Bosworth and Voils, 2006; Horne and Weinman, 1998). First, processing occurs in parallel at a cognitive and emotional level along the three stages. Second, the stages are not necessarily unidirectional; there is rather a dynamic interaction between the stages as patients can move both forward and backward between stages. For example, a patient recognizes that he has pain (representation), decides to ignore it (coping), the patient realizes the pain is not going away (evaluation), the patient takes an analgesic (re-entering coping), and feels better (re-evaluation). One of the advantages of the SRM is that it addresses the criticism of most previous models which assume that health-related behaviours arise from a single "one-off" rational decision based on a cost-benefit analysis, control beliefs, or beliefs about social norms. However, the model was criticized for its complexity and lack of standardized instruments for testing it, which makes it difficult to operationalize (Bosworth and Voils, 2006; Horne and Weinman, 1998). In addition, the SRM seems to be of little use when the cognitive representation of a threat is low (Bosworth and Voils, 2006). For, example, in asymptomatic diseases like hypertension or osteoporosis, patients may perceive the threat as low and may not complete the self-regulation processes which underlie the SRM of illness.

Figure 1.4: The Self-Regulatory Model



1.7.4 The beliefs about illness and medicines

Patients' beliefs about their illness or medicines may influence their decisions about taking their medications. Research has found that patients' perceptions about the necessity of their medications weighed against their concerns about potential adverse effects were related to their adherence to medications. In one study involving 324 patients from four chronic disease groups (asthma, renal, cardiac, and oncology), patients who had a higher belief in the necessity of their medications had higher reported adherence ($r=0.21$, $p<0.01$), whereas patients who had higher concerns regarding their medications had lower reported adherence to medications ($r=-0.33$, $p<0.01$). Further, stepwise multiple linear regression analysis showed that medication beliefs accounted for 19% of the explained variance in adherence, and were more powerful predictors than clinical or sociodemographic factors (Horne and Weinman, 1999).

Beliefs about medicines were also linked to patients' adherence to medications in hypertension (Horne et al., 2001), HIV (Horne et al., 2007), and asthma (Horne and Weinman, 2002a), depression (Hunot et al., 2007) and renal transplant patients (Butler et al., 2004b). Interestingly, it was found that cultural background appeared to influence patients' beliefs about medications, and subsequently their adherence to these medications (Horne et al., 2004).

1.7.5 Human error theory

Reason's accident causation model (1990) is the most frequently used model in explaining medical error. It assumes that error results either from the individual, through unintentional or intentional actions, or due to organizational factors. Unintentional errors produced by the individual can take the form of slips (resulting from lack of attention) or lapses (resulting from failure in memory, i.e., forgetting). In contrast, intentional errors can be divided into mistakes (when individuals use the wrong rule to achieve something) or violations (when individuals know the right rule but choose not to use it). Further, mistakes can be rule-based or knowledge-based. Rule-based mistakes occur when an individual uses the wrong rule to achieve an action, while knowledge-based mistakes occur in novel situations when the patient has to figure out a new rule based on his/her existing knowledge (Reason, 1990).

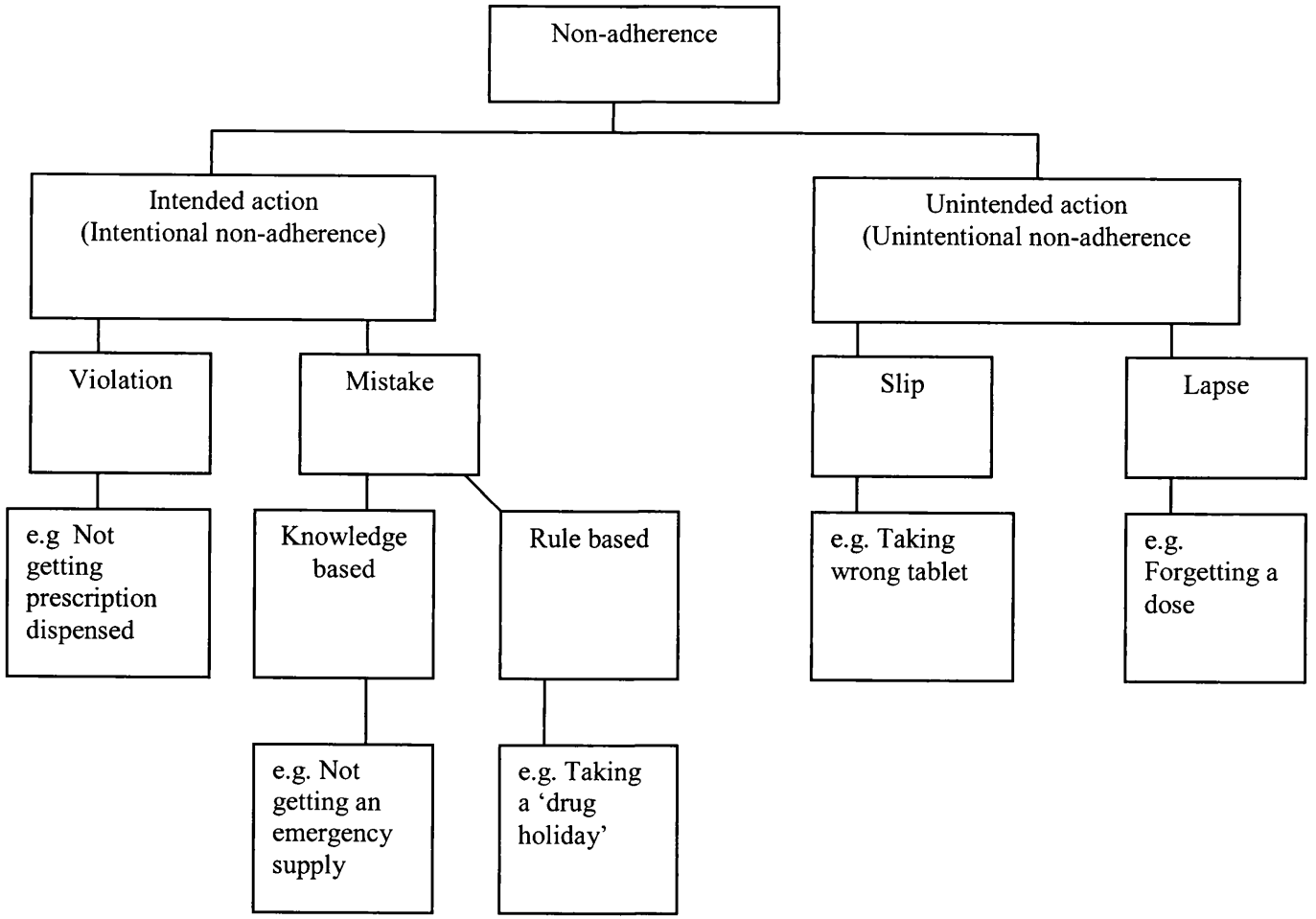
Further to the role of mistakes and violations, human error theory incorporates the role of organizational factors in encouraging errors. For example, management decisions can lead to an error-encouraging environment (these are also termed "latent conditions"). Local conditions, i.e., conditions that occur at the time of an error, may also play a role in increasing the possibility of making an error.

Barber (2002) argued that Reason's accident causation model can be adapted for use in explaining patients' nonadherence to medication. He explained how intentional or unintentional nonadherence could perfectly fit in under the different concepts of Reason's accident causation model, giving the following examples:

- A rule-based mistake may occur when a patient deliberately stops taking the medication for a period of time (or takes a "drug holiday") in fear of addiction for example, even when the drug is non-addictive.
- A knowledge-based mistake may occur when a patient runs out of an important medication, and then chooses to wait a few days before seeing the doctor instead of obtaining an emergency supply from the pharmacy.
- A violation may occur when the patient deliberately chooses not get the prescription dispensed due to dissatisfaction with the prescribing doctor.
- A slip may occur when a patient accidentally takes the wrong tablet.
- A lapse may occur when a patient forgets to take the dose.
- A latent failure may include the remuneration system for pharmacists, which encourages pharmacists to aim for dispensing as many prescriptions as possible, instead of properly counseling patients to ensure their adherence.
- Local factors in the hospital that encourage nonadherence may include being short staffed, poor lightening, etc.

Figure 1.5 illustrates how the human error framework can be applied to understand nonadherence to medications, providing examples of the type of nonadherence that could fall into each subcategory.

Figure 1.5: The Human Error Framework



In a pilot study using human error theory to explain nonadherence (Barber et al., 2005), the authors interviewed 87 patients who had been prescribed a new medication for a chronic condition. Patients were asked whether they had been adhering to their medication, and reasons for nonadherence were explored and analyzed according to the human error theory. Findings revealed that human error theory was more useful in explaining unintentional nonadherence (slips and lapses) than intentional nonadherence among the sample (mistakes and violations). Error producing conditions and latent failures were also useful factors contributing to patients' nonadherence to medication in the study.

Although empirical evidence supporting the use of human error theory is limited, it provides a fruitful research area because it could explain both intentional and unintentional nonadherence to medications, unlike social cognition models which can only predict intentional nonadherence. The theory also recognizes the role of organizational errors and other factors that have not been incorporated in previous theories. Barber (2002) highlighted that advantages of such recognition includes a shift away from blaming nonadherent patients which may encourage patients to disclose nonadherence behaviours. This in turn will allow healthcare providers to recognize the problem and intervene to resolve it.

In summary, nonadherence to treatment of chronic disease is a worldwide problem of striking magnitude which can lead to adverse clinical consequences for the patient and a considerable financial burden to the healthcare system. There is a vast amount of research focusing on the problem of nonadherence to medications. However, it is complicated and limited by the wide variation in the way adherence was assessed and operationalized. There are many different ways to assess nonadherence to medications, although there is still no gold standard and it is recommended to use more than one method in combination. Moreover, there is lack of specific demographic, disease or treatment-related factors that distinguish between adherers and nonadherers. It is argued that nonadherence to medication occurs as a result of a complex interaction between different variables and is unlikely to be caused merely by a single factor (Meichenbaum and Turk, 1987). Social, economical, healthcare provider-related or the healthcare system-related factors may be also be involved. Furthermore, theories of social psychology have been widely used to explain and predict patients' adherence behaviours. More recently, beliefs about medicines and

human error theory have also been applied to explain nonadherence to medications in particular. However, the evidence supporting the use of these theories to explain nonadherence to medications is mixed and there is still no single theory that would perfectly address the complexity of the problem of nonadherence to medications.

The next section will focus on nonadherence to medications in T2DM, stating the prevalence of the problem, its significance and consequences. This will be followed by a review of studies focusing on medication adherence in T2DM, including both international and Middle Eastern studies, to help understand the possible factors and barriers that would interfere with medication-taking in patients T2DM.

1.8 Nonadherence to medication in T2DM

1.8.1 Prevalence and significance

In diabetes, nonadherence to treatment behaviours is a major problem and may constitute the most serious barrier to better management of the disease (Vermeire et al., 2003). A systematic review has shown that the overall rate of adherence with oral hypoglycemic agents was 36-93% in retrospective and prospective studies, whereas insulin adherence among patients with T2DM was 62-64% (Cramer, 2004). Further, a recent systematic review of studies conducted between 1990 and 2005 showed that adherence to treatment in patients with diabetes was inadequate with typical reported rates of 36-87%. In the same review, patient adherence varied among oral agents only (36-87%) versus concomitant or insulin only (54-81%) (Lee et al., 2006).

Although nonadherence to treatment regimens (including medications) is common in all chronic diseases and is not unique to diabetes, it may be particularly problematic in diabetes given the complexity of treatment and life-long duration of the disease (Rosenstock, 1985). Diabetes is a chronic disease that requires daily self-management, with patients performing about 95% or more of the daily management without consulting healthcare professionals (Funnell and Anderson, 2000; Anderson, 1995). Patients with T2DM face daily challenges, having to make decisions about diet, smoking, physical activity, clinic attendance, glucose monitoring and medication regimen within the context of other goals, values, priorities, health issues, family demands, and other personal concerns that make up their lives (Funnell and Anderson, 2000; Trento et al., 2006).

Adherence to a daily complex regimen in diabetes elicits considerable burden in patients which may interfere with their coping with the disease (Kennedy, 2001).

In addition to the burden on the patient, nonadherence to treatment regimens in diabetes can have a considerable financial burden on national economies. The WHO estimated that treating 10 million patients with T2DM costs the United States $29 billion annually, with per-patient costs rising 2-3.5 fold once a patient develops (preventable) microvascular and macrovascular complications (WHO, 2003).

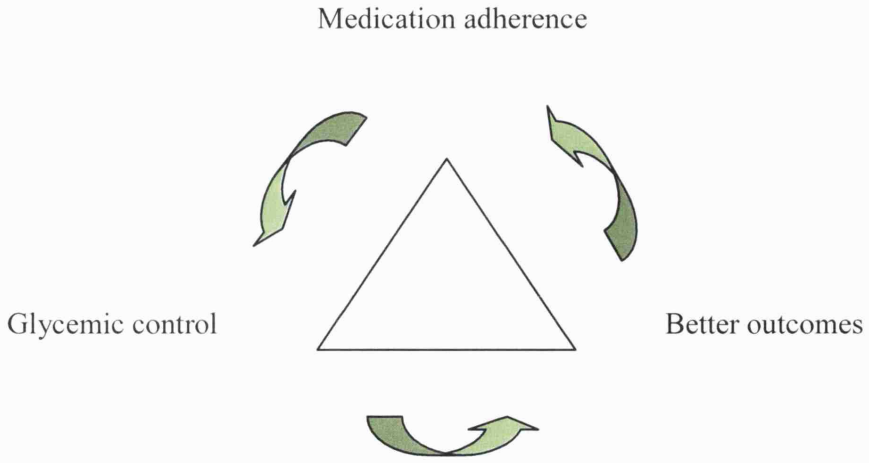
1.8.2 Glycemic control, medication adherence, and better outcomes of T2DM: A triangle

Several landmark clinical trials have shown that improving glycemic control can decrease the occurrence of microvascular complications of diabetes, including retinopathies, nephropathies, and neuropathies (The Diabetes Control and Complications Trial (DCCT) Research Group, 1993; UK Prospective Diabetes Study (UKPDS) Group, 1998a; UK Prospective Diabetes Study (UKPDS) Group, 1998b). Similarly, improving glycemic control can also prevent the macrovascular complications of diabetes, including coronary artery disease, cerebral vascular disease, and peripheral vascular disease; which frequently result in otherwise preventable strokes, ulcerations and amputations (Stratton et al., 2000; Haffner et al., 1998).

Given the recognized link between diabetes-related complications and inadequate glycemic control, improving patients' adherence to medications can improve outcomes of diabetes. Evidence have shown that adherence to diabetes medications was associated with better glycemic control in patients with T2DM. For example, one study found that for each 10% increase in adherence rate to oral hypoglycemic medications (calculated based on prescription refill data), HbA1c levels decreased by 0.16% ($p<0.0001$) (Schectman et al., 2002). In another study, each 25% increase in adherence to oral hypoglycaemic medications was associated with 0.05% reduction in HbA1c levels (95% CI -0.08% to -0.01%) (Ho et al., 2006). Further, a study utilizing a validated 4-item self-report scale for assessing adherence to medications (Morisky et al., 1986), has found that patients' adherence to medication was associated with a 10% decrease in HbA1c levels ($p=0.0003$) (Krapek et al., 2004).

In addition to improving the glycemic control in T2DM, research has found that improving patients' adherence to medications in diabetes can decrease healthcare costs and hospitalizations. A recent systematic review highlighted that economic benefits of medication adherence in diabetes were a decrease in health care costs ranging from 8.6-28.9% with each 10% increase in medication possession ratio (MPR).The decrease in cost was mostly due to a decrease in hospitalization (Lee et al., 2006). Another study conducted in the United States involving 900 patients with T2DM examined the association between adherence to oral hypoglycemic medications (defined as MPR <80%) and subsequent hospitalization. Findings revealed that a decreased adherence to medications was associated with a significant increase in the rate of hospitalizations (OR 2.53, 95%,CI 1.38-4.64, $p \leq 0.01$) (Lau and Nau, 2004). Further, a population-based study involving 11532 patients with T2DM from a large integrated health care delivery organization in the United States has found that the risk of hospitalization and all-cause mortality significantly increased in patients who were nonadherent to their medications (defined as those having <80% adherence level based on prescription refill data). For those who were nonadherent to their medications, the odds ratio for hospitalization was 1.58 (CI=1.38-1.81, $p<0.001$) and for all cause mortality OR was 1.81 (CI=1.46-2.23, $p<0.001$) (Ho et al., 2006). Figure 1.6 illustrates the link between medication adherence, glycemic control and diabetes outcomes.

Figure 1.6: The link between medication adherence, glycemic control and diabetes outcomes



Based on the previously illustrated evidence, studying adherence to medication in T2DM is an area of paramount importance. This is especially the case with systematic reviews concluding that finding effective ways to enhance adherence to medical treatment could have a far larger effects on health than any treatment itself (Haynes et al., 2005; Haynes, 2001). There is therefore a need to identify variables that enable patients to adhere to their treatment, which can be the target for designing effective interventions by modifying these variables. This has been the focus of worldwide initiatives to help patients control their diabetes and achieve better outcomes of the disease (WHO, 2003).

Despite a preponderance of research exploring predictors of nonadherence to medications in T2DM, results have been inconsistent. The following section will review the literature in terms of the barriers to medication adherence in T2DM in an attempt to gain an understanding of the different factors that could explain nonadherence in this particular group of patients.

1.8.3 Barriers to medication adherence in T2DM reported in worldwide literature (evidence from USA, Canada, UK, Germany, Italy, France, Belgium, Thailand and Croatia)

It is imperative to mention that most studies of nonadherence to medications in diabetes were mostly done in the Western world, particularly the USA, Canada, UK, Germany, Italy, France, Belgium and Croatia. Researchers have employed various study designs to explore this problem, using either qualitative or quantitative methodologies or a combination of both. Quantitative studies mostly involved using questionnaires for testing the various factors that might predict patients' adherence/nonadherence to medications (e.g., demographic variables, disease or regimen-specific variables, healthcare system-related issues), or testing theories (e.g., self-efficacy, locus of control, social support, beliefs about medicines) using validated questionnaires, sometimes even combining constructs of various theories in an effort to explain as much of the variance in adherence to medication behaviour that could be explained by these constructs.

In contrast, qualitative studies mostly involved conducting interviews or focus groups among patients or doctors' to explore their perspectives about the problem. One of the major advantages of qualitative studies is allowing for a deeper understanding of the complexity of the problem illustrating the possible dynamic interactions between all the

relevant factors (Brown et al., 2002). Below is a review of variables that can act as barriers to patients' adherence to medication, based on qualitative and quantitative studies that targeted patients with T2DM. Special emphasis will be on qualitative studies, which provided the richest data, allowing patients to explain how and why certain barriers existed to gain a deeper understanding of the problem of nonadherence in this particular group of patients:

Patient's poor knowledge about T2DM has been reported in the literature. In some studies, participants reported they had little or inaccurate knowledge about diabetes (Vinter-Repalust et al., 2004; Dietrich, 1996; Adams, 2003; Vermeire et al., 2003; Stone et al., 2005; Hernandez et al., 1999; Anderson et al., 1996; Blanchard et al., 1999). In other studies, participants reported that their doctors supplied them with insufficient information about diabetes (Lauritzen and Scott, 2001; Vermeire et al., 2003), or even conflicting information (Vermeire et al., 2003). Moreover, studies using focus groups of doctors (Brown et al., 2002; Wens et al., 2005) and in-depth interviews with patients (Dietrich, 1996) reported that patients often failed to recognize the seriousness of diabetes and often underestimated their illness. In support, O'Connor et al. (1997) found that negative respondents to a diabetes care program viewed their diabetes less seriously than positive responders. Further, patients often did not realize the association of poor glycemic control with diabetic complications (Lauritzen and Scott, 2001; Vinter-Repalust et al., 2004; Blanchard et al., 1999), and where the association was recognized patients believed there was nothing they could do to prevent these complications (Vermeire et al., 2003). This knowledge deficit combined with absence of complications in the early stages of diabetes signals a problem and may constitute a major barrier to their adherence to medications.

In many cases, knowledge was often acquired rather than learned from healthcare providers, with family members, friends and other patients with diabetes being the major source of information and education for patients (Dietrich, 1996; Phillips, 2007; Utz et al., 2006; Adams, 2003; Hill-Briggs et al., 2003; Stone et al., 2005; Lohri-Posey, 2006; Anderson-Loftin and Moneyham, 2000; Greenhalgh et al., 1998). Although findings from various studies showed that knowledge of patients with T2DM was far from optimal, the implications of these findings for adherence are unclear because few studies related knowledge directly to medication taking behaviour.

Lack of diabetes education may also be a problem. One qualitative study using focus groups of rural diabetic African Americans cited lack of diabetes education as a barrier to daily self-management of diabetes (Utz et al., 2006). In another study also from the USA, patients reported receiving little informal education from the nurse or doctor about medication, diet, or exercise (Anderson-Loftin and Moneyham, 2000). It is worth noting that education style may also present specific problems. Information overload, covering topics too fast, and confusing information were cited as problems in one study of diabetic patients from five different countries, including the USA, Germany, France, Italy and the UK (Lautenschlager and Smith, 2006).

Fear of medication adverse effects may impede patients' adherence to treatment in diabetes. In one study from the USA, physical and emotional adverse effects of diabetes medications were cited by many patients as important factors in determining treatment satisfaction and treatment preference (Hayes et al., 2006).

Patients' lack of motivation can present another barrier to medication or treatment regimen adherence (Brown et al., 2002; Wens et al., 2005). In one study from Canada focusing on the doctors' perspective, doctors reported that patients nonadherence to treatment was not due to a lack of information but rather, a lack of motivation (Brown et al., 2002). Another study from Belgium has found that patients failed to recognize nonadherence to medication as problem (Vermeire et al., 2003), which may explain the lack of motivation to adhere. Further, it was found that attitudes such as denial, passivity, and unrealistic perspectives were evident in patients who lacked motivation towards treatment (Brown et al., 2002). For example prior experience with a family member with diabetes resulted in a fatalistic attitude towards diabetes. Blanchard et al. (1999) reported that pessimism was evident in the majority of the sample in his study of 16 African American patients, which may have presented a barrier to their adherence behaviour. Empirical support for the association between lack of patients motivation/negative attitudes and their adherence behaviour was provided by another study from the USA which showed that patients with poor diabetic control had a more negative orientation towards their illness than patients with good diabetic control (Hill-Briggs et al., 2003), suggesting that these patients may have been less adherent to their medications.

Patients' fear of reporting nonadherence behaviour to doctors may itself act as a barrier to their adherence to medication. This was cited by patients in a focus group-based qualitative study including a total of 47 patients with T2DM from Belgium (Vermeire et al., 2003). In this study, patients explained how doctors could not understand the difficulties they face and get frustrated with them for not adhering to their treatment. Patients' frustration due to inability to achieve control despite perfect adherence to treatment may also prevent future adherence to treatment. This has been cited by patients in other studies from the USA and the UK (Phillips, 2007; Beverly et al., 2007).

Cost of medications was cited by many patients as a barrier to daily self-management of diabetes (Utz et al., 2006; Brown et al., 2002; Hayes et al., 2006; Lautenschlager and Smith, 2006; Anderson-Loftin and Moneyham, 2000). For example, one study among African Americans showed that the majority of patients needed help obtaining free or low cost medications, supplies and equipment. Cost of treatment may be more pronounced in poor communities which have difficulties obtaining health insurance, such as African Americans (Utz et al., 2006; Anderson-Loftin and Moneyham, 2000) and American Indians (Lautenschlager and Smith, 2006).

Complexity of diabetic treatment and difficulty of incorporating it into daily routines may also play a role. This was revealed in many studies (Phillips, 2007; Utz et al., 2006; Beverly et al., 2007; Hayes et al., 2006; Vermeire et al., 2003). In one study from Belgium using focus group methodology, patients reported that complexity of therapeutic regimens combined with a knowledge deficit hindered adherence to everyday treatment. Patients also reported that adherence to diet and lifestyle changes was more difficult than taking medications (Vermeire et al., 2003) .

Locus of control has been extensively studied in relation to adherence or nonadherence behaviours in diabetes; however, results have been inconsistent. Some have shown internal HLOC to be associated with improved metabolic control or better adherence to diabetes self-care regimens (O'Hea et al., 2005), while others have found no such link (Reynaert et al., 1995; Montague et al., 2005; Hayes et al., 2000), or even a negative association (Peyrot and Rubin, 1994; Edelstein and Linn, 1987; Peyrot and McMurry, Jr., 1985). Therefore, it is suggested that locus of control is a weak predictor of adherence behaviours in diabetes based on the current evidence.

Nevertheless, locus of control appeared as a theme in several qualitative studies, with some participants recognizing the control of the disease was within themselves (Dietrich, 1996; Hunt et al., 1998), whilst others believing that the control of diabetes was external and that there was nothing they could do about it (Adams, 2003). Depending on the strength of external locus of control beliefs, it can hinder or completely avert patients' adherence to treatment. In one study using focus groups of urban African Americans with T2DM, participants noted that spirituality and religion played an important role in their illness and their efforts to manage it. Some participants even mentioned knowing members of their community who did not seek healthcare for their diabetes because they believed only God could heal them (Utz et al., 2006).

In addition to the role of personal faith or religious beliefs in influencing patients' locus of control, it might also act as a barrier to adherence to medications especially in communities with high degrees of fatalism. For example, during the holy month of Ramadan, Muslim diabetics often alter their intake of medication during periods of fasting in Ramadan, even without medical advice (Lawton et al., 2005). The impact of personal faith in shaping patients views on health, life and self-care practices in diabetes was salient in many other communities including Thai women, First Nation adults in Canada, African Americans, American Indians, Hispanic/Latinos, British Bangladeshis and Hmong people (Devlin et al., 2006; Puavilai and Stuifbergen, 2000; Hernandez et al., 1999; Utz et al., 2006; Adams, 2003; Greenhalgh et al., 1998).

Low or lack of self-efficacy beliefs may also constitute a barrier to treatment adherence in T2DM. One study found that self-efficacy explained 33% of the variance in self-care scores one month after self-efficacy scores were measured, with a particularly strong correlation between self-efficacy for insulin self-injection and subsequent adherence to the injection regimen (Hurley and Shea, 1992). In support, several studies of patients with T2DM have found that a sense of self-efficacy was associated with adherence to medication (Skelly et al., 1995; Aljasem et al., 2001; Nelson et al., 2007; Padgett, 1991) and improved glycemic control (Sousa et al., 2005). Nevertheless, other studies found no such association between self-efficacy and glycemic control (Chlebowy and Garvin, 2006; Via and Salyer, 1999; Padgett, 1991).

Social support or rather a lack of it, was frequently cited as a barrier for patients when coping with their diabetes or incorporating it into their daily lives, and therefore might be an important factor in their adherence to medications. Studies from the USA, UK, Thailand and Croatia suggest that diabetic patients found social support received from family or co-workers was helpful in accepting their illness and adjusting to it (Dietrich, 1996; Vinter-Repalust et al., 2004; Utz et al., 2006; Lohri-Posey, 2006; Puavilai and Stuifbergen, 2000; Burke et al., 2006), while the absence of such support was associated with the contrary (Vinter-Repalust et al., 2004; Puavilai and Stuifbergen, 2000; Adams, 2003). However, excessive social support may be disadvantageous, as patients reported this increased their stress and frustration (Lohri-Posey, 2006; Beverly et al., 2007).

The relationship with healthcare providers was also a common theme in qualitative studies of patients with T2DM and might have affected their adherence to treatment. Studies from the USA, UK, Belgium and Croatia employing focus groups, interviews and other methods revealed that physicians often patronized patients, which often lead to their negative feelings (Vinter-Repalust et al., 2004; Phillips, 2007; Dietrich, 1996; Greenhalgh et al., 1998; Vermeire et al., 2003; Wens et al., 2005). Moreover, patients often felt that physicians' lack of time was a major barrier that prevented them from addressing all their questions and concerns (Dietrich, 1996). This was confirmed by a Canadian study taking into account the doctors' perspective (Brown et al., 2002). In other studies, patients reported that doctor's unrealistic instructions and scare tactics were unhelpful (Anderson-Loftin and Moneyham, 2000), which might have also influenced their adherence to treatment or medications.

In addition, linguistics and cultural background of providers may constitute a barrier to communication to some patients. In one study among British Bangladeshis, patients reported language barriers when speaking to professionals (Greenhalgh et al., 1998). Further, qualitative interviewing of 13 Latinas with T2DM found that primary care providers who shared a common language and culture with patients was seen as an advantage, although it was less critical than their caring and respect (Adams, 2003).

In addition to patient-provider communication, communication among healthcare providers was found important in other studies, in which patients cited that poor communication between healthcare providers affected the management of their diabetes

(Phillips, 2007). This was also confirmed by another study in which GPs reported there was poor communication between diabetes centers and GPs which divided the care process (Wens et al., 2005).

Lack of trust in healthcare providers may also cause nonadherence to medications. This was reported in a study of British Pakistani and British Indian patients with T2DM, where many patients cited that healthcare professionals of the Indian subcontinent were untrustworthy because it was perceived that they lack the necessary training and expertise. Patients also felt that these doctors offered their own friends or relatives better treatment, and had a financial interest in prescribing ineffective medications (Lawton et al., 2005). In another study using focus groups including African Americans, Hispanic/Latinos, American Indians, and Hmong people with T2DM, some patients reported lack of confidence in healthcare providers due to personal and historical factors (Devlin et al., 2006).

In addition, satisfaction with healthcare providers appears to play a role in determining patients' adherence to medications. One study from the USA showed that negative responders to treatment (those with less than 20% improvement in glycemic control 6 months after a diabetes care program) tended to be more satisfied with their providers than positive responders (O'Connor et al., 1997). This was unexpected and could be explained by the fact that patients who were more satisfied with their providers may have taken less control of their illness and handed this task over to their providers.

Other healthcare provider-related factors reported which may affect patients' adherence include lack of skills or knowledge about diabetes (Brown et al., 2002) and lack of remuneration or reimbursement to healthcare providers for patient education (Wens et al., 2005; Brown et al., 2002).

Patients' beliefs about their illness or medicines may be a precipitating factor to their adherence/nonadherence to medication. Qualitative interviewing with 32 British Pakistani and British Indian patients with T2DM revealed that patients' perceptions of medications led some to adjust their oral hypoglycemic agents in ways that conflicted with medical advice (Lawton et al., 2005). Patients reduced their intake or skipped some of their tablets deliberately in fear of adverse effects or long-term health implications. In another

study from Canada, patients stated their belief that diabetes was preventable and could be cured (Grams et al., 1996). This false belief about their illness may be a serious barrier to their medication adherence. For example, if they find that their illness remained uncured despite perfect adherence to their medications, they might stop taking their medications altogether.

Use of alternative therapy, including herbs and traditional remedies was reported in many studies from the USA (Devlin et al., 2006; Lautenschlager and Smith, 2006; Anderson-Loftin and Moneyham, 2000), and may have decreased adherence to prescribed diabetic medications. This was especially common in communities of low socioeconomics and low literacy. In one study exploring how low-income American Indians manage their disease, patients reported using healing ceremonies, herbs, pow-wows, sweat-lodges, and consumption of swamp tea in place of, or in addition to, conventional medicines (Lautenschlager and Smith, 2006).

1.8.4 The Middle East situation, where do we stand on adherence research?

As the initial literature search found no studies in the Middle East, a more comprehensive literature search was conducted, comprising an electronic, as well as a manual approach. This was done to encompass all the possible barriers patients might face when adhering to their medications in this particular part of the world. Although some obstacles and barriers might be similar in all patients with diabetes regardless of their race, or cultural background, it is likely that other barriers might emerge specifically in this particular area, given its unique cultural and religious characteristics.

The literature search was not limited to diabetes as based on preliminary search using PubMed, MEDLINE, EMBASE, and International Pharmaceutical Abstracts, only few studies about this particular condition were found. Therefore, all studies of chronic diseases were included, hoping that findings from these studies will illustrate the possible barriers Middle Eastern patients with T2DM might face when adhering to their medications.

1.8.4.1 Review of the Middle East literature

A literature review was conducted using the databases MEDLINE, EMBASE,

CINAHL, PsychINFO, Web of Knowledge, International Pharmaceutical Abstracts, Global Health and PubMed, and the search terms (complian* or adheren* or concordan* or therap* refusal or therapeutic alliance AND Middle East or Kuwait or Saudia Arabia or Bahrain or Oman or Qatar or the United Arab Emirates or Egypt with and without combination with the search terms (medica* or treatment or therap* or regimen*).

As this search was unsuccessful in finding relevant studies, a hand-search was also carried out for the major clinical journals of Kuwait and the Middle East which could be found online (using Google), or at the British Library (BL), School of Oriental and African Studies (SOAS) library and London School of Hygiene & Tropical Medicine (LSHTM) library. Issues of journals were hand-searched for up to the past 20 years, depending on their availability. Several Journals were found and hand-searched:

Kuwait Medical Journal 2001-2010 (March) available online

Journal of the Gulf and Arabian Peninsula Studies 1990-1999 available issues at SOAS) and 2000- 2010 (issue136) available online

Middle East Journal of Family Medicine 2003 V1(1)-2010 V8(2) available online

Middle East Health 1997-2010 (March-April) available at BL

Middle East Pharmacy 1998-2006 V14(6) available at BL

Eastern Mediterranean Health Journal 1996 V1(1)-2010 V16(4) available online

Medical Principles and Practice 1998-2010 V19(4) available online

Annals of Saudi Medicine 2000- 2010 V30(2) available online

Saudi Medical Journal (using the term compliance or adherence, searching online index 2000-2010)

Bibliographies of relevant articles were also scanned for more relevant studies. The search yielded only 24 studies, of which only 16 were relevant (i.e. studies of adherence to medications in chronic diseases in Middle Eastern Arab countries (Khattab et al., 1999; Roaeid and Kablan, 2007; Kamel et al., 1999; Bassili et al., 1998; Al-Sowielem and Elzubier, 1998; Khalil and Elzubier, 1997; Jabbar and Al-Shammari, 1993; Elzubier et al.,

2000; Youssef and Moubarak, I, 2002; Abdulghani et al., 2002; El-Shazly et al., 2000; Fido and Husseini, 1998; Al-Jahdali et al., 2007; Al-Saffar et al., 2005; Al-Saffar et al., 2003; Fahey et al., 2006). Table 1.1 summarizes these studies, highlighting the methods used to measure adherence/nonadherence to medications, estimates of nonadherence found in the populations of the studies, and predictors found related/ or unrelated to nonadherence to treatment in these studies.

1.8.4.1.1 Studies of adherence/nonadherence to medication in general

Studies found have addressed the extent and predictors of nonadherence to medication across different chronic diseases including hypertension, diabetes, asthma epilepsy, and depression. In Kuwait, studies of nonadherence to medications are very scarce. Only three studies were found that have addressed the issue of nonadherence, and all were in patients with psychiatric diseases (Al-Saffar et al., 2005; Al-Saffar et al., 2003; Fido and Husseini, 1998).

Overall, studies estimated that nonadherence to medications in Kuwait and the Middle East is between 1.4 and 88%. The wide discrepancy in these estimates may be due to the different scope of studies as they targeted patients with different conditions. However, all studies found suffered methodological flaws and caution must be exercised before drawing conclusions from these estimates.

Firstly, most of these studies were cross-sectional in nature, using self-report as the only method of measuring adherence to medications, which might have introduced recall, reactivity and social desirability biases, compromising the validity of these estimates. In most studies, patients had to self-report their adherence to medications in interview-based questionnaires which were administered by doctors, which further compromises the validity of self-report. Patients tend to exaggerate their adherence to medications to their treating doctor, either to gain their approval or in fear that their admitting to nonadherence would affect the quality of care they would receive (Vermeire et al., 2003).

Table 1.1: Studies of adherence to medications in chronic diseases in Middle Eastern Arab countries

Study (author, country, date)	Disease condition	Sample size	Aspects of adherence studied	Method of data collection	Method of measuring nonadherence	Estimate of nonadherence	Variables found linked nonadherence	Variables not found linked to nonadherence
Khattab et al. 1999, Saudi Arabia.	Diabetes (both types).	294.	Adherence to diet, appointments and anti-diabetic medications.	A diabetic follow-up card designed specifically for the study (patient's interviewed by the doctor, who assessed their degree of compliance and recorded it in the follow-up card).	Pill count+ self-report through an interview with doctors (Compliance was estimated as good, fair, or poor if patients missed no doses, 1-3 doses, or 4 doses per month, respectively).	1.4% had poor compliance (misses >4 doses/month) 98.2 % had good/fair compliance to their medications (% 14 fair , 84.2% good) *Data are based on the assessment of the last interview/assessment by the doctor, i.e. cross-sectional).	None of the variables under study.	-Patients' age, sex, literacy, employment, marital status. - type of diabetes, family history, duration of diabetes) - No. of drugs, type of drugs, degree of diabetic care, degree of control).
Abdulghani et al.2002, Saudi Arabia .	Epilepsy.	147 children.	Adherence to medications and appointments.	Prospective study (in measuring compliance to appointments) However, compliance to medications was measured cross-sectionally.	Self-report by parents of no. of doses missed over the last week. Noncompliant patients were those who missed a total of one day's dosage/week.	14%.	- Type of seizure. Reported reasons for noncompliance: Wrongly registered appointments, forgetfulness, busy parents.	- Child's age, sex, nationality, family size, area of residence. -Attendance for appointments. - Side effects. - Susceptibility to illness consequences. - More belief in alternative medicine.

Study (author, country, date)	Disease condition	Sample size	Aspects of adherence studied	Method of data collection	Method of measuring nonadherence	Estimate of nonadherence	Variables found linked nonadherence	Variables not found linked to nonadherence
Roaeid and Kablan 2007, Libyan Arab Jamahiriya.	Diabetes (both types).	805 (health care free of charge).	Adherence to diabetes care activities (diet, exercise, blood pressure checks, eye exams, HbA1c measurement, blood and urine glucose monitoring, and medications).	Cross-sectional questionnaires filled by doctors.	Self-report, through an interview with doctors. No clear definition of noncompliance.	27.1% reported they were not taking their medications regularly.	- Not assessed.	- Not assessed.
Kamel et al. 1999, Egypt	Diabetes (both types).	300 insured patients.	Adherence to diet, smoking cessation, physical activity, medications, periodic check-ups (BP, eye exams, blood and urine glucose monitoring), self-care activities (foot care, skin care and weight monitoring).	Cross-sectional questionnaires filled during an interview.	Self-report through an interview: Compliance was poor when <50%, satisfactory when 50-75%, and very good when >75% of medications were taken -not clear how percentages were calculated, and over what period of time.	1.7% had poor 20% had satisfactory 78.3% had very good compliance to their medications.	-	Knowledge of medication names and types, and administrative procedures of insulin.

Study (author, country, date)	Disease condition	Sample size	Aspects of adherence studied	Method of data collection	Method of measuring nonadherence	Estimate of nonadherence	Variables found linked nonadherence	Variables not found linked to nonadherence
Al-Sowielem and Elzubier 1998, Saudi Arabia.	Hypertension.	190.	Adherence to medications.	Cross-sectional study using structured questionnaires administered by trained interviewers.	Self-report+ therapeutic outcome (BP) (DBP>90 mmHG). No clear definition of compliance.	Noncompliance was 25.3% based on self-report. 65.8% based on blood pressure measurements.	Age (-), literacy (+), regularity of follow-up (-). Younger age, more educated patients with less frequent follow ups.	-Difficulty with compliance, continuity of care, preference for place of care, no. of drugs, mode of diagnosis, comorbidity.
Al-Saffar et al. 2003, Kuwait.	Depression.	176.	Adherence to medications.	Cross sectional study through patients' interview.	Self-report (non-compliance was defined as failure to take medications as prescribed). and pill counts (non-compliance was defined as taking <80% of their tablets).	24% based on self-report. 30% based on pill counts.	- Female sex (+), intentions to take therapy (-), unsure whether illness is more psychological than medical (-) and disagreeing with that view(-), uncertainty whether doctors can do little (-), belief that depression is best treated by medications (-). - Concern about addictive nature of therapy (+).	- Patient characteristics. - side effects.

Study (author, country, date)	Disease condition	Sample size	Aspects of adherence studied	Method of data collection	Method of measuring nonadherence	Estimate of nonadherence	Variables found linked nonadherence	Variables not found linked to nonadherence
Al-Saffar et al. 2003, Kuwait.	Depression.	152 (1st follow-up). 117 (2nd follow-up).	Adherence to medications.	Cross-sectionally measured adherence at two points of time (at 2 and 5 month).	Self-report (non-compliance was defined as failure to take medications as prescribed) and pill counts (non-compliance was defined as taking <80% of expected intake).	Nonadherence to medications in the control group at both follow-ups was 88%.	Reported reasons of nonadherence: Feeling better, inability to remember due to being so unwell, inability to see usual doctor, persuasion from friends, medicine didn't seem to be working, side effects, concerns regarding dependency.	- Side effects. -Belief that the doctor really understood their condition. - Concern of therapy's restrictions on lifestyle/work.
Bassili et al 1998, Egypt.	Asthma.	250 children.	Adherence to medications.	Cross-sectional questionnaires filled by doctors.	Self-report through an interview with the doctor (compliance assessed through direct/indirect questions followed by final judgment by the doctor that the patient was either compliant or non/poorly compliant).	2.8% noncompliant or poorly compliant with symptomatic management during acute attacks. 38.4% noncompliant or poorly compliant with prophylactic management (avoiding precipitating factors and use of preventive drugs).	- Not assessed.	- Not assessed.

Study (author, country, date)	Disease condition	Sample size	Aspects of adherence studied	Method of data collection	Method of measuring nonadherence	Estimate of nonadherence	Variables found linked nonadherence	Variables not found linked to nonadherence
Jabbar and Al-Shammari 1993, Saudi Arabia.	Epilepsy.	104.	Adherence to medication.	Prospective study. Unclear about data collection tool and who administered it.	Pill count (patients who missed a total of three days' doses/month were noncompliant).	30.8%.	-Education (-), adverse effects of disease on patients (+) Reasons for noncompliance: - Disbelief in the value and need for adherence to treatment. - Forgetfulness.	- Age. - Sex. - Marital status. - Family history. - Duration and type of seizure.
Al-Jahdali et al. 2007, Saudi Arabia.	Asthma.	334 adults.	Adherence to inhaled corticosteroid medications.	Prospective study using structured interviews with an investigator.	Self-report No clear definition of nonadherence.	38%.	Age (+), Education (-), Negative perception of ICs e.g., side effects, fear of addiction (+) Reported reasons: Belief that ICs should be used only as needed, forgetfulness, feeling lazy, feeling fine, feeling better with bronchodilators.	- Severity of asthma. - Duration of asthma.

Study (author, country, date)	Disease condition	Sample size	Aspects of adherence studied	Method of data collection	Method of measuring nonadherence	Estimate of nonadherence	Variables found linked nonadherence	Variables not found linked to nonadherence
Elzubier et al. 2000, Sudan.	Hypertension.	198.	Adherence to medications.	Cross sectional structured questionnaires.	Pill counts, mainly, verified by BP measurements, patients self-report was also considered (Noncompliant patients were those taking <80% of their medications).	About 40%.	Inability to pay for medications (+) Presence of complications (+) having uncontrolled blood pressure (+).	- No of drugs. - Dosage regimen. - Means of obtaining drugs (free/bought). - Regularity of drug intake. - Absence of disease symptoms. - Side effects of drugs. - Lack of belief in drugs.
Fido and Husseini 1998, Kuwait.	Psychiatric patients.	120.	Adherence to medications.	Prospective study using a checklist.	Self-report Non-compliance was defined as failure to take medications as prescribes for a period greater than a week.	55%.	-Age (-), male sex, being single, education (-) -Previous multiple hospital admissions. Reported reasons for noncompliance: Fear of dependence, fear of social stigma, complexity of treatment regimen, side effects.	-

Study (author, country, date)	Disease condition	Sample size	Aspects of adherence studied	Method of data collection	Method of measuring nonadherence	Estimate of nonadherence	Variables found linked nonadherence	Variables not found linked to nonadherence
Khalil and Elzubier 1997, Saudi Arabia.	Hypertension.	347 (69.4% response rate).	Adherence to medication.	Prospective questionnaire filled by six trained interviewers.	Pill count (average of two visits two weeks apart), verified by BP measurement. Noncompliant patients were those taking <80% of their medications, based on the average.	47%.	Sex (male), age (+), side effects (+), presence of complications(-) follow up in PHC rather than hospital(+), duration of disease (+), duration of treatment (+), no of drugs (+), education (-) Reasons for non-compliance (asymptomatic nature of disease, shortage of drugs, side effects, forgetfulness, lack of health education).	- Continuity of care with one physician. - Marital status - Source of drugs (free, bought) - Complexity of regimen.
El-shazly et al. 2000, Egypt.	Diabetes (both types).	1000 Insured and non-insured patients.	Adherence to medication, appointments, diet, blood and urine self monitoring of glucose.	Cross sectional study using questionnaires filled by trained doctors.	Unclear how compliance was measured.	11% (15% in non-health insured patients, and 6% in health insured patients).	Being non-insured (+).	- Not assessed.

Study (author, country, date)	Disease condition	Sample size	Aspects of adherence studied	Method of data collection	Method of measuring nonadherence	Estimate of nonadherence	Variables found linked nonadherence	Variables not found linked to nonadherence
Youssef and Moubarak 2002, Egypt.	Hypertension.	316 health insured patients.	Adherence to medications, and lifestyle measures (smoking cessation, ideal weight, diet, exercise).	Cross sectional questionnaire.	Self-report. Full compliers were those not missing a single dose. Partial compliers were those taking 90% or more of the prescribed pills during the previous month. Noncompliers are those taking less than 90% of their pills.	About 26%.	Education (-) side effects (+), blood pressure control (-), presence of complications (+), smoking (+), compliance with fat restriction and salt restriction (-), knowledge of hypertension(-), perceptions of benefits of treatment (-) and susceptibility to complications (+). Most frequently reported reasons for non-compliance: Feeling that blood pressure was normal, forgetfulness, wanting a drug holiday, side effects.	- Patients demographic variables (age, sex, marital status). - Duration of illness. - No. of drugs. - Dose frequency - Presence of other illness. - Compliance to ideal body weight. -Compliance with exercise. - Perception of danger of hypertension.

Study (author, country, date)	Disease condition	Sample size	Aspects of adherence studied	Method of data collection	Method of measuring nonadherence	Estimate of nonadherence	Variables found linked nonadherence	Variables not found linked to nonadherence
Fahey et al. 2006, UAE.	Hypertension.	203 patients.	Adherence to medication.	Cross sectional study using a modified 7-item Morisky scale and a ten-item questionnaire developed for the study to elicit doctor's perception of patients' adherence.	Self-report and Doctor's estimation of patients' adherence (80% or more of doses taken correctly) Both methods were compared to target blood pressure, effectiveness of treatment, quality of communication, patient knowledge, seriousness of the condition.	Based on patients' self-report, nonadherence (those taking 80% or less of their doses) was 48%. Based on doctors' estimation nonadherence was 29%.	Adherence to medication based on doctors' evaluation was positively correlated to treatment effectiveness, communication quality, patient knowledge and condition seriousness. Adherence to medication based on self-report was positively correlated with achieving target blood pressure and negatively associated with the doctors' evaluation of the seriousness of the disease.	-

Moreover, with the exception of one study (Fahey et al., 2006), none of the studies using self-report as the method of measuring adherence have used validated questionnaires to measure adherence to medication. For example, some asked patients about the number of tablets they had missed over a specific period of time (Khattab et al., 1999; Kamel et al., 1999; Youssef and Moubarak, I, 2002; Abdulghani et al., 2002), while others simply asked patients whether they were taking their medications as prescribed (Fido and Husseini, 1998; Roaeid and Kablan, 2007; Al-Saffar et al., 2005; Al-Saffar et al., 2003). Yet in some studies, no clear definition of adherence was used, and it was unclear how patients self-reported their adherence to medications (Al-Sowielem and Elzubier, 1998; Al-Jahdali et al., 2007; El-Shazly et al., 2000).

1.8.4.1.2 Studies of adherence/nonadherence to medications in diabetes

No studies were found addressing the issue of adherence/nonadherence to diabetic medications in Kuwait. As for the other Arab countries, only four studies where found (Khattab et al., 1999; Roaeid and Kablan, 2007; Kamel et al., 1999; El-Shazly et al., 2000) estimating that about 1.4-27.1% of diabetic patients were nonadherent to their medications in the Middle East. However, drawing conclusions from these figures is limited by several inherent flaws in the study designs, methods of assessing adherence to medication, definitions, and sampling strategies employed.

One of the major drawbacks of the studies is that each study used a different definition of adherence/nonadherence. In two of the four studies (Roaeid and Kablan, 2007; El-Shazly et al., 2000), there was no clear definition of adherence/nonadherence included at all.

As for the methods used in assessing adherence to medications, there was also inconsistency which makes comparisons difficult between these studies. Two studies used self-report only (Roaeid and Kablan, 2007; Kamel et al., 1999), while another used self-report in addition to pill counts (Khattab et al., 1999), and the last study was unclear about how nonadherence was determined (El-Shazly et al., 2000). In addition, although both Kamel et al. (1999) and Khattab et al. (1999) classified adherence as poor, satisfactory/fair and good/very good, they differed in how patients were designated into each category. Khattab et al. classified patients into these categories based on the number of tablets they missed per month, whereas Kamel et al. based their classification on the percentage of

tablets taken by patients compared to those that they should be taking. In Roaeid and Kablan's study, adherence was simply determined by doctors who enquired whether patients took their medications as prescribed or not (a method with an increased risk of reactivity and social desirability biases).

Moreover, with the exception of one study (Khattab et al., 1999), sampling strategies in all four studies included patients with both type 1 and T2DM, and the extent of nonadherence to medication was not estimated for each type separately. This makes it difficult to predict the extent of nonadherence to medication in patients with T2DM in particular, which is the focus of this thesis.

Type 1 diabetic patients are essentially treated with insulin, whereas T2DM is treated mainly with oral hypoglycemic medications and the use of insulin is reserved for later stages of the disease. In addition, the average age of onset varies substantially between the two conditions. With these variations, it is most likely that patients may have different barriers and concerns about their medication, and therefore, the extent of nonadherence to medication is most likely to be different in both types of the disease.

Furthermore, none of the four studies properly assessed predictors and/or barriers of adherence/nonadherence to medications in patients with diabetes in the Middle East. This was simply because this was not the scope of any of the four studies, although Khattab et al. (1999) attempted to find associations of adherence/nonadherence to medications with patient, disease, or care characteristics and met with no success. This was unsurprising as systematic reviews have failed to find links between demographic, care and disease characteristics and patients' adherence to medications (Haynes, 1976a).

1.8.5 T2DM as a major health problem in Kuwait

Diabetes is emerging as major clinical and public health concern among the Kuwaiti population. The reported prevalence rate of known T2DM in 1990 was 7.6%, ranging from 5.6 to 10% in different governorates (Abdella et al., 1996). In 1996, the overall prevalence rate of T2DM in Kuwaiti adults of 20 years of age and over was as high as 14.8% (Abdella et al., 1998). In addition, according to the WHO's latest statistics, the prevalence of diabetes in Kuwait was 104,000 out of 2,779,000 of the total population in 2000 and it is expected to increase to 319,000 in 2030 (WHO, 2007).

The burden of diabetes in Kuwait is high, and it has a serious impact on morbidity and mortality (Abdella et al., 1998), as well as hospital admissions due to complications.

Given the continually increased burden of the disease (increasing the healthcare costs and decreasing patients' quality of life) and the large increase in the development of complications each year, nonadherence to treatment appears a likely explanation for the problem. Despite the availability and accessibility of the Kuwaiti population to the best available and most advanced treatments for diabetes, patient outcomes are far from optimal and the development of complications continues to be a problem in many patients, leading to blindness, end-stage renal disease, stroke, coronary artery disease and peripheral vascular disease leading to ulcerations and limb amputations.

There is evidence that patients' adherence to medication in T2DM is sub-optimal worldwide. Systematic reviews estimated that nonadherence to medications in T2DM is high, reporting frequencies of 7-64% for oral hypoglycaemic medications, and 19-46% for insulin only or insulin concomitant therapy (Cramer, 2004; Lee et al., 2006).

The literature search concluded that nonadherence to medication remains an unresolved problem despite decades of research (Vermeire et al., 2001). It was highlighted that one of the most striking reasons for the lack of progress in the adherence research is the absence of the patient's perspective (Donovan, 1995). Although there are some studies in the literature exploring patients' perceptions of illness and medications as well as barriers and facilitators of adherence to treatment in T2DM in other parts of the world, there are no studies exploring these issues in Kuwaiti patients with T2DM.

In addition, traditional Western perspective models used to explain nonadherence to medications may be inappropriate for Kuwaiti patients, and other unexplored factors might emerge because nonadherence to medications represents a dilemma that may be deeply rooted in the lifestyle and culture of the Kuwaiti population. If good predictors of patients' nonadherence can be identified, interventions to improve adherence can be devised.

1.8.6 Aims of thesis

This thesis aims to:

1. To explore barriers to adherence to medications, and to a lesser extent, barriers to other diabetes self-care behaviours (e.g., medication, diet plans, exercise, self-blood glucose monitoring, and foot care) among Kuwaiti participants with T2DM.

2. To assess the prevalence of nonadherence to diabetes medications (and other diabetes self-care behaviours) among Kuwaiti patients with T2DM and identify factors related to it based on findings from the exploratory study.

CHAPTER 2

AN EXPLORATORY STUDY OF KUWAITI T2DM PATIENTS' PERPECTIVE OF BARRIERS TO ADHERENCE TO MEDICATION AND OTHER DIABETES SELF-CARE BEHAVIOURS

2.1 INTODUCTION

Located in the north-east corner of the Arabian Peninsula, Kuwait is one of the smallest countries in the world in terms of its land area (17,818 sq/km). According to the 2005 census, the population of the country stands at approximately 3 million, of which, only 992,000 are Kuwaiti nationals (Al-diwan Al-Amiri, 2010). The state of Kuwait is divided into six governorates; Al-Asima, Hawalli, Al-Ahmadi, Al-Farwaniya, Al-Jahra, and Mubarak Al-Kabeer. The governorates are further subdivided into several districts.

In terms of the healthcare services, the public health system is the predominant healthcare system in Kuwait and is governed by the Ministry of Health (MOH). It is based on three levels of health care delivery: primary, secondary and tertiary health care. Primary health care is delivered through a series of health centers. These include general or family health clinics, maternal and child care clinics, diabetic clinics, dental clinics, and preventive care clinics, school health services, ambulance services and police health services are also available. Secondary health care is provided through six general hospitals, while tertiary health care is provided through a number of national specialized hospitals and clinics. The health care delivery system is regionalized so that each of the six general hospitals, along with a number of primary health centers which refer to it, constitutes a health region (Ministry of Information, 2010).

Health care services are provided free of charge for all Kuwaiti nationals. Before 1994, non-Kuwaiti nationals were also entitled to free medical services, but now they are charged for certain non-emergency procedures. A small standard administration fee of 1-2KD (i.e., about 2-£4) is now required from all non-Kuwaiti nationals for admission to polyclinics and hospital, respectively. However, all emergency and outpatients services are

free of charge and non-Kuwaiti nationals are not charged for medication provided by government hospital pharmacies on prescriptions from hospital doctors.

According to the International Diabetes Federation (IDF), Kuwait is one of the six countries in the Middle East and North African Region which are among the world's 10 highest for diabetes prevalence and impaired glucose tolerance IGT prevalence. The ageing of the population, together with the high socio-economic and lifestyle standards has contributed to the increase in diabetes prevalence as a result of oil production. The country has undergone major social and economic changes, including progressive urbanization, decreasing infant mortality and increasing life expectancy. Consequent to urbanization, the lifestyle of Kuwaiti people shifted towards the westernized pattern, including changes in nutrition, less physical activity, tendency to increased obesity and more smoking among the Kuwaiti population (IDF, 2010). As a result, type 2 diabetes mellitus (T2DM) is emerging as a major public health concern, with a reported incidence of 14.8% among Kuwaiti adults over 20 years of age (Abdella et al., 1998).

The evidence shows that good quality of life and delayed complications can be achieved with well-controlled diabetes (Rubin and Peyrot, 1999; UK Prospective Diabetes Study (UKPDS) Group, 1998a; The Diabetes Control and Complications Trial (DCCT) Research Group, 1993). Management of diabetes relies mainly on adherence to medications, in addition to other self-care behaviours including diet modification, exercise, self blood glucose monitoring (SBGM), foot care and smoking cessation.

Despite decades of research focusing on adherence to medications, in Kuwait this area of research still remains in its infancy with only three studies addressing the area of nonadherence to medications in Kuwait (Al-Saffar et al., 2005; Al-Saffar et al., 2003; Fido and Husseini, 1998). All of these studies, however, involved psychiatric patients. Up to date, there is a lack of evidence in the literature investigating nonadherence in T2DM among the Kuwaiti population, and steps to address this major public health problem are of prime importance. As discussed in Chapter 1, section 1.8.3 many studies in the Western world have explored nonadherence to medications and shed some light on barriers to medication adherence in T2DM patients, however these barriers may not be applicable to Kuwaiti patients. The lifestyle of Kuwait's must be understood within a framework of Islamic religion, Arabic tradition and other cultural customs, which may influence adherence to

medications among this population. Identifying barriers to medication adherence could aid the development of targeted interventions designed to improve adherence to medications. This could have a far larger effects on patients' health than any treatment itself (Haynes et al., 2005; Haynes, 2001).

2.2 AIMS AND OBJECTIVES

2.2.1 AIM

To explore barriers to adherence to medications and barriers to other diabetes self-care behaviours among Kuwaiti participants with T2DM.

2.2.2 OBJECTIVES

1- To explore the extent of nonadherence to medications among participants, and identify the causes of nonadherence.

2- To identify factors associated with nonadherence to medications in Kuwaiti T2DM patients:

- Knowledge about diabetes, its etiology, its complications, its management strategies.
- Views and experiences regarding diabetes medications.
- Views and experiences with alternative/herbal medicine.
- Views and experiences regarding their health care providers.
- Views and experiences on the current health care system at the Ministry of Health.
- The impact of diabetes on participants' lives.
- Actual or perceived social support.

3- To investigate adherence to other diabetes self-care behaviours (e.g. diet, exercise, SBGM and foot care) among participants and to identify factors associated to nonadherence to these aspects of therapy in T2DM.

2.3 METHODS

This section will describe the methods used and justify the choice of specific measures and procedures to meet the study objectives.

2.3.1 Study design and rational for methods chosen

Due to the exploratory nature of the research aim and objectives of this part of the thesis, qualitative methods were chosen. Qualitative methods are considered most appropriate

for "how" and "why" questions (Smith, 2002). Unlike quantitative methods, qualitative methods provide rich descriptions and explanations of the processes in identifiable local contexts (Miles and Huberman, 1994). With qualitative data, one can precisely explore which events lead to which consequences, and derive fruitful explanations (Miles and Huberman, 1994). In addition, qualitative methods were more appropriate at this stage as findings of the exploratory study were meant to be incorporated into and inform the development of a quantitative survey which would be used to test the relevance of these findings, and assess the prevalence of nonadherence to medications and other diabetes self-care behaviours among a larger sample of Kuwaiti patients with T2DM.

Having chosen a qualitative approach, the next step was to determine which qualitative method would be most appropriate to meet the research aim. Although focus groups can be used to meet my research aim, they were not chosen as they require participants to be mobile, motivated, and confident to express their opinions in the presence of others. In Kuwait, focus groups appear not to have been used before so there might be problems with patients' acceptability of the method. Culturally, it is neither usual nor favourable for patients to discuss their issues with strangers, especially in groups of mixed gender. In addition, focus groups may not allow deep exploration of patients' perceptions. One study employing the methods of group interviews in addition to individual interviews found that more in-depth discussions were gained from individual interviews compared to group interviews (Mitchell, 1996).

In contrast, qualitative in-depth interviews provide a more private context, whereby respondents can freely express their individual opinions, and the researcher may have a better opportunity to deeply explore the processes and patterns that shape peoples' behaviours and attitudes. In addition, in-depth interviews enable the researcher to clarify ambiguities, ask for more details, and check inconsistencies and misinterpretations (Bowling, 2004). Taking the aim and objectives of the study and the limitations of each method into consideration, qualitative in-depth face-to-face interviews were chosen as the method for data collection.

2.3.2 Development of the interview topic guide

To meet the aim and objectives, a semi-structured topic guide was developed. Topics included were based on a review of the literature of factors that may influence medication adherence. The interview topic guide included both open-ended and closed questions. Closed

questions were mostly used to gather factual data (e.g., are you currently treated with tablets, insulin or both for your diabetes?). Open-ended questions were used to capture and expand on the participant's experience relevant to the topic of interest (e.g., could you describe your experience of taking your diabetes tablets/insulin?). Furthermore, probes were also used to aid in deeper exploration of the participant's perspectives, as recommended by Smith (2000). For example, in relation to the above question, probes used were (effectiveness, practical difficulties, adverse effects?). It should be noted that leading questions were avoided as they could introduce bias. Bowling (2004) explained that some respondents may be uncertain about their answers and may be more reluctant to contradict the interviewer who appears to know the answer he/she is expecting. Patients would most probably agree with the answer the interviewer is expecting in order to skip through to the next question (Bowling, 2004). The interview topic guide was divided into nine main topics, as illustrated in Table 2.1.

Table 2.1: The interview topic guide

Interview Topic Guide
Diagnosis
Knowledge about diabetes and medications
Views and experiences with diabetes medications
Views and experiences with alternative/herbal medicines
Views and experiences with healthcare providers (doctors, pharmacists, nurses, dieticians)
Views and experiences with current health care system at the Ministry of Health
Impact of diabetes on participant's life
Actual/ perceived social support
Adherence to other diabetes health care behaviours (diet, exercise, SBGM, foot care)

As illustrated in Table 2.1, the topics were mainly designed to stimulate participants to talk about issues that might be related to their adherence to their oral hypoglycemic medications or insulin (e.g., their experiences with diagnosis, knowledge about diabetes/its medications, experiences with diabetes medications, experiences with alternative/herbal medicines, experiences with healthcare providers, experiences with current health care system, impact of diabetes on their lives, actual/ perceived social support).

Although it was not the main interest of this research to deeply explore issues related to barriers to adhering to other aspects of diabetes management (e.g., diet, exercise, SBGM, foot care), these were briefly explored. Using closed questions, participants were asked whether they performed each of these self-management behaviours (e.g., do you exercise?).

If they answered with a "yes", they were further asked to describe what and how they do this (e.g., what kind of exercise do you do and how often?). If participants answered with a "no", they were asked to describe barriers preventing them from doing so (e.g., if not, what are the reasons?). The full interview topic guide is attached in Appendix 1.

The interview topic guide allowed the researcher to identify barriers participants might have faced while adhering to their medications (and other diabetes self-care behaviours) and to expand on their individual experiences. Two remarks relating to the interview topic guide are worth noting. Firstly, the interview topic guide was not rigid; more questions were added during the course of the interviews as issues of concern were raised by participants. Therefore, the researcher followed and expanded on arising issues to ensure obtaining participants' individual experiences and concerns. Secondly, respondents were allowed to talk freely and in no particular order as recommended by Smith (2000), which allowed exploration of topics according to the issues raised by participants. In this way, the researcher was able to tell which issues were most relevant and important to each participant.

2.3.3 Measurement of adherence to medications

As a way of triangulation, participants' adherence/nonadherence to their medications were assessed using self-report in two ways: using interview data (as will be detailed in Section 2.4.2.1), and a validated measure for assessing adherence to medications, the Morisky Adherence Scale (MMAS).

The MMAS, developed by Morisky et al. in 1986 was originally developed to measure adherence to antihypertensive medications. The original questionnaire included four items related to medication-taking behaviour and showed adequate psychometric properties in the original study (Morisky, et al., 1986). The scale was later developed and modified to an 8-item medication adherence scale, by supplementing it with additional items addressing the circumstances surrounding adherence behaviour. The modified scale was validated using a sample of 1367 patients with hypertension, and had improved psychometric properties, with a reported internal reliability of 0.83 (Cronbach's alpha). Sensitivity of the measure to identify patients with poor blood pressure control was also improved and estimated to be 93%, and the specificity was 53%. Concurrent validity of the scale was established by assessing correlation of the scale scores with those of the previously validated 4-item scale using Pearson's correlation coefficient (Pearson correlation of 0.64; $p<0.05$). Predictive

validity of the scale was established by assessing associations between adherence with blood pressure levels, knowledge, attitude, social support, stress, coping and patient satisfaction with clinic visits; all variables were significantly associated with medication adherence and in the predicted directions ($p<0.05$). Patients who displayed high knowledge of the medical regimen, higher satisfaction with medical care, positive family member social support, and stronger coping behaviour were significantly more likely to have high levels of adherence. On the other hand, patients who reported high levels of stress, greater complexity of the medical regimen, and poor perceived health status were found to have significantly lower levels of medication adherence. Confirmatory factor analysis indicated that the eight-item scale was uni-dimensional and the items loaded well on the single factor (Morisky et al., 2008). Due to the favourable psychometric properties, it was decided to use it in this study for assessment of participants' adherence to their medications.

However, the Morisky 8-Item Adherence Scale was developed, validated and tested for use in English language and the empirical evidence supporting the validity and reliability of the scale was based on a study conducted among English-speaking patients. It was therefore necessary to translate and adapt the measure before it could be used in this research. Parallel blind technique was employed (Behling and Law, 2000), which involves the use of two translators independently translating an instrument to the target language. The two translations were then compared and discrepancies in the translation were noted and resolved by discussion.

The agreed translated version was then assessed by an expert panel against the English version, and the final version was piloted among Kuwaiti T2DM patients for comments on the comprehensibility and appropriateness of the language in the Kuwaiti cultural context. For the detailed methods of translation and adaptation of the 8-item Morisky Questionnaire, and the rational for the selection of these methods, refer to Chapter 3 (Section 3.3.1.2.8), as the methods employed were the same as those used for translation of other research instruments used in Chapter 3. Table 2.2 illustrates the items of The Morisky 8-Item Adherence Scale.

Table 2.2: Items of The Morisky 8-Item Adherence Scale

The Morisky 8-Item Adherence Scale
1-Do you sometimes forget to take your [health concern] pills?
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 [health concern] medicine?
3-Have you ever cut back or stopped taking your medication 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 [health concern] medication?
5-Did you take your [health concern] medicine yesterday?
6-When you feel like your [health concern] is under control, do you sometimes stop taking your medicine?
7-Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your [health concern] treatment plan?
8-How often do you have difficulty remembering to take all your medications?

Participants were asked to rate their responses relating to items 1-7 using a dichotomous response yes/no (yes=1, No=0). Responses relating to the last item were on a five-point Likert scale (0 = never/rarely, 1= once in a while, 2 = sometimes, 3= usually, and 4= all the time). Items 1-4, and 6-8 were then reverse coded in order to make the scale range from low adherence to high adherence. Item 8 was also standardized by dividing this item by 4, resulting in a scale with a range of 0 to 8.

Adherence level of participants was then categorized according to the scale's authors instructions using a three categorical breakdown of score values of the scale which were based on research among patients diagnosed with essential hypertension, such that:

- Low Adherence (< 6)
- Medium Adherence (6 to <8)
- High Adherence (= 8)

Adherence level of participants is reported in the Results, Section 2.4.2.2.

2.3.4 Ethical approval

The study was approved by Research Ethics Committee of the Ministry of Health (MOH), State of Kuwait. A copy of the ethics approval is attached in Appendix 2.

2.3.5 Sampling and recruitment of patients

A purposive maximum variation sampling technique was applied. This involves purposefully picking a wide range of variation on dimensions of interest (Patton, 1990). Although the sample obtained was not meant to be statistically representative of all Kuwaiti patients with T2DM, efforts were made to ensure that the sample recruited reflected the diversity of Kuwaiti patients with T2DM. Patients of various demographic and clinical characteristics were included (the sample varied in terms of age, gender, area of residence, education level, employment status, marital status, duration of diabetes, place of diabetes care, mode of treatment, dosage regimen, presence of complications and presence of comorbidities). Therefore, the data collected allowed a range of perspectives to be identified.

A sample of Kuwaiti patients with T2DM was recruited from different general practices and hospitals of Kuwait. Patients were approached as they presented for their diabetes outpatient appointments. Before the researcher approached patients, she made sure to inform the doctors in each of the diabetes clinics about her presence and about the nature and aim of her research. They were also provided with a leaflet which briefly explained the study, and included contact details of the researcher for further information (Appendix 3). This was done to ensure their cooperation and avoid their frustration. At the beginning of the study, it was envisaged that doctors would assist in recruiting patients for interviews as the researcher imagined, due to the novelty of qualitative research in Kuwait, that patients may not cooperate unless the doctor recommended them to do so. However, during the piloting stage of the research, the researcher found that patients were cooperative and were happy to be interviewed and tape recorded. Therefore, the researcher decided to approach and recruit patients herself without involving doctors. This was to avoid bias that may result from doctors selecting certain patients. In addition, although doctors were not provided with the interview schedule, many questions were directed at exploring patients' relationship with doctors and problems associated with the care they provided. If doctors were involved in patient recruitment, patients would have found it difficult to disclose negative information about their doctors.

Recruitment of patients from the Kuwait Diabetes Association (KDA) was also considered at the beginning of the study. The KDA is the only support group available to diabetic patients in Kuwait, and is located in Kaifan area. Some Kuwaiti diabetic patients are

registered with it and regularly attend there to buy blood glucose monitoring equipment and test strips which are sold to them at half price. However, the KDA was not used for recruiting patients, as there would be bias towards including patients who were possibly highly motivated. Patients who buy test strips and blood glucose monitoring equipment may be more likely to be adherent to their medications and thus less likely to be facing problems adhering to their medications. It was therefore ruled out as a place for patient recruitment.

Sampling was guided by emerging data and continued until no new themes appeared (i.e., when saturation of data was achieved). This was achieved with 20 participants. All but three participants were recruited from various clinics and hospitals as they presented for their diabetes outpatient clinic appointments. As for the three participants, the first participant was known to the researcher (a relative who had T2DM), the second participant was a friend of the first participant who also had T2DM, and the third participant was a relative of a friend of the researcher who also had T2DM. Interviews with these participants were meant to constitute the piloting and testing stage of the interview schedule. However, the themes which emerged from these interviews were similar to those obtained from other participants. It was therefore decided not to exclude them from the sample. The first three participants were interviewed at home. The remaining 17 participants were interviewed at the hospital or polyclinics were they were recruited from, as they preferred. The researcher gave them the choice to be interviewed later at a time and place of their convenience. Several options were offered, including a private room at the Kuwait Diabetes Association, a seminar room at the Health Sciences Centre (part of Kuwait University), a local cafe, or participants' own homes. Participants were also given the chance to select an alternative setting they might have preferred. The aim was to ensure that the context was private, quiet, comfortable and not intimidating. Apart from the first three, all other participants preferred to be interviewed at the hospital/clinics immediately after their consent. With regards to the specific location of interviews, 13 participants were interviewed in the outpatient open area, while 4 participants who were interviewed in a closed blood laboratory room.

The researcher introduced herself as a PhD student who was independent and separate from the hospital or polyclinic health care team. This was done to ensure obtaining patients' honest and accurate views. The researcher then explained to the participants that the aim of the study was to explore their views and experiences with their medications, as well as their

disease and how they managed it. The agenda of the interview was hidden (i.e., was not too obvious for participants) as participants were given only a vague idea of the central topic of the study so that spontaneous reactions could be obtained instead of thought out positions. Participants were assured that their participation is voluntary, and that their views will be anonymous and confidential. Participants were also assured that the conduct of the study would have no impact on the healthcare they received by their healthcare professionals (e.g., doctors, pharmacists, nurses, etc.), as their responses would be anonymous and would not be communicated to their healthcare providers. Participants were also assured that there were no right or wrong answers and that their honest views and opinions were the primary interest of the study. If respondents were willing to and could spare the time, they were given a patient information leaflet which further explained the study's aims and processes, along with contact details of the principal researcher for further details (Appendix 4). Once, they had agreed to participate, participants were asked to sign a written consent (Appendix 4) to allow the interview to be digitally-recorded, transcribed, analyzed and published. Confidentiality and anonymity were re-emphasized at this point.

2.3.6 Inclusion and exclusion criteria

Tables 2.3 and Table 2.4 list the inclusion and exclusion criteria for this study.

Table 2.3: Inclusion criteria for this study

Inclusion criteria
Kuwaiti, 18 years of age and older. Diagnosis with T2DM Prescription of medications for management of diabetes (oral hypoglycaemic tablets, insulin or both)

Table 2.4: Exclusion criteria for this study

Exclusion criteria
Non Kuwaitis, and those aged under 18 Patients with Type 1 diabetes mellitus or gestational diabetes Patients with T2DM who are diet controlled Patients with salient physical distress or cognitive dysfunction hindering their ability to participate

2.3.7 Conduct of the interviews and transcript production

Interviews were conducted, digitally-recorded and transcribed verbatim in Arabic by the principal investigator. Field notes (e.g., participants' emotions, facial expressions, pauses, change in tone, interruptions) were also taken and included in the transcripts. This was done

to ensure capturing important information about the context that might facilitate data analysis. Photographs of the location were also taken using a mobile phone camera to help with remembering the context of each interview, which proved helpful when analyzing the data. Reflective remarks were also included into the transcripts, as recommended by the literature (Miles and Huberman, 1994). These were entered as memos to differentiate them from the original interview data. Reflective remarks included:

- Personal reactions to participants' remarks or actions.
- Elaboration or clarification of an incident that seem significant.
- Doubts about the quality of some of the data.
- Mental notes to pursue an issue further in the next contact.
- Cross-allusions to material in another part of the data.

Careful attention was given to the way the interviews were concluded, as the investigator was aware that participants may provide rich information at the end of interviews. The principal investigator concluded the interviews in the following manner:

'I think we have covered everything I needed to ask you. Thank you very much, you have been most helpful. Is there anything else you think that you wanted to say?'

After concluding, the recorder was switched off, and the participant was thanked again. Some participants provided rich information once the tape recorder was switched off. These were recorded as soon as possible after the respondent had left. Any additional field notes were also recorded. The outcome of this process was incorporated into the transcripts. Interview transcripts were then ready for analysis.

2.3.8 Translation

Translation was necessary in this study, as the research team members in the United Kingdom (N.B. and T.B.) were both non-Arabic speakers. To allow for discussion regarding findings and analysis of data among the research team, decisions regarding translation needed to be made, particularly in relation to when the process of translation needed to take place (before vs. after the coding data of transcripts). It was decided for data analysis, coding, and theme generation to be all conducted in Arabic. Final themes were translated into English language. This approach was adopted for the following reasons:

- It would have the advantage of preserving the cultural meanings and conceptions in the Arabic language linguistic expressions that are difficult to translate into English and might affect the final results if translation was done in the early stages, i.e. before data analysis.
- There is lack of semantic and conceptual equivalence across languages. Although identifying words or phrases in the target language that had meanings matching those in the source language may have been possible, it would have been labor intensive and would not add to the quality of overall findings.
- If translation preceded data analysis, it would have compromised the quality of analysis to ensure the quality of translation, which was less important considering the aims of this research.

The literature highlighted problems in data analysis when translation preceded data analysis. This was noted in one study using semi-structured interviews of Cantonese patient and nurses. Although there was no major differences in the major categories identified whether analysis was carried out directly from Chinese transcripts or from the translated transcripts into English language, there were minor differences in the generation of themes within each category. Difficulties also emerged relating to translation of words for which there is no true equivalence within the source language (Twinn, 1997). Previous work by the same author showed that during analysis of translated data, an enquiry about a particular response from one respondent prompted the request for translation of a section of the interview by another bilingual nurse. As her interpretation was quite different, a third nurse was asked to translate the data. Interestingly, all three translations were different from one another (Twinn, 1994). Therefore, it was decided to analyse data of interviews and field notes in Arabic, then to translate the final themes into English. This was done simultaneously and independently by the principal researcher and another bilingual researcher (B.A.). Then, final themes were compared for consistency and inconsistencies were resolved by discussion.

2.3.9 Data analysis approach

Framework analysis was used the method for analysis of qualitative data. The method, first developed during the 1980s at the National Centre for Social Research, is a matrix-based analytic method which facilitates rigorous, transparent and systematic data management allowing researchers to move back and forth between different levels of abstraction without losing sight of the 'raw' data (Ritchie et al., 2003). Framework analysis

derives its name because it involves the use of a 'thematic framework', which is used to classify and organize data according to key themes, concepts and emerging categories. This carried out in a systematic process of sifting, charting and sorting material according to key issues and themes (Ritchie and Spencer, 1994). The approach was selected due to its several advantages, which suit the demands and constraints of applied policy research. The main strength of the approach is that it allows for reconsideration and reworking ideas because the analytical process is documented and is therefore accessible. Ritchie and Spencer (1994) highlighted six key features or advantages for framework analysis, as illustrated in Table 2.5.

Table 2.5: Key features and advantages of framework analysis

Key features	Explanation
Grounded or generative	It is heavily based on, and driven by, the original accounts and observations of the people it is about.
Dynamic	It is open to change, addition and amendment throughout the analytic process.
Systematic	It allows mechanical treatment of all similar units of data.
Enables easy retrieval	It allows access to, and retrieval of, the original textual material.
Allows between and within case-analysis	It enables comparisons between, and associations within cases to be made.
Accessible to others	The analytic process, and the interpretations derived from it, can be viewed and judged by people other than the primary analyst.

The framework analysis approach involves five distinct though highly interconnected stages, and data analysis was carried out according to these stages in the following manner as recommended by Ritchie and Spencer (1994):

1- Familiarization: In this stage the principal researcher read all interview transcripts to become familiar with the range and diversity, and to have an overview of the body of data gathered. The researcher immersed herself in the data, listening to tapes, reading transcripts along with field notes. During this stage, the researcher started making notes, jotting down and listing key ideas and recurrent themes.

2- Identifying a thematic framework: The researcher returned to the notes and attempted to identify key concepts and themes to which the data could be examined and referenced. This stage ended with creating a thematic framework within which the data could be sifted and sorted. The thematic framework was set-up drawing-upon *a priori* issues (those informed by the original research aims introduced by topic guide), emergent issues raised by participants, and analytical

themes which were based on recurrent views or experiences. The thematic framework was refined intuitively and moved from being largely descriptive and heavily rooted in *a priori* issues to being more responsive to emergent and analytical themes. This was done by constantly making judgments about meaning, relevance and importance of issues as well as connections between ideas.

3- Indexing: At this stage, the researcher systematically applied the thematic framework or index to individual transcripts. It should be noted that when indexing, single passages contained several themes, the researcher paid attention to this. This multiple indexing allowed capturing patterns of association between data.

4- Charting: This stage involved formulating a picture from the data as a whole by considering the range of attitudes and experience for each issue or theme. The data are removed from their individual contexts and rearranged according to the themes. Charts were devised with headings and subheadings derived from the thematic framework, from a priori research questions, or according to considerations about how best to present and write up the findings. Charts were devised for each key subject area and entries were made for several participants (i.e., cases) on each chart. That way, charting of data into matrices assisted in spotting similarities and differences between cases. Each matrix included a theme, and the subthemes that constitute it. Columns represented the separate subthemes, and rows represented the cases (i.e., participants). This way the researcher was able to summarize in each cell what each participant had said with regards to each theme/subtheme. References to line numbers were also included in each cell summarizing the data, to facilitate referring to the original text for more details. In cases where the participant had failed to discuss a theme at all, it was noted as N.D. (not discussed) inside the relevant cell. This helped the researcher differentiate between those who did not discuss a theme at all, and those for whom the issue was raised but found not relevant and they did not wish to elaborate on it. An example of one matrix is attached in Appendix 5. Cases were kept at the same order for each subject chart, and the height of the row for each case was kept the same so that the whole data set for each case could be reviewed easily.

5- Mapping and interpretation: At this stage, the researcher began to pull together key characteristics of data and to map and interpret the data set as a whole. Although emergent categories, associations and patterns started during the indexing and charting stages, the deeper and systematic process of detection was done at this stage. In order to capture the overall picture, the researcher weighed up the salience and dynamics of issues and searched for a structure, rather than a multiplicity of evidence.

2.3.10 Validity and reliability of analysis

A researcher (M.W.) who is a Kuwaiti assistant professor at the Faculty of Pharmacy of Kuwait University was approached to ensure the reliability and validity of coding of Arabic transcripts due to his particular experience in qualitative research and his personal interest in the area of adherence to medications, in addition to his competence in Kuwaiti language and culture as a native speaker. Two interview transcripts, interview 14 and interview 16 (2/20, 10%), were co-coded separately and independently by (M.W.) and the main investigator (F.A.). The two then met and compared their codes. Disagreement between the researchers was calculated based on both:

- Cases of disagreement in concepts (i.e. when the researchers identified totally different concepts in the data).
- Cases of missed coding by either researcher (i.e. when M.W. or F.A. missed coding a segment of text while the other had coded it)

However, cases where both researchers saw similar concepts in the data, but the wording of one was more specific than the other, were not considered as a disagreement. For example:

'S.A.: The doctor doesn't teach you. He only examines me, writes me the medications, and then when he sees something wrong, he gets frustrated and gets mad at me. He would say "why didn't you take two tablets?" for example. But telling me that diabetes can lead to this or that, no, he doesn't tell you that.'

(Patient 14, line 77)

This segment was coded as "criticism of health care provider" by M.W., while F.A. was more specific and coded it as "relationship with doctor: paternalism". Since both were related

to the same underlying concept, this was not counted as a disagreement.

The number of agreements/disagreements between the two researchers in coding was counted, and inter-coder reliability was estimated using the following formula:

$$\text{Intercoder relibility} = \frac{\text{Number of agreements}}{\text{Number of agreements} + \text{number of disagreements}}$$

For the first transcript (interview 14) F.A. and M.W disagreed in concepts in two instances, and F.A. missed coding a segment of text in a third instance, giving a total of three instances of disagreements. The number of agreements was 41. Therefore:

$$\text{For interivew 14 intercoder relibility} = \frac{41}{3 + 41} = 93\%$$

For the second transcript (interview 16), there were no disagreements in concepts, but F.A. missed coding a segment of text which was coded by M.W. (i.e., resulting in one disagreement). The number of agreements was 55. Therefore:

$$\text{For interivew 16 intercoder relibility} = \frac{55}{1 + 55} = 98\%$$

In the end of this process all disagreements were resolved by discussion and all interview transcripts were re-visited to check for occurrence of the modified/added codes based on this outcome of this process. Due to the high inter-coder reliability achieved after the second transcript, it was decided to cease the validity check after two transcripts (the initial target was three transcripts).

In addition to the above, the researcher also consulted the research team in the UK (N.B. and T.B.) for their extensive experience in the area of adherence to further ensure the validity of coding, and ensure that important concepts related to medication adherence have not been missed by F.J or M.W. To achieve this, five coded interview transcripts (5/20, 25%) were translated by the main investigator to the English language, along with the coding index. To ensure validity and accuracy of translation, the translated transcripts and the coding index were checked by another PhD researcher from the School of Pharmacy, University of London (B.A.). She was selected due to her competence in the language and culture of Kuwait as a native speaker. After checking the translated transcripts, the UK research team

(N.B. and T.B.) reviewed the coding separately. The team were generally satisfied with the coding index and coding process. However, slight modifications were suggested and a few more codes added to the coding index (N.B. highlighted 10, T.B. highlighted 4). All interview transcripts were re-visited to check for occurrence of the modified/added codes based on the outcome of this process. In addition, several measures were also taken to ensure validity of findings:

- A large amount of quotes with rich data were used, this allowed illustration of contexts within which the data emerged.
- If new codes were added, all previous interviews were re-visited and examined for the relevance of these codes. This ensured consistency and thoroughness of coding.
- Generation of themes and conclusions from data was described in detail in the results section, to ensure transparency for the reader.
- Where themes emerged, a search for negative cases was carried out and explanations were sought to explain the opposing views. This also ensured including all findings rather than selected views.
- The interview topic guide was flexible, and more questions were added to it as themes emerged to test relevance and confirmation of the findings in subsequent participants and to seek further clarification of ambiguous findings.
- As discussed before, two teams of researchers with experience in adherence research were involved in coding, theme generation and data analysis. Discussions with the teams were invaluable to clarify ambiguities and ensure credibility of findings.
- All participants were contacted after completion of data analysis. Final themes were shared with participants and they were asked whether the final themes represented what they were trying to deliver during interviews.
- Results were compared with evidence from previous studies of diabetic patients with T2DM from other countries as a final check for validity.

2.3.11 Use of computer software

A qualitative data indexing software package MAXQDA 2007 was used to facilitate coding and retrieval of data. This software is designed to allow researchers using qualitative data to systematically evaluate and interpret their texts. The software allowed coding segments of text, storing the transcribed text in an organized form, searching and retrieval of

particular segments of texts for inspection, linking relevant data to form categories, writing memos, counting frequencies of words or phrases, drawing of conclusions and verification.

2. 4 RESULTS

Twenty one Kuwaiti patients with T2DM were approached by the main investigator. All but one agreed to participate in the study. Time constraint was the reason for rejection, as the patient did not have time to be interviewed at the same time and also did not wish to be interviewed at a later point of time. Interviews were carried out between February and June, 2008. As detailed in Section 2.3.5, seventeen out of twenty interviews were conducted at the polyclinic or hospital where the participants were approached and the remaining three were conducted at the participants' homes. In the hospitals/polyclinics, participants were interviewed immediately after consenting as most participants preferred this, and showed no signs of rush or distress. The interviews were conducted at a quiet place at the hospital or polyclinic where participants were recruited (e.g., in the outpatient waiting area, at the blood glucose monitoring lab, or the head nurse's room). Careful attention was given to make sure no one was around who could overhear or affect the flow of the interview, which made interruptions minimal. One participant was interviewed with her carer, which was her son. In this case, the researcher reminded the participant and the carer about the importance of the responses being from the participant herself. In instances where the carer gave his responses, the researcher re-directed the questions back to the participant and re-emphasised the importance of her individual answers to questions.

Participants were interviewed using a semi-structured interview topic guide (Appendix 1). The topic guide was followed in each interview, however, where new issues emerged in one interview, the researcher asked about these in subsequent interviews, as a way of triangulation and confirming the findings as described earlier. Interviews duration ranged from 11 to 47 minutes, with a mean duration of 29 minutes. At the end of the interviews, all participants were asked to fill in the 8-item Morisky scale to assess their adherence to their diabetes medicines. All participants preferred that the main investigator read the questionnaire for them, and they responded accordingly.

2.4.1 Demographic and clinical profile of participants

Interviews were conducted with 20 Kuwaitis with T2DM. The age of participants ranged from 35 to 74 years (mean age 53.7 years). The sample participants were equally

distributed by gender. Eighteen participants were married and living with their families. Two participants were single (one divorced, one widowed), although one of them was still living with other family members. Fourteen participants were living in urban areas of Kuwait, while the other six were living in rural areas. Sixteen patients had another chronic disease(s) in addition to their diabetes (i.e., cardiovascular disease, rheumatic /skeletal disease, respiratory disease, gastrointestinal disease, or other metabolic disease such hypothyroidism). As for education level of the sample, seventeen had received at least some formal education, and three were illiterate by self-report. Among the educated sample, education level varied greatly, from having completed one year of primary school through completing university level. Participants reported being diagnosed with diabetes for a variable duration of time (5 months-30 years). As for mode of treatment, fourteen patients were tablet-treated, one was insulin-only treated, and five were treated by combined therapy of tablets plus insulin. As for dosage regimens, one patient had a once daily regimen, nine patients were on a twice daily dosage regimen, six were on a three times daily regimen, and four were on four times or more daily regimen. Half of the participants (n=10) had already experienced complications from diabetes (i.e., heart disease, retinal damage, kidney disease and peripheral neuropathy). Table 2.6 summarizes the demographics and clinical variables of the participants.

Table 2.6: Demographics and clinical variables of participants

Demographics of Participants (N=20)			
Gender Male: 10 (50%) Female: 10 (50%)	**Area of residence** Urban: 14 (70%) Rural: 6 (30%)	**Duration of diabetes** < 1 year: 2 (10%) 1 year: 2 (10%) 5-10 years: 5 (25%) >10 years: 11 (55%)	**Comorbidity** Yes: 16 (80%)
Age (years) 30-39: 1 (5%) 40-49: 6 (30%) 50-59: 8 (40%) 60-69: 3 (15%) ≥70: 2 (10%) Range: 35-74 yrs Average: 53.7 yrs	**Employment** Working: 6 (30%) Retired: 10 (50%) Never worked: 4 (20%)	**Diabetes treatment** Tablets: 14 (70%) Insulin: 1 (5%) Tablets + insulin: 5 (25%)	**Evidence of diabetic complications** Yes: 10 (50%)
Marital status Married: 18 (90%) Divorced: 1 (5%) Widowed: 1 (5%)	**Education** University: 6 (30%) High school: 7 (35%) Intermediate: 3 (15%) Primary: 1 (5%) Uneducated: 3 (15%)	**Dosage regimen** Once daily: 1 (5%) Twice daily: 9 (45%) Three times daily: 6 (30%) ≥ Four x daily: 4 (20%)	**Place of diabetes care** Primary care: 13 (65%) Secondary care: 2 (10%) Shared care: 5 (25%)

2.4.2 Nonadherence level among participants

As previously detailed in the Methods, Section 2.3.3, nonadherence was assessed based on two self-reported methods, as a way of triangulation. Data from different methods were compared carefully to reach a classification for participants' level of adherence that was most plausible. At the time of conducting the interviews, it was not possible to collect HbA1c data from patients' medical notes, which prevented further comparison between self-reported adherence and clinical outcome. This section explores in detail nonadherence to medications among the sample using interview and MMAS data.

2.4.2.1 Nonadherence assessment from interview data

Twenty interviews were transcribed and coded in Arabic language by the researcher. Adherence of participants was assessed by carefully examining statements by which participants described their use of their medications. To make sure this was done in a systematic way, a coding frame was developed which listed all themes denoting nonadherence to medications.

The coding frame was dynamic and flexible, as more themes were added as they appeared in the interviews. Once a new theme was added to the coding frame, all previous transcripts were re-assessed for the occurrence of this theme. Table 2.7 illustrates the coding frame used for classifying and categorization of nonadherence among participants.

As illustrated in Table 2.7, statements that described participants' nonadherence to medicines were coded and classified in two different ways:
1- Intentional/unintentional: based on whether it was done consciously (deliberately) by patients, for example:

- Those who deliberately altered or stopped the use of the medicine (e.g. to avoid adverse effects, to suit their travel plans, to relieve the body, etc.) had intentional nonadherence.
- Those who, meant to, but failed to take the medicines as prescribed due to certain constraints (e.g., limitations in memory, limited access to healthcare, competing demands, etc.) had unintentional nonadherence.

2- Continuous/contextual/one-off nonadherence: based on the frequency of the occurrence of nonadherence, for example:

- Those who were nonadherent on a daily basis had continuous nonadherence.
- Those who were nonadherent only in specific situations (e.g. when travelling/being away from home, when distractions occur, etc.) had contextual nonadherence.
- Those who were nonadherent at only one particular point (or period) of time for any given reason, but never again, had a one-off nonadherence.

It is worth noting here that this classification is not clear-cut and categories may overlap, as some participants may be intentionally nonadherent at certain times and unintentionally nonadherent at other times. Similarly, some participants may be nonadherent in certain situations, but continuously. In addition, participants may be continuously nonadherent, but may also have instances of a one-off nonadherence or contextual nonadherence for example:

- Patients 1, 5, 9, and 11 all mentioned that they continuously do not take their medications at all in case of travelling. Similarly, Patient 13 mentioned that he continuously takes less of his medications when travelling. Although these behaviours occurred continuously, they happened only in the context of travelling. In order to be systematic in categorization of nonadherence, those who exhibited altered medication use within certain contexts, regardless of whether it was occasionally or continuously, were categorized as contextual nonadherers, as illustrated in the above examples. This is to differentiate them from those who are continuously nonadherent, on a daily basis.
- Patient 19 mentioned that he always took two tablets instead of the three prescribed by his doctor to avoid getting dizzy (i.e., continuous nonadherence). He also mentioned that two weeks ago, he had completely stopped taking his tablets altogether to test being without medications (i.e. one-off nonadherence). In addition, he mentioned that sometimes he tended to forget his tablets as a result of getting distracted (i.e. contextual nonadherence). Therefore, this patient had all three types nonadherence: continuous, contextual and one-off.
- Patient 16 mentioned that she sometimes forgot to take her insulin when she went out (i.e., unintentional nonadherence), although she also mentioned that sometimes

she would deliberately not take her insulin along with her if she was going out for a long time to prevent her insulin from getting spoiled due to the hot weather (i.e., intentional nonadherence). Therefore, this patient had combined intentional and unintentional nonadherence.

Table 2.7: Coding frame used for classifying and categorization of nonadherence

Themes denoting nonadherence to medications	Nonadherence coded as	Nonadherence coded as
Forgetting (e.g. due to distractions, tiredness, travelling/being away from home, having too many medications, timing of the dose).	Unintentional	▪ Contextual (if it occurs in certain situations) ▪ Continuous (if it happens all the time) ▪ One-off (if it happened once in a lifetime)
Slipping (e.g. taking the wrong medication by mistake).	Unintentional	▪ Contextual (if it occurs in certain situations) ▪ Continuous (if it happens all the time) ▪ One-off (if it happened once in a lifetime)
Changing of medications use (e.g., when feeling better, when feeling worse, when travelling, due to lack of awareness regarding medications/diabetes).	Intentional	▪ Contextual (if it occurs in certain situations) ▪ Continuous (if it happens all the time) ▪ One-off (if it happened once in a lifetime)
Avoiding to take medications (e.g. when going out, in situations where can be overseen by others due to social stigma).	Intentional	▪ Contextual ▪ Continuous (if it happens all the time) ▪ One-off (if it happened once in a lifetime)
Stopping medications (e.g. taking drug holidays from time to time to relieve the body, completely stopping use of medications after having observed no benefit or improvement).	Intentional	▪ Contextual (if it occurs in certain situations) ▪ Continuous (if it happens all the time) ▪ One-off (if it happened once in a lifetime)
Skipping doses occasionally (e.g. in fear of double dosing in case of forgetting, or to decrease potential for adverse effects).	Intentional	▪ Contextual ▪ Continuous (if it happens all the time) ▪ One-off (if it happened once in a lifetime)
Taking less of medications (e.g. due to adverse effects/fear of their occurrence or drug interactions/fear of their occurrence).	Intentional	▪ Contextual ▪ Continuous (if it happens all the time) ▪ One-off (if it happened once in a lifetime)
Experimenting with different patterns of dosing regimens (e.g. to improve effectives, decrease/avoid adverse effects, test oneself without/with less medicines).	Intentional	▪ Contextual ▪ Continuous (if it happens all the time) ▪ One-off (if it happened once in a lifetime)

Table 2.8 lists some statements from the interviews illustrating how participants' nonadherence was categorized based on the above categorizations.

Table 2.8: Quotes illustrating how types of nonadherence were classified

Quote	Intentional or unintentional	Contextual, continuous or one-off
'When I travel, I sometimes take less of my medications.' Patient 13, male, rural area, line 151.	Intentional	Contextual
'Sometimes, you know, when I'm out with family or when I'm invited outside for dinner I would take a couple of tablets instead of my insulin injection.' Patient 2, male, urban area, line 49.	Intentional	Contextual
'Sometimes when I'm travelling, the timings of my meals would change inevitably so the timings of my insulin injections would also change.' Patient 4, female, urban area, line 81.	Unintentional	Contextual
'I once took my husband's medicine by mistake.' *'I sometimes get distracted by housework and simply forget to take my medicines.'* *'I once stopped taking my Glucophage® tablet for a day to see if I could get away without it.'* *'I often forget whether or not I had taken my medicines, so when in doubt I would skip the dose rather than take it, to avoid taking the dose twice.'* Patient 10, female, urban area, lines 19, 37, 127,208.	Combined Intentional and Unintentional	Contextual and One-off
'I take my insulin twice only, even though my doctor prescribed it as three times daily because I am afraid I might get hypoglycaemias at night.' Patient 6, male, urban area, line 69.	Intentional	Continuous
'Two weeks ago, I stopped my medication completely, to rest my body because I was feeling a bit dizzy.' *'I take one tablet instead of the two I'm already prescribed because I feel dizzy when I take them both.'* *'Sometimes I forget to take my tablets, you know, you get distracted talking to people over dinner or lunch and forget your medicines.'* Patient 19, male, urban area, line 164 and line 162.	Combined Intentional and Unintentional	Combined Continuous, Contextual and One-off
'When I'm invited or going out somewhere, I forget to take my insulin along, and sometimes I wouldn't take it with me because of the weather, you know insulin needs to be kept in the cool so I don't take it when I go out. I take it when I get back home.' Patient 16, female, urban area, line 26-30.	Combined Intentional and Unintentional	Contextual

2.4.2.2 Nonadherence assessment from the 8-item Morisky Medication Adherence Scale (MMAS)

Assessment of nonadherence based on MMAS was based on the instruction of the scale's authors, as detailed in the Methods Section 2.3.3. According to the MMAS scores,

participants' adherence level was categorized as low (if MMAS score < 6), medium (if MMAS score 6 to <8) or high (if MMAS score= 8).

In addition to specifying the adherence level of participants, where existed, nonadherence of participants was assessed using the MMAS data in two ways (as in interview data):

1- Intentional/unintentional nonadherence:
   - Unintentional nonadherence by MMAS resulted if participants responded with a "yes" to items 1, 4, and 8 which denoted forgetting medications either generally, in travel or due to finding difficulties in remembering to take all medications.
   - Intentional nonadherence by MMAS resulted if participants responded with a "yes" to items 3 or 6 which denoted cutting back or stopping taking medication without telling the doctor because of feeling worse when taking medications or when feeling that diabetes was under control.

Note: Items 2, 5 and 7 were not used to classify participants as intentional or unintentional nonadherers as it was not possible to do so using these items:

   - Item 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 medicine?).
   - Item 5 (Did you take your diabetes medicine yesterday?).
   - Item 7 (Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your diabetes treatment plan?).

2- Continuous/contextual/one-off nonadherence:
   - Contextual nonadherence by MMAS resulted if participants responded with a "yes" to any item on the MMAS, which denoted whether the patient sometimes forgets to take his/her medications, whether the patient ever missed taking the medication over the past two weeks, whether the patient ever cuts back or stop taking the medications when feeling worse while taking them, whether the patient sometimes forgets to take the medications in travel or when away from home, whether the patient took the medications yesterday, whether the patient sometimes stops taking the medications when feeling that the disease is under

control, whether the patient ever feels hassled sticking to the treatment plan, and whether the patient ever finds difficulty remembering to take all medications.

Note: Continuous and one-off nonadherence were difficult to be captured using MMAS, as items wording hindered this. This will be explained further in Section 2.4.2.4.

Table 2.9 lists all research participants, compares their nonadherence behaviours based on interview data and MMAS responses. It also categorizes participants' nonadherence along the intentional/unintentional and the continuous/contextual/one-off dimensions, based on data from both the interview and the MMAS.

From Table 2.9 it can be seen that assessing patients' adherence to their medication is not a straightforward task, as it is difficult to extrapolate a pattern between intentionality and continuity of nonadherence, and data from different methods of adherence assessment (i.e., interviews, MMAS) may provide conflicting classification/categorization of patients' nonadherence in relation to these dimensions.

Figure 2.1 compares participants' adherence status based on interview data compared to their adherence level based on the MMAS, whereas Figure 2.2.and Figure 2.3 explore the relationship between intentionality of nonadherence (intentional/unintentional/combined) in relation to continuity of behaviuor (continous/contextual/one-off/combined) based on data from both interviews and the MMAS. Based on both methods interviews, 16/20 participants were nonadherent (n=16).

Table 2.9: Participants adherence behaviours based on interview data and MMAS data

Patient	Interview data		Contextual, continuous, or one-off nonadherence		Adherence level	Intentional or unintentional nonadherence	
	Continuous Nonadherence	Contextual Nonadherence	Based on interviews	Based on MMAS	Based on MMAS score	Based on interviews	Based on MMAS
1	-	▪ In travels (doesn't take medicines at all) ▪ Forgets (when tired, in case of distractions).	Contextual Nonadherence	Contextual Nonadherence	Medium Adherence (6.75)	Intentional and Unintentional	Unintentional
2	-	▪ When going out with family (takes tablets instead of insulin). ▪ When an adverse effect occurs such as hypoglycemia (stops medicines on own).	Contextual Nonadherence	Adherent	High Adherence (8.00)	Intentional	Adherent
3	-	-	Adherent	Contextual Nonadherence	Low Adherence (5.75)	Adherent	Unintentional
4	-	▪ In travel (might change timing of does).	Contextual Nonadherence	Contextual Nonadherence	Medium Adherence (7.75)	Unintentional	Unintentional
5	-	▪ In travels (doesn't take medicines at all). ▪ Forgets (poor memory). ▪ When unsure whether he took the medicine or not, he just skips it to avoid double dosing.	Contextual Nonadherence	Contextual Nonadherence	Low Adherence* (3.5)	Intentional and Unintentional	Intentional and Unintentional
6	▪ Takes insulin BD instead of TDS (fearing hypoglycemia). ▪ Takes Glucophage® OD or BD instead of TDS (depending on food intake).	-	Continuous Nonadherence	One-off Nonadherence	Medium Adherence (7.00)	Intentional	Unintentional
7	▪ Takes Glucophage® tablets BD instead of TDS (depending on food intake). ▪ Modifies doses (according to strength of tablets supplied).	▪ Takes a drug holiday sometimes (when feeling better). ▪ Forgets (when distracted by visitors or housework, when invited out, or at weddings).	Combined Continuous and Contextual Nonadherence	Contextual Nonadherence	Low Adherence (2.5)	Intentional and Unintentional	Intentional and Unintentional

Patient	Interview data		Contextual, continuous, or one-off nonadherence		Adherence level	Intentional or unintentional nonadherence	
	Continuous Nonadherence	Contextual Nonadherence	Based on interviews	Based on MMAS	Based on MMAS score	Based on interviews	Based on MMAS
8	-	-	Adherent	Adherent	High adherence (8.00)	Adherent	Adherent
9	▪ Takes Glucophage® BD instead of TDS (when feels well, feels no need for three tablets).	▪ In travel or when invited for food (doesn't take medicines). ▪ Forgets (when out in the desert). ▪ When adverse effects such as diarrhea occurs (stops medicines on own). ▪ Takes a drug holiday sometimes (to test being without medicines).	Combined Continuous and Contextual Nonadherence	Contextual Nonadherence	Low Adherence* (3.00)	Intentional and Unintentional	Intentional and Unintentional
10	▪ Changes timings of doses (in relation to meal timings).	▪ Forgets (when distracted by housework, when in a rush). ▪ Slipped once and took husband's medicines instead of own. ▪ Took a drug holiday once (to test being without Glucophage®). ▪ When unsure whether he took the medicine or not, he just skips it to avoid double dosing.	Combined Continuous, Contextual and One-off Nonadherence	Contextual Nonadherence	Low Adherence* (5.5)	Intentional and Unintentional	Intentional and Unintentional
11	▪ Takes less of medicines (fearing adverse effects, beliefs medicines could harm, not convinced of dose, lack of understanding, no observed benefit).	▪ In travel or when invited for food (doesn't take medicines). ▪ Sometimes skips medicines (fear of adverse effects, beliefs medicines could harm, no observed benefit).	Combined Continuous and Contextual Nonadherence	Contextual Nonadherence	Low Adherence (4.75)	Intentional	Intentional and Unintentional
12	▪ Takes Glucophage® OD instead of TDS (fearing hypoglycemia, due to small food intake).	-	Continuous Nonadherence	Contextual Nonadherence	Low Adherence (5.00)	Intentional	Intentional and Unintentional

Patient	Interview data		Contextual, continuous, or one-off nonadherence		Adherence level	Intentional or unintentional nonadherence	
	Continuous Nonadherence	Contextual Nonadherence	Based on interviews	Based on MMAS	Based on MMAS score	Based on interviews	Based on MMAS
13	▪ Omits doses (according to meal patterns)	▪ In travel (decreases doses dramatically, feels no need). ▪ Stopped diabetes medicines altogether for a few years in the beginning of diagnosis (lack of awareness). ▪ When with other people (avoids medicines due to social stigma). ▪ Forgets (due to distractions, when out with friends).	Combined Continuous, Contextual and One-off Nonadherence	Combined Contextual and One-off Nonadherence	Low Adherence* (2.5)	Intentional and Unintentional	Intentional and Unintentional
14	▪ Takes Glucophage® OD instead of BD (due to stomach ache, taking people's advice).	-	Continuous Nonadherence	Combined Continuous and Contextual Nonadherence	Medium Adherence (6.00)	Intentional	Intentional and Unintentional
15	-	▪ Skips the before food tablets (when forgets to eat first). ▪ Forgets (when out).	Contextual Nonadherence	Contextual Nonadherence	Medium Adherence (7.00)	Intentional and Unintentional	Intentional
16	-	▪ When out (doesn't take insulin). ▪ Forgets (when out).	Contextual Nonadherence	Contextual Nonadherence	Low Adherence (5.75)	Intentional and Unintentional	Unintentional
17	-	-	Adherent	Adherent	High Adherence (8.00)	Adherent	Adherent
18	▪ Skips morning tablets (according to food intake).	▪ Modifies doses (according to food intake). ▪ Forgets (distractions, after lunch).	Combined Continuous and Contextual Nonadherence	Contextual Nonadherence	Low Adherence (5.00)	Intentional and Unintentional	Unintentional
19	▪ Takes Glucophage® BD instead of TDS (due to dizziness, small food intake).	▪ Decreased intake to one tablet for a whole week (to test being without medicines). ▪ Forgets (due to distractions, after food).	Combined Continuous, Contextual and One-off Nonadherence	Combined Contextual and One-off Nonadherence	Low Adherence (5.00)	Intentional and Unintentional	Intentional and Unintentional

Patient	Interview data		Contextual, continuous, or one-off nonadherence		Adherence level	Intentional or unintentional nonadherence	
	Continuous Nonadherence	Contextual Nonadherence	Based on interviews	Based on MMAS	Based on MMAS score	Based on interviews	Based on MMAS
20	-	-	Adherent	Adherent	High Adherence (8.00)	Adherent	Adherent

*Participants with a missing MMAS item. Categorization of adherence was done after handling missing items

Figure 2.1: Scatterplot of participants' adherence status based on interview data compared to their adherence level based on the MMAS. Each 'o' represents a participant within the specific category (n=20).

MMAS / Interviews	Adherent	Nonadherent
High adherence	o o o	o
Medium adherence		o o o o o
Low adherence	o	o o o o o oo o o o

Figure 2.2: Scatterplot illustrating intentionality of nonadherence in relation to continuity of behaviour based on data from interviews. Each 'o' represents a participant within the specific category (n=16)

Nonadherence based on interview data	Intentional	Unintentional	Intentional + Unintentional
Continuous+ Contextual+ One-off			o o o
Contextual+ One-off			
Continuous+ Contextual	o		o o o
One-off alone			
Contextual alone	o	o	o o o o
Continuous alone	o o o		

Figure 2.3: Scatterplot illustrating intentionality of nonadherence in relation to continuity of behaviuor based on data from MMAS. Each 'o' represents a participant within the specific category (n=16)

Nonadherence based on MMAS data	Intentional	Unintentional	Intentional + Unintentional
Continuous+ Contextual+ One-off			
Contextual+ One-off			o o
Continuous+ Contextual			o
One-off alone		o	
Contextual alone	o	o o o o o	o o o o o o
Continuous alone			

The following section closely examines issues relating to the use of different methods of adherence assessment (interviews vs. MMAS). For ease of illustration, each categorization of nonadherence (intentional/unintentional vs. continuous/contextual/one-off) will be discussed separately, followed by a general comment common to both.

2.4.2.3 Exploring nonadherence from the intentional/unintentional dimension

- There were discrepancies of participants' nonadherence when different methods of self-report were employed (i.e., interviews and MMAS). What one method suggested was sometimes different or even conflicting to the other, and here are examples:
  - Based on interview data, patient 1 was classified as a combined intentional and unintentional nonadherer, as he admitted to stopping his medications on purpose in travel, and sometimes forgetting to take his medications, especially when he was tired. However, when the MMAS was used, only one aspect of his nonadherence was detected which is the unintentional nonadherence. The patient's responses to the items reflected that he found difficulty in remembering to take his medications at times. A possible explanation for that is that it might be the MMAS items did not include anything that would represent the patient's intentional nonadherence behaviour, so this aspect of his nonadherence was not detected using the MMAS.
  - Based on interview data, patient 2 was deemed an intentional nonadherer, as he admitted to altering the use of his medication when he is away from home, taking tablets instead of insulin. However, when the MMAS was used, the patient was found to be highly adherent to his medications, with a perfect MMAS score of 8. Similar to patient 1, it may be that items in the MMAS did not include anything that would represent the patient's behaviour, so his intentional nonadherence was not detected using the MMAS.
  - Based on interview data, patient 3 was classified as being adherent to his medications. However, responses to items on the MMAS reflected that the patient sometimes forgets to take his medications in general and in travel, and although rarely, he finds difficulty in remembering to take his medications at times. Therefore, the patient was categorised as an unintentional nonadherers by MMAS.

- Based on interview data, patient 6 was classified as an intentional nonadherer to his medications as he admitted to taking his insulin twice instead of three times to avoid hypoglycaemia, and also taking less of his Glucophage® tablets, depending on his food intake. However, when the MMAS was used, the patient was classified as an unintentional nonadherer as his responses to one of the items illustrated that he forgot to take his medications with him in travel. Similar to patients 1 and 2, it may be that items in the MMAS did not include anything that would represent the patient's intentional nonadherence behaviour, so his intentional nonadherence was not detected using the MMAS.
- Based on interview data, patient 12 was classified as an intentional nonadherer because she admitted to taking two instead of three tablets of Glucophage® prescribed to avoid hypoglycemias. However, based on MMAS the patient was classified as a combined intentional and unintentional nonadherer because her responses to MMAS items revealed that she cut back or stopped her medications as a result of feeling worse while taking medications, and that she sometimes forgot to take her medications when she travelled or went away from home.

- Even when both interview data and MMAS data were in agreement with regards to the categorization of patients' nonadherence into a certain category (e.g. intentional/unintentional), it was noted that sometimes, this classification was arrived at using different incidents the patient had in mind when responding to interview questions/MMAS items related to nonadherence. For example:
  - Patient 10 was classified as both an intentional and unintentional nonadherer, combined, based on both interview and MMAS data. Despite this agreement in classification, based on interview data, the patient was decided to be intentionally nonadherent because she had admitted to changing the timings of her insulin injections according to her meals pattern, taking a drug holiday for a certain period of time to test being without medications, and skipping the dose in case of forgetting whether she took her dose or not (to avoid double dosing). However, based on MMAS responses, the patient was decided to be intentionally nonadherent because she reported stopping her medications sometimes when she felt better.

- Similarly, based on interview data, the patient was decided to be unintentionally nonadherent because she had admitted to forgetting to take her medications due to distractions, doing housework or being in a rush. She also admitted to slipping at one occasion, mistakenly taking her husband's medication instead of her own. However, based on MMAS responses, the patient was decided to be unintentionally nonadherent because she reported difficulty in remembering to take all her diabetes medications sometimes.

- Generally, data from interviews were better at detecting intentional nonadherence compared with MMAS. With five participants (patient 1,2,6,16,18) it was possible to detect intentional nonadherence using interviews, but not with MMAS. In contrast, data from MMAS were better at detecting unintentional nonadherence. For example, with four participants (patient 3, 6, 12, 14) it was possible to detect unintentional nonadherence with MMAS but not with interview data.

2.4.2.4 Exploring nonadherence from the continuous/contextual/one-off dimension

It was more difficult to compare nonadherence of participants based on interview and MMAS data considering this dimension. In this respect, three remarks are important to note here:

- While interviews provided meaningful data allowing detection and separation of those who were continuously nonadherent, those who were nonadherent only in specific situations or within certain contexts (i.e., contextual nonadherers), and those who were nonadherent at a one particular point or period of time but never again (one-off nonadherers), it seems that data from the MMAS were of limited use in this respect. This is mainly because, looking at the MMAS items, it seems that they are worded in such a way as to allow detection of contextual nonadherence only, but not continuous nonadherence or one-off nonadherence. For example the items were designed to assess whether the patient forgets to take his/her medications *sometimes*, whether the patient ever missed taking the medication *over the past two weeks*, whether the patient ever cuts back or stop taking the medications *when feeling worse while taking them*, whether the patient *sometimes* forgets to take the medications *in travel or when away from home*, whether the patient took the medications *yesterday*, whether the patient *sometimes* stops taking the medications *when feeling that the disease is under control*, whether the patient

ever feels hassled sticking to the treatment plan, and whether the patient *ever* finds difficulty remembering to take all medications. Therefore, all 8-items inquire about nonadherence within specific contexts only and it was too optimistic to think that those who were continuously nonadherent or those who had a one-off nonadherence incident would be detected using these items. It is therefore unsurprising that only contextual nonadherence could be detected using the MMAS in most patients (13/17). In the four exceptional cases (patient 6, 13, 14, 19), it was possible to detect a one-off nonadherence or continuous forms of nonadherence in addition to contextual nonadherence using the MMAS. For example, while patient 6 was responding to item 4 (*When you travel or leave home, do you sometimes forget to bring along your diabetes medication?*), he expanded that it had only happened to him once, so this patient was categorized as a one-off nonadherer. Similarly, in case of patient 13 and patient 19, while responding to item 3 (*Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?*) they both explained that this had happened to them only once. Therefore, it was possible to detect a one-off form of nonadherence with these two patients using MMAS. In case of patient 14, based on her responses to MMAS items, it was possible to categorize this patient as a continuous nonadherer (in addition to being a contextual for forgetting to take her medications sometimes) because while responding to item 3 (*Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?*), she expanded that she *always* cuts back on taking her medication to avoid upsetting her sensitive stomach.

Table 2.9 illustrates that interview data were more comprehensive in terms of capturing the continuous forms of patients' nonadherence. Seven patients (Patient 7,9,10,11,13,18,19) who were categorized as contextual nonadherers using the MMAS, had also been continuously nonadherent based on the interview data, one of these (patient 10) even showed a one-off form of nonadherence in addition.

- Similar to when the intentional/unintentional dimension was examined, examination of nonadherence based on the contextual/continuous/one-off dimension showed discrepancies in categorization of participants' nonadherence when interviews vs. MMAS were used, for example:

- Based on interview data, patient 3 was classified as being adherent to his medications, however he was classified as a contextual nonadherer based on his MMAS responses, where he admitted to forgetting to taking his medications sometimes, especially in travel, and finding difficulty in remembering to take all his medications. This highlights that limitations in recall may exist when patients are asked to report previous behaviour at different points of time, and that different incidents may be remembered at each time. This might be a possible explanation for why the patient was adherent in interviews, but contextually nonadherent by MMAS. It is also possible that the patient may have found it easier to admit to nonadherence when prompted by questions, as in the MMAS items.
- Similarly, patient 6 was categorized as a continuous nonadherer based on interview data because he admitted to take less of his insulin and Glucophage® doses everyday to avoid getting hypoglycemias. However when MMAS responses were examined, the patient was deemed a one-off nonadherer as while responding to item 4 (*When you travel or leave home, do you sometimes forget to bring along your diabetes medication?*) he expanded by mentioning that this had happened to him only once.
- Patient 12 was classified as a contextual nonadherer based on MMAS responses because she admitted to being hassled at times about sticking to her medications and finding difficulty remembering to take all of her medications. However, when interview data were examined, the patient was classified as a continuous nonadherer because she admitted to take her Glucophage® once instead of three times daily as prescribed by the doctor, to avoid hypoglycaemias. A possible explanation for the discrepancies in categorization of patients 6 and 12 when using interview vs. MMAS data may link back to the first point which highlights the limited usefulness of the MMAS at detecting continuous forms of nonadherence.

- It is also worth noting here that, as with the intentional and unintentional dimension of nonadherence, even when both interviews and MMAS data suggested the same categorization for a given patient there were sometimes discrepancies in how the categorization was reached. This was because some patients apparently had

different incidents in mind during interviews and while responding to MMAS items. For example:

- When MMAS data were examined, patient 1 was categorized as a contextual nonadherer because he was hassled about sticking to his medications at times, and sometimes found difficulty remembering to take all of his medications. However, based on interview data, patient 1 was classified as a contextual nonadherer because he admitted to not taking his medications in travel (in addition to forgetting to take his medications at times). This issue was evident with five other patients (patient 2, 4, 5, 15 and 16).

2.4.2.5 General comment/conclusion

Assessing adherence using different patient self-reported methods is not straightforward and data provided by each method should be interpreted with caution, as different patients were sometimes categorized differently when different methods were used, as illustrated above. Therefore, categorization of patients using one method only may be incomplete, and should be assessed with reference to the other.

It is worth nothing that, in both methods, the interviews and the MMAS, patients were asked to recall their medication-taking behaviour in general, without specifying a certain period of time and therefore one might expect that nonadherence data would be similar using each method. However, there were differences in participants' answers and three possible explanations seem plausible. Firstly, two out of the 8 items of the MMAS actually do specify a time period for patients to recall their behaviour:

- Item 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 medicine?"
- Item 5 "Did you take your diabetes medicine *yesterday*?"

This might have made it easier for participants to recall their behaviour when the MMAS was used. Secondly, as previously described, is that the MMAS scale items seems to be worded in such a way to allow detection of contextual forms of nonadherence and overlooks the continuous forms of nonadherence where the patients continuously altered their medication use. Interview data were therefore better at detecting continuous nonadherence. Thirdly, data from interviews and MMAS may have been inconsistent

simply because participants were asked about their behaviour at two different points of time. Therefore, they may have recalled and reported different incidents of nonadherence with different methods of self-report.

As for the categorization of nonadherence as intentional/unintentional using interviews compared to MMAS, it was found that interviews fared better at detecting intentional forms of nonadherence compared to MMAS. A possible explanation might be that MMAS items did not cover all possible scenarios denoting intentional nonadherence for patients to admit to. In contrast, the MMAS fared better at detecting unintentional nonadherence, with three of its items clearly worded to capture and denote forgetting.

It is best to compare two or more methods to assess nonadherence to medications based on self-report. What is missing from one method might be completed or better explained through the other. For example if one patient was found intentionally nonadherent in interviews but unintentionally nonadherent in MMAS, then the patient is probably a combined intentional and unintentional nonadherer. Similarly if a patient was found contextually nonadherent in MMAS and continuously nonadherent in interviews, then the patient is most probably a combined continuous and contextual nonadherer.

However, problems arise when adherence assessment from one method contradicts that of the other. For example, a patient may be found adherent in one method but nonadherent in another (e.g. patient 2 was adherent based on MMAS data but nonadherent based on interview data, in contrast to patient 3 who was adherent based on interviews but nonadherent when MMAS was used). As it is more likely that those who report nonadherence to medications are likely to be telling the truth (compared to those who report adherence), it was decided that, wherever patients admitted to committing nonadherence, whether in interviews or MMAS, they would be categorized as nonadherent.

Table 2.10 lists participants' final adherence/nonadherence categorization based on data from both interviews and MMAS.

Table 2.10: Participants' final adherence/nonadherence categorization based on data from both interviews and MMAS

Patient	Contextual Continuous or one-off	Adherence level (based on MMAS)	Intentional or Unintentional
1	Contextual Nonadherence	Medium Adherence	Intentional and Unintentional
2	Contextual Nonadherence	High Adherence	Intentional
3	Contextual Nonadherence	Low Adherence	Unintentional
4	Contextual Nonadherence	Medium Adherence	Unintentional
5	Contextual Nonadherence	Low Adherence*	Intentional and Unintentional
6	Combined Continuous and One-off Nonadherence	Medium Adherence	Intentional and Unintentional
7	Combined Continuous and Contextual Nonadherence	Low Adherence	Intentional and Unintentional
8	Adherent	High Adherence	Adherent
9	Combined Continuous and Contextual Nonadherence	Low Adherence*	Intentional and Unintentional
10	Combined Continuous, Contextual and One-off Nonadherence	Low Adherence*	Intentional and Unintentional
11	Combined Continuous and Contextual Nonadherence	Low Adherence	Intentional and Unintentional
12	Combined Continuous and Contextual Nonadherence	Low Adherence	Intentional and Unintentional
13	Combined Continuous, Contextual and One-off Nonadherence	Low Adherence*	Intentional and Unintentional
14	Combined Continuous and Contextual Nonadherence	Medium Adherence	Intentional and Unintentional
15	Contextual Nonadherence	Medium Adherence	Intentional and Unintentional
16	Contextual Nonadherence	Low Adherence	Intentional and Unintentional
17	Adherent	High Adherence	Adherent
18	Combined Continuous and Contextual Nonadherence	Low Adherence	Intentional and Unintentional
19	Combined Continuous, Contextual and One-off Nonadherence	Low Adherence	Intentional and Unintentional
20	Adherent	High Adherence	Adherent

*Participants with a missing MMAS item. Categorization of adherence was done after handling of missing item

2.4.2.6 Relating different types of nonadherence

This section explores whether different types of nonadherence, as categorized in this study, would be related, i.e. whether intentional/unintentional types of nonadherence is associated with continuous/contextual or one-off nonadherence. Table 2.11 below lists all study participants, and the different types of nonadherence they exhibited, based on data from both interviews and the MMAS.

Table 2.11: Types of nonadherence among participants

Patient	Intentional	Unintentional	Continuous	Contextual	One-off
1	✔	✔		✔	
2	✔			✔	
3		✔		✔	
4		✔		✔	
5	✔	✔		✔	
6	✔	✔	✔		✔
7	✔	✔	✔	✔	
8					
9	✔	✔	✔	✔	
10	✔	✔	✔	✔	✔
11	✔	✔	✔	✔	
12	✔	✔	✔	✔	
13	✔	✔	✔	✔	✔
14	✔	✔	✔	✔	
15	✔	✔		✔	
16	✔	✔		✔	
17					
18	✔	✔	✔	✔	
19	✔	✔	✔	✔	✔
20					

✔ Patient exhibited this type of nonadherence.

Table 2.11 illustrates that both intentional and unintentional nonadherence are more associated with contextual than with continuous nonadherence. Continuous and contextual nonadherence are both common among intentional and unintentional nonadherers. All but one of intentional nonadherers (14/15) and all but one of unintentional nonadherers (15/16) had contextual nonadherence. A similar proportion of intentional nonadherers (10/15) and unintentional nonadherers (10/16) had continuous nonadherence. Therefore, there was no pattern to be extrapolated.

2.4.2.7 Limitations to use of the MMAS

Although it was tested on only 20 participants, several limitations were noted when using MMAS in assessing nonadherence to medications in this study. One limitation was

due to methodological issues relating to the way it was administered to participants. However most of the limitations were related to the wording of the items, and the design of MMAS responses. This section discusses the limitation of MMAS in more detail.

- Although the MMAS was administered by the researcher to all 20 participants as they have requested, unfortunately for some reason responses to item 7 (*Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your blood pressure treatment plan?*) were missing for patients 5, 9, 10, and 13. It is not clear why the researcher missed to take the participants' responses to this item in particular so frequently. When implications of this were examined, fortunately, with 3 out of these 4 participants (patient 5, 9, and 13) the missing response for the item would not have made a difference in their overall score, and therefore categorization into low, medium or high adherers (i.e., their adherence would have been categorized in the same way whether they had provided a "Yes" or a "No" answer). In the one case (patient 10) where it would have mattered, the researcher had consulted interview data to try to extrapolate the participant's response to this item. In the interview, the patient had admitted that adherence to her insulin and tablets were a real inconvenience to her and therefore, her response to item 7 was extrapolated to be a "Yes", making her total score 5.5, and redeeming her a "low adherer".
- It is not clear from the instructions provided by the scale's authors whether scores should be rounded up to the nearest whole number or left as they are, including two decimal places. These decimals were inevitable as the operationalization instructions for item 8 suggested inverting the score for this item and then dividing it by four which results in scores including one or two decimal places. If rounding up was recommended, four patients would have ended up with a different level of nonadherence; patient 4 would have ended up having a high adherence level (rather than medium adherence) and patients 3, 10 and 16 would have had a medium adherence level (instead of low adherence).
- As a result of the above-mentioned point, patient 4 ended up having a medium nonadherence level despite having a nearly perfect score of 7.75 out of 8.00. The patient had a perfect response to all about one item, responding by "Once in a while" to the 8th item (*How often do you have difficulty remembering to take all*

your medications?) and therefore scoring a 0.75 instead of 1 for this item. Implications of this means that this patient ended up having a medium adherence level, just like anyone else who scored low on two different items.

- Some items were not easily interpreted by participants or were interpreted differently by different participants, which may have biased their total scores. For example, for item 1 in particular (*Do you sometimes forget to take your diabetes medicines?*), patient 11, 14 and 18 all provided a "Yes" response and they all followed by mentioning that this had occurred very rarely. Patient 15 also mentioned that he tends to forget his medications very rarely, yet he provided a "No" answer, probably because he thought that the rarity of such incident did not warrant a "Yes" response. A five-point Likert scale may have been more appropriate and averted problems like this, instead of the rigid dichotomous Yes/No responses provided by the MMAS.

  As for item 4 (*When you travel or leave home, do you sometimes forget to bring along your diabetes medication?*), there was also a problem of interpretation by different patients. For example patient 6 responded by a "Yes" but mentioned that he had done so only once, while patient 11 responded by a "Yes", but mentioned that he did this continuously and on purpose and not because of forgetting (i.e., continuous nonadherence). Although both patients had responded by a "Yes", they were exhibiting entirely different forms of nonadherence behaviour; an unintentional, one-off nonadherence in the first case and an intentional, continuous nonadherence in the second case. As previously discussed, a five-point Likert scale may have averted problems like this and allowed for accommodation for the diversity of participants' behaviours.

- Some items were not applicable to some patients but patients still provided responses to them anyway for the sake of completing the questionnaire which might have introduced bias. For example, item 4 (*When you travel or leave home, do you sometimes forget to bring along your diabetes medication?*) was not applicable for patient 14 because she had never travelled since she was diagnosed with diabetes (however, she still provided a "No" response). Similarly, item 3 (*Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?*) was not applicable for patient 13 because he once had

stopped taking his diabetes medications not because of feeling worse while taking them, but because of lack of awareness as his doctor had not told him the need to continue taking them indefinitely at diagnosis (however, he still provided a "Yes" response).

- The MMAS seems to over-estimate the importance of some issues in leading to unintentional nonadherence behaviour and overlooking other issues. For example, three out of its eight items are worded to detect whether patients "forget" to take their medicines. However, the MMAS ignored other causes of unintentional nonadherence such as lack of awareness, manual dexterity problems, poor vision which might interfere with medication taking, etc. As for intentional nonadherence, the MMAS items are worded in such a way to allow detection of those who took less of their medications, either when feeling worse or when feeling that their diabetes was under control. These items do not represent all possible reasons for intentional nonadherence. In addition, the MMAS items ignore those who may take more of their medications for whatever reason.
- Although the MMAS can detect both intentional and unintentional nonadherence, it is difficult to specify the exact reasons of nonadherence that had occurred, apart from those which were explicitly mentioned by the items (i.e. forgetfulness, stopping or cutting back on medications because of feeling worse or feeling that diabetes is under control). As far as the continuous/contextual/one-off nonadherence dimension is concerned, the MMAS is not useful at detecting other than the contextual aspect of nonadherence, as previously illustrated.

2.4.3 Thematic framework:

As detailed in the Methods Section 2.3.9, a thematic framework was used to facilitate data analysis. The following section further illustrates the thematic framework used in this study. The final thematic framework used in this study included eleven major topics, which were based on the interview topic guide as well as emerging themes. Therefore eleven matrices were created. Themes and subthemes which emerged relating to each topic were placed in the relevant matrix as separate columns, then participants' views relating to these were summarized in each cell, as described previously. Emerging themes were explored in later interviews for confirmation/clarification. For example, one participant explained that taking medications in front of people was embarrassing and

considered having diabetes as socially stigmatizing. Therefore, *social stigma* was created as a theme that may have influenced medication adherence. In all subsequent interviews the researcher enquired about this issue for further clarification and confirmation (Could you describe your feelings regarding having to take your medications when surrounded by other people, e.g. friends, family, colleagues, etc.?). The thematic framework was therefore flexible. Once a new theme/subtheme emerged, all previous transcripts were also checked for its recurrence. Table 2.12 illustrates matrix topics, and types of themes/subthemes included in each matrix.

Themes/subthemes related to each of the eleven topics highlighted in Table 2.12 fell into three major categories: (1) barriers/facilitators of medication-taking (2) barriers to other diabetes self-care behaviours (i.e., diet, exercise, self-blood glucose monitoring, and foot care) (3) information/service needs. The first two categories were part of the research objectives. The third category emerged from interviews and was placed in a separate category. Table 2.13 lists all themes/subthemes that emerged from interviews in relation to each of the major categories.

Section 2.4.4 will discuss all themes/subthemes found in this study, along with direct quotes of participants' interviews. Because of the unique life and attitudes of the participants in this study, it was decided to use a large number of quotations to illustrate a new culture's perspective which is vastly neglected by the literature. In quotations, where dots were used, it indicated that some text have been taken out to draw attention to the main point being illustrated.

Table 2.12: Matrix topics and types of themes/subthemes included in each matrix

Matrices	What it included
Patient characteristics/clinical variables.	This matrix included themes/subthemes related to participants' demographic, social, and clinical variables. Information relating to whether or not participants' adhered to diet, exercise, self-blood glucose monitoring, and appointments was briefly included in this general matrix. This matrix was mainly used as a classification matrix to show variation of the sample in terms of characteristics for comparison purposes.
Knowledge about diabetes	This matrix included themes/subthemes related to participants' knowledge about their diabetes, or medications, regardless of whether it was correct or not.
Impact of illness	This matrix included themes/subthemes related to how diabetes had affected the participants' life.
Coping with diabetes	This matrix included themes/subthemes related to participants' strategies of coping with diabetes/its diagnosis.
Management of diabetes	This matrix included themes/subthemes related to how participants managed their diabetes on a daily basis, i.e., whether (and how) they followed any diet plan, performed any exercise, self-monitored their blood glucose levels, or checked their feet. Response to diabetes-related emergencies were also included in this matrix. Medication-taking behaviours were not included in this matrix.
Health care providers	This matrix included themes/subthemes related to healthcare providers, e.g., their style of communication with patients, education and counseling, attitude towards patient care, etc.
Health care system	This matrix included themes/subthemes related to the health care system, e.g., access issues, organization issues, policy issues, etc.
Medicines	This matrix included themes/subthemes related to medications, e.g., use of alternative medicines, beliefs about medicines, types/reasons of nonadherence to medicines, and anything else related to medications as they emerge from interview data. Issues of social support relating to medication-taking, self-efficacy with regards to medication-taking were also included in this matrix.
Diet nonadherence	This matrix included themes/subthemes related to any reasons for nonadherence to diet.
Exercise nonadherence	This matrix included themes/subthemes related to any reason for exercise nonadherence.
Information/Service needs	This matrix included themes/subthemes related to any proposed/suggested information or service needs.

Table 2.13: themes/subthemes that emerged from interviews in relation to each category

Category	Themes/subthemes identified within this category
Barriers/facilitators of medication-taking	**Health care provider related factors** Attitude towards patient care Paternalism and lack of compassion Little/no patient education and counseling Favouritism/inequality of care provision Inflexibility with appointments Inadequate care/medical examination Discontinuity of care **Personal factors** Knowledge about diabetes/medications Beliefs about medicines Medications are necessary for the management of diabetes Medications are ineffective at controlling blood glucose levels Medications are harmful chemicals, and they have adverse effects Doctors overprescribe medications Brands/country of origin of medications influence their quality Perceptions of social support Attitude towards illness Denial Down-playing severity of diabetes Fear of diabetes Fatalism and God-centered locus of control Doctor-centered locus of control Perceptions of self-efficacy Perceptions of expertise with the disease and body awareness Social stigma Impact of illness on patient's life Irregular meal patterns Poor glucose control **System/policy related factors** Unavailability of medications Perceptions of access difficulties Perception of inequalities of medication supply and services Lack of trust in the government health care system
Barriers to other diabetes self-care behaviours	**Diet** Food cravings Social gatherings Lack of dietary awareness Lack of motivation Eating like rest of family members Lack of time **Exercise** Comorbidity Laziness/lack of motivation Weather Considering activities of daily living as exercise Social/cultural restrictions Fear of hypoglycemia Lack of time **SBGM** Fear of becoming stressed about it/obsessed with it Fear of getting inaccurate results Fear of not liking the result Monitoring strips no longer supplied by the Ministry Lack of awareness regarding necessity of SBGM Lack of time **Foot care**
Information/service needs	Required services Required supplies Information needs

2.4.4 Final themes identified

2.4.4.1 Barriers/facilitators of medication-taking

2.4.4.1.1 Health care provider-related factors

Several themes emerged with regards to health care providers which might have influenced adherence to medications (or other diabetes self-care behaviours) among study participants. This section describes subthemes related to these health care provider-related factors.

2.4.4.1.1.1 Attitude towards patient care

Participants viewed the attitude of their health care providers (e.g., doctors, pharmacists, dieticians, nurses) as a central part in the overall management of their diabetes. This could have implications not only on adherence to medications but also to other self-management behaviours, such as diet, exercise or self-blood glucose monitoring.

2.4.4.1.1.1.1 Paternalism and lack of compassion

Most participants (17/20, 85%) perceived their doctors to take full charge during the consultation process; making the ultimate decision about therapy without explaining the process or considering the views/preferences of the patient. This is illustrated in the following scenarios:

> *'The doctor doesn't say much, he would only prescribe the medications and that's it! Even when I try to discuss something about my medications, he just doesn't care or pay attention.'*
>
> *(Patient 15, male, urban area, line 42-52)*

> *'I heard from my friends about a new medication which is a combination of Glucophage® and Daonil® together in the same tablet and I thought it is very convenient because instead of having to take two tablets I would just have to take one. When I told my doctor about this, he just said "No...No...No!" He just dismissed the idea and ended the discussion without even explaining why.'*
>
> *(Patient 13, male, rural area, line 173-179)*

Some participants gave detailed descriptions of the consultation process which demonstrated that their doctors used a traditional, paternalistic approach in providing patient care. This is different from the more contemporary, patient-centred approach which is widely celebrated in the Western countries:

'The doctor doesn't say anything. He just looks at my medical file and my medication booklet which are in front of him, and then he re-writes the medications for me... he would just write the medications for me, hand me the medical file and send me to the pharmacy to have them dispensed.'

(Patient 11, male, rural area, line 62)

'The doctor looks at your lab results, writes your prescription quickly, and that's it.'

(Patient 13, male, rural area, line 87)

An extreme case of paternalism was described by one participant. This scenario demonstrated how some doctors were basically not open for to discussion or having their decisions challenged by patients:

'My blood sugar level was high so the doctor wanted to put me on injections and I didn't want that. She (the doctor) just told me (in a threatening tone) "That's it! No more tablets for you, you are going straight on injections!", I said "Dr. please, I would like to continue taking my tablets, I admit that ate some sweets and that's what messed up my blood sugar levels, I promise I.." but then she (the doctor) said (angrily) "You are not the doctor here, I am, so that's the end of discussion!"'

(Patient 8, female, rural area, line 114)

It is worth highlighting here that while some participants disapproved of paternalism; others advocated this approach and found it natural for doctors to be fully responsible for making decisions regarding their treatment. Five out of twenty participants (25%) had no wish to be involved at all in influencing their own treatment plans and thought that doctors were better suited to perform the task:

'To be honest with you I know nothing about these things (medications), I don't....

It is better if the doctor decides for me.'

(Patient 2, male, urban area, line 119-127)

'How could I ask about something I don't know about? (meaning he should not dare ask his doctor about medications prescribed) You just can't. If you know nothing about something (medications) then you can't do that....I don't read and I don't write, how could I understand? I have no choice but to trust the doctor in that.'

(Patient 11, male, rural area, line 64)

'Despite my pharmaceutical background being a pharmacy technician, I think you have to leave it up to the people who know best, the Science people (doctors).'

(Patient 6, male, urban area, line 81)

However, two other participants (10%) wanted more involvement in their own treatment plan:

'I would like the doctor to discuss with me my therapeutic options so I could make my choice.'

(Patient 4, female, urban area, line 147)

'The doctor made the decision about my medications from the beginning... of course it would have been better if he took my opinion about it... I didn't even know I had options to choose from!'

(Patient 1, male, urban area, line 221-225)

Some participants (6/20, 30%) perceived their doctors as uncompassionate and being indifferent towards their actual needs, as illustrated in this quote:

'I keep telling my doctor that I don't like to take too much insulin because it makes me put on weight. I don't like it but he still just wants me to use more and more insulin!'

(Patient 12, female, rural area, line 149)

Two of the six participants (33%) reported more negative experiences as a result of their doctor's lack of compassion; for example one participant's perceived her doctor to be inconsiderate and hurtfully judgmental:

'I gave up going to doctors anyway. I don't trust them anymore because they don't treat me right. You wouldn't believe what the doctor said to me once! She said to me "You have already lived your life to the maximum, how could you expect to live any longer, it's just not fair!" I couldn't believe she actually said that to me! It was so disrespectful and hurtful, my son wanted to sue her for it but I stopped him. I am a peaceful person and I wouldn't want to create problems for anyone, but I never followed up here with any doctor for my diabetes ever since and I do not wish to. Now I am managing my diabetes on my own by going to a private pharmacy.'

(Patient 8, female, rural area, line 107-131, 274-250)

As for pharmacists, three out of twenty participants (15%) reported having negative experiences with pharmacists. One participant felt very negative about pharmacists in general, complaining of their unhelpful attitude towards patients and accusing them of talking down to patients:

'Pharmacists would never say anything at all, you'd be lucky if they said "hi" back to you! You just go there and they would talk down to you.'

(Patient 8, female, rural area, line 170-175)

The other participant described an encounter with a "careless" pharmacist who would not provide him with medication instructions:

'I remember a situation where I asked the pharmacist "How many times shall I take this medication?" and he answered (angrily) "It's all written on the label!". He was so mad at me for asking so I just said "Ok, I'm sorry!", then I asked him "What is it for?", here I don't think he even answered me, I can't remember exactly what happened... all I know is that he didn't give me a satisfying answer.'

(Patient 1, male, urban area, line 357)

The third participant described another encounter with a pharmacist, whom he perceived as insensitive and inconsiderate which led the participant to confront him about his unprofessional behaviour and file a complaint about it:

> *'I recall a pharmacist at the central pharmacy once who was sitting there in the back laughing at patients and making insensitive comments. It was totally unprofessional and I thought I should give him a lesson about how to respect people. I told him "who are you laughing at! This is your job, either do it properly and show professional behaviour or quit! You are so rude and you should be ashamed of yourself!" I reported him to the manager later.'*
>
> *(Patient 3, male, urban area, line 81-87)*

When speaking of other healthcare providers, a similar experience emerged with one participant (5%) who complained to a local news paper about an incident with nurses at the eye examination clinic:

> *'I had a very bad experience when I went to do my eye screening yesterday. The room was full of nurses in addition to two more doctors. There wasn't even a place for me to sit. And then as the nurse was applying my eye drops her phone starting ringing and she literally stopped to answer her phone call and started chatting over the phone! I mean we were in the middle of the process and she just answered her phone and told the other nurse to complete applying my eye drops. There was such a chaos in the clinic as I was having an eye exam, she was talking and laughing on the phone, other people were coming in and out. I was really upset that I wrote a complaint in the local paper about the incident.'*
>
> *(Patient 3, male, urban area, line 37)*

In general, participants discussed doctors more than pharmacists or other healthcare providers. Over half of participants (13/20, 65%) reported they were generally satisfied with their doctors, compared to (7/20, 35%) who reported their satisfaction about pharmacists.

Despite the negative views many participants held about their doctors, some participants (6/20, 30%) thought highly of their doctors, with four participants describing their doctors as "friends" or "equals:

'To be honest with you they (doctors) are all like my friends. All of them treat me like a friend, God bless them.'

(Patient 2, male, urban area, line 131)

'My doctor always tells me to come so he could have a nice chat with me. He likes me.'

(Patient 1, male, urban area, line 141)

'The doctors treat me as an ex-colleague to be honest.'

(Patient 6, male, urban area, line 273)

'I have my doctor's mobile number so I call him all the time, for example whenever I needed to schedule or cancel an appointment.'

(Patient 3, male, urban area, line 259-261)

2.4.4.1.1.1.2 Little/no patient education and counselling

As for patient education and counseling, all but one participant (19/20, 95%) complained they had received little/no education from their doctors. Doctors were criticized for not explaining enough to patients about the nature of diabetes, diabetes medications, and the necessary lifestyle changes to prevent complications of diabetes. A couple of participants (2/20, 10%) even reported a lack of education and counseling after modifications in their medications were made. In cases where diabetes education was given, it was considered rather too little, or too late i.e., after complications of diabetes had already developed. In general, consultations with doctors left a lot to be desired, even for those participants who had a friendly relationship with their doctors. Table 2.14 highlights some participants' quotes, showing lack of education by their doctors in many areas.

Table 2.14: Quotes illustrating lack of patient education by doctors

Finding	Quotes	Patient, Line
Lack of education about diabetes	*'When I was first diagnosed in 1992 the doctor prescribed me a tablet and I took it for some time but then I stopped it. I thought diabetes was like the flu, something that would take a month at worst to resolve. The doctor hadn't explained it to me so I wasn't aware of what diabetes was.'*	*Patient 13, male, rural area, line 15-20*
Lack of education about diabetes complications	*'The doctors don't tell you about the complications of diabetes or refer you to do the necessary routine tests until it's too late. I was told that diabetes could damage the eye's retina only after I had already developed retinal damage, and the same with kidney damage; when I had already developed kidney damage, only then I was told about how diabetes might have caused it.'*	*Patient 2, male, urban area, line 175*
Lack of education about diabetes medications	*'I would have liked to know so much more about my medications than what the doctor had told me. For example, what's the maximum recommended dose of Glucophage® ? I still don't have any idea. Does it have any adverse effects? What are they?... Do I have to strictly take it on time? She told me it is to be taken with or after meals, but does it really matter? What happens if I don't do that? I like to be precise, you know... What shall I do if I missed a meal, do I still have to take the tablet?...And what about water? Should I take it with a lot of water?...And what happens if I take it with another medication, are there any interactions?'*	*Patient 18, female, urban area, line 89-92, 103-106*
Lack of education about necessary lifestyle changes	*'In the beginning, I was never told to watch my diet. I used to eat loads of sweets, creamy desserts, cakes, you name it! I didn't know that I shouldn't. No one has ever told me. It is only recently, after years of having diabetes, that I realized this, from looking at the posters in the clinic ...It's been around 10 years now since I've known about all of these.'*	*Patient 4, female, urban area, line 117-125, 157*
Lack of education after dosage modifications	*'Now the doctor has increased my dosage from half a tablet to one tablet. Maybe because it (blood sugar) has increased? I don't know, I haven't been told why the dosage was increased'.*	*Patient 19, female, urban area, line 25-27*

As for pharmacists, participants reported a lack of education and counselling by pharmacists. Almost half the participants (11/20, 55%) perceived pharmacists to have a negligible or minimal role in providing care for patients with diabetes, seeing their role as limited to providing dosage instructions:

> *'Pharmacists don't provide any medication counselling, I just hand them my prescription and they just dispense me my medications. That's how it is normally.'*
>
> *(Patient 4, female, urban area, line 137-139)*

> *'At the pharmacy they would just give you your medications and that's it, they don't say anything, about what this medication is... you don't communicate much with*

pharmacists, it's not like you have the chance to sit down or talk as you do with doctors, it's just about dispensing medications only.'

(Patient 2, male, urban area, line147)

'Pharmacists never give any advice about medications at all, you'd be lucky if they said "hi" back to you.'

(Patient 8, female, rural area, line 170)

'Pharmacists just tell you take this medication once, twice, or three times, that's it!'

(Patient 11, male, rural area, line 94)

In Kuwait, pharmacists often provided their dosage instructions by sketching a number of lines on the medication packaging which corresponds to the number of times the patient is supposed to take the medication. Pharmacists likely assumed that the patient would find this easy and straightforward, however many participants found it to be confusing:

'To us the pharmacist is just the person who dispenses and writes instructions on the medications for us. To be more precise, it's not even written, the pharmacist would just sketch a number of lines on the medication package corresponding to the number of times you should take that medicine, and it is up to you to figure the exact timings! (laughing).'

(Patient 18, female, urban area, line193)

'Pharmacists just draw a number of lines which corresponds to the number of times you are supposed to take the medication and never say anything about adverse effects or give you any warnings. I swear I have never seen any pharmacist who did his job properly with a live conscience.'

(Patient 16, female, urban area, line 154)

Because of the perceived lack of a clinical pharmacist involvement in patients' care, some participants (8/20, 40%) failed to acknowledge pharmacists as potential participants in providing their care and perceived pharmacists solely as suppliers of medications. To

these participants, a pharmacist is just the person to whom they turn at the end of their visit to collect their medicines, nothing more. In fact, some thought that pharmacists were not responsible or capable of more than dispensing their medications and therefore avoided communicating with pharmacists. These participants thought it was the doctor's job to tell them everything they were supposed to know about their medications:

> *'We never ask pharmacists, we only collect our medications from them and leave, because if there was anything to know, the doctor would have told us about it in the first place, right? It is the doctor's job to tell you, not the pharmacists!'*
>
> *(Patient 16, female, urban area, line 154)*

> *'Pharmacists don't tell you anything about medications because they are not doctors! It is the doctors who tell me and I just go to the pharmacy to collect the medications.'*
>
> *(Patient 8, female, rural area, line 172)*

> *'I don't ask the pharmacist, because the doctor would have already explained everything to me, I only ask when I'm not sure. I depend mainly on the doctor.'*
>
> *(Patient 19, male, urban area, line 84)*

Despite highlighting the doctor as the main educator and communicator, all three participants reported their doctors as poor communicators. For example, the doctor was criticised for the authoritative attitude and scary technique shown when providing diabetes education, not providing education about situations like hypo or hyperglycemias, or never explaining why medication dosage instructions were changed.

Having considered the role of the pharmacist as exclusively the supplier of medications, anything that would interfere with that role brought dissatisfaction on part of participants. Some participants (9/20, 45%) seemed to have judged pharmacists' competence based on how fast they dispensed their medications, how many tablets they provided at refills, whether they had written the dosage instructions on the medication labels , or whether they had treated them well while dispensing the medications, as the following quotes illustrate:

'I'm satisfied with them (pharmacists) because you don't get any delays. They dispense the medications quickly.'

(Patient 4, female, urban area, line 137-139)

'One of the biggest problems I have with the pharmacy is the extremely long queues that people have to endure in order to get their prescriptions filled.'

(Patient 3, male, urban area, line 217)

'When I come to the pharmacy they would give me the exact number of tablets written by the doctor, not even a single more tablet. They should be more generous! It's not like it's from their own pockets.'

(Patient 11, male, rural area, line 175)

'Pharmacists are good, very good. They treat you nice.'

(Patient 14, female, rural area, line 85)

'Pharmacists are very nice and thoughtful and they try to help as much as possible. For example, they would write the instructions on the label for you just in case you had forgotten. Also, when I ask them for a few extra tablets to cover the few days until my next appointment, they would provide me with it if it was possible.'

(Patient 5, male, urban area, line 293)

Only a few participants (3/20, 15%) could actually recall situations where by pharmacists have been helpful to them. Unfortunately, in all of these instances, participants followed their stories by emphasizing the rarity of such situations:

'Throughout the many years that I've been a diabetic, there has been only one time when the pharmacist provided me with a useful tip about my medications. He advised me not to take my calcium tablets with dairy products, and to at least leave 2 hours in between taking my calcium and any consumption of dairy products. That was very useful, I didn't know that!'

(Patient 2, male, urban area, line 137)

'Pharmacists never explain anything to you unless you ask. I asked them about something years ago and they explained it to me. It happened only once!'

(Patient 15, male, urban area, line 56)

'Pharmacists were useful to me only once, which was when I asked them about why vitamins were no longer available at the Ministry. They brought their index and looked up the answer for me. This is the only instant I felt genuine attention from them.'

(Patient 1, male, urban area, line 379)

There was a general insufficiency in participant's knowledge about medications, and 9/20 (45%) desired more involvement of pharmacists in providing much-needed medication counseling:

'The pharmacist would go "once...twice...three times" (pointing numbers with his hands), how about telling me more about this medication! What does it do? What are the adverse effects? When I ask, they hardly provide any answers, and when they do, they do it with an attitude... With pharmacists it's like: here's your medication, everything's written on it, just take it and leave!'

(Patient 1, male, urban area, line 341, 383)

Apart from doctors and pharmacists, participants rarely mentioned other healthcare providers as having a role in their care and/or providing them with education and counseling. It may well be because participants were rarely referred to other health care providers by their doctors. Although it was not the focus of the study to explore views about other healthcare providers, several findings emerged in this regard and were noteworthy. Only a quarter of participants (5/20, 25%) reported being referred to a dietician at some point of time and only six out of twenty participants (30%) mentioned being referred to an eye specialist.

However, some participants reported they were never referred to a dietician:

'No one has ever provided me with dietary advice. I used to eat all the wrong things

for many years because I didn't know what I should and what I shouldn't eat.'

(Patient 4, female, urban area, line 59, 117)

Others reported they were never referred to an eye specialist:

'I was never given a transfer to do the eye screening. I think I should have been, I mean, it's always good to have these check-ups especially that I had just turned 40. I am someone who is very concerned about my health, so I wish if I had that eye screen.'

(Patient 18, female, urban area, line 241)

Nonetheless, where a transfer to multi-disciplinary healthcare providers was made, it was usually either to a dietician or an eye specialist for a retinal examination. A quarter of participants (5/20, 25%) mentioned receiving dietary advice by a dietician. However, these participants criticized dieticians for providing too little dietary advice, which was limited to providing a dietary instructions sheet at the beginning of diagnosis and only taking weight and height measurements during appointments thereafter. There was little or no dietary counseling or follow-up:

'Dieticians don't tell much, they would just measure my weight and height each visit and then it's good bye! Height is something that is never going to change, you know, so I don't even get that part (laughing). They only provide a diet instructions sheet on the very first visit and that's it. There is no actual follow-up or ongoing advice.'

(Patient 2, male, urban area, line 149)

For another quarter of participants (5/20, 25%), dietary advice was provided by their doctor along with advice regarding other lifestyle changes, such as exercise. It was usually as brief, random tips during the medical consultations:

'The doctors tell you what to eat and what to avoid. They advise you to avoid sweets and to take your medications.'

(Patient 7, female, rural area, line 147)

'The doctor tells me not to eat sweets.'

(Patient 11, male, rural area, line 29)

'The doctor recommended 30 minutes of exercise a day for me, starting with 10 minutes and working up till 30 minutes per day.'

(Patient 2, male, urban area, line 107)

'The doctor encouraged me to exercise, he especially recommends walking.'

(Patient 1, male, urban area, line 57)

2.4.4.1.1.1.3 Favouritism/inequality of care provision

Inequality of care and favouritism was raised by a few participants (3/20, 15%) as an issue of concern. For example, one participant thought that doctors tended to treat patients based on appearances; the simpler they looked, the less respect and attention they would get from the doctor:

'The doctor would just look at the patient, if the patient appeared simple and modest the doctor would just talk down to him and not treat him right, or might even kick him out!'

(Patient 8, female, rural area, line 174)

Another participant doubted the integrity of doctors and perceived them to favor people with whom they are acquainted, such as their friends or relatives, and provide them with better care, saving the better medications for these particular patients:

'Let me tell you something, they (doctors) would never prescribe the good medications for me or for you. They would give them to other people, the "special" people. They have the good medications, it's all available but they would never give it to me for example, they save the good stuff for some other people.'

(Patient 11, male, rural area, line 185-190)

As for pharmacists, a couple of participants (2/20, 10%) also reported perceptions of inequality and favouritism. One participant perceived pharmacists to treat patients

they knew better than others:

'They (pharmacists) would never treat you right unless they personally know you. They have never been helpful to me my entire life, not even once have they said anything about the medications to me!'

(Patient 8, female, rural area, line 170-175)

The other participant perceived that pharmacists would dispense more quantities of medications to people they know, and follow the rules only with people they did not know:

'When I asked for an extra month's supply they (pharmacists) declined to provide me with it, I'm sure they wouldn't have if they personally knew me'

(Patient 9, male, urban area, line147)

2.4.4.1.1.1.4 Inflexibility with appointments

Doctors were criticized by a couple of participants (2/20, 10%) for being too rigid about their appointments; implying that they would not help patients if an appointment was missed. Flexibility in appointments was desired, as illustrated in the following quote:

'Once, I have missed my appointment. I just completely forgot about it, but when I came here five days later the doctor wouldn't let me in. I really wish he was more flexible. I only forgot my appointment twice, ever since I had diabetes.'

(Patient 12, female, rural area, line 159-161)

2.4.4.1.1.2 Inadequate care/medical examination

A quarter of participants (5/20, 25%) criticized doctors for not taking the time to examine patients thoroughly during the consultation, and not performing what were seen as the necessary routine checks, as illustrated in the following quotes:

'Doctors are supposed to assess the psychological state of patients because blood sugar levels might go up when the patient is under stress, you know. It is very important that doctors assess the patient's psychological state by referring us to a psychologist to rule out stress... my previous doctor used to check my blood pressure, my feet, and would ask me if I had pain or any symptoms troubling me.

Now, they don't do any of that, he would just look at my blood pressure and my blood sugar levels and that's it! Unless you specifically ask or complain about something he would never say anything.'

(Patient 16, female, urban area, line13, 47)

'My current doctor didn't even check my blood pressure! She is supposed to check my blood pressure, check on my feet, ask me things, but none of that really happened.'

(Patient 9, male, urban area, line 123-125)

Two other participants (2/20, 10%), however, held an opposite view and thought that doctors exaggerate the number of clinical investigations they require, and questioned the necessity of these. One participant noted this was particularly annoying because carrying out the tests was not correlated with any change in treatment or medications:

'What's the use of having 200 tests? (meaning too many tests), I just brought one test result from the hospital, the doctor just looked at it and said "ok", What is it that is OK? How do I know if it was if nothing was ever changed in my medications? He just puts them in the file and that's it.'

(Patient 11, male, rural area, line 251)

'Whenever I come to the doctor he ends up giving me loads of papers and referrals to do lab tests but as I come out of the consultation I think to myself "what am I going to do with all of these?" so I just throw them all in the bin on my way out.'

(Patient 13, male, rural area, line 91)

2.4.4.1.1.3 Discontinuity of care

Discontinuity of care was seen as a concern by some participants. Seven participants (7/20, 35%) had the doctor who usually treated them changed. For the majority of these participants (6/7, 85%), the previous doctor was usually the preferred one and therefore their transfer to another doctor was seen as neither helpful nor appreciated:

'I don't have a specific doctor, every time I check in with somebody else.'

(Patient 16, female, urban area, line 45)

'My previous doctor was really nice and good, ever since he left I never came here for my diabetes.'

(Patient 8, female, rural area, line 168)

'I would like to have the same doctor every time but sometimes a doctor might get transferred... it is best if you had a constant doctor, you would feel much more comfortable.'

(Patient 5, male, urban area, line25)

'My previous doctor was nice, he would sit down with me and explain to me things, he gave me the time, but he left now and I don't know where he is.'

(Patient 13, male, rural area, line 91)

2.4.4.1.2 Personal factors

Several themes emerged with regards to personal factors which might have influenced adherence to medications (or other diabetes self-care behaviours) among study participants. This section describes subthemes related to these personal factors.

2.4.4.1.2.1 Knowledge about diabetes/medications

Knowledge about diabetes or its treatment was deficient among many participants (13/20, 65%). Some participants (8/20, 40%) had misconceptions about diabetes or its treatment, which might have implications on adherence to medications. For example, one participant reported that he never realised that diabetes was a chronic disease which required a lifelong treatment with medications until years after his diagnosis:

'I thought diabetes was like the flu, just a month or so at most and it would be gone. So I took my tablet for a while and then I stopped it for years until things got worse. That's when I came back to the doctor and realized.'

(Patient 13, male, rural area, line 17)

Another participant reported that for years after her diagnosis, she thought that it was okay to eat whatever she wanted, as long as she was taking her diabetes medications. She never realized that managing diabetes required diet modification along with taking medications:

'I didn't know anything about diabetes in the beginning of my diagnosis and even for many years after that. I used to take my medications and then eat whatever I like of sweets, cakes, cream, you name it! I didn't know that I shouldn't have.'

(Patient 4, female, urban area, line 53-61, 117, 263)

At the time of the interviews, two participants (10%) still did not acknowledge the seriousness of diabetes. One described it as nothing but an increase or decrease of blood glucose levels which was nothing serious at all:

'Diabetes is very simple...it's nothing but an increase or decrease in blood glucose levels, so there is nothing the doctor can do to you, and you can manage it on your own, I do that... Diabetes is not a disease at all; even kids can have it once the pancreas shuts down.'

(Patient 8, female, rural area, line 124,220)

The other participant perceived his diabetes as not serious because "it's only in the urine, not in the blood":

'You know my diabetes is not the type you get in the blood, it's in my urine only so thank God it won't affect anything else.'

(Patient 11, male, rural area, line 13)

As for medications and medication-taking, a couple of participants (2/20, 10%) had a misconception with regards to the use of medications in travel. They perceived that there was no need to take their medications in travel because when they travel they would be less stressed and more mobile which they felt kept their blood glucose levels under control:

'When I travel I feel like I don't need my medications because I'd be moving around so much... I sometimes don't take my medications in travel, and when I check my blood

glucose it would be within normal levels.'

(Patient 1, male, urban area, line 117)

'When I travelled I've never taken any of my diabetes medications. I didn't feel like I needed them... I was so relaxed and I was moving around all the time. Once you're relaxed you'd forget that you even have diabetes.'

(Patient 5, male, urban area, line 331-349)

One other participant supported this misconception, perceiving that if you ate less, exercised more and slept well there might be no need for you to take any diabetes medications:

'I know I am alright. I am well, you know I eat well, and I sleep well. People who feel well should thank God, not take these medicines blindly!...Shall I tell you when diabetes shall be cured completely that you won't even need medications? It happens when you starve yourself eating nothing but dates and drinking nothing but milk, moving around in the desert all day like our ancestors used to do. That's when you'll get cured of diabetes.'

(Patient 11, male, rural area, lines 98, 195)

One participant showed a lack of knowledge as to how to take his Daonil® tablets (hypoglycaemic tablets belonging to the sulphonylurea group) in case he missed taking them immediately before meals. This participant thought that tablets must be skipped if they were not taken immediately before meals:

'Sometimes when I'm invited out for dinner or something and I don't have my Daonil® tablets on me I just eat, then when I come back home I don't take my tablets because they were supposed to be taken before food. They only work if taken before meals.'

(Patient 15, male, urban area, line 15-31)

Despite the above misconceptions and deficiencies in knowledge, some participants had some knowledge about diabetes, what caused it, what made it worse, and what lifestyle

changes were needed to manage it. Diet control and exercise were cited the most as necessary self-management behaviours of diabetes, although not all who had recognized this necessity were actively engaged in such behaviours.

Table 2.15 lists participants who acknowledged the necessity of diet and exercise against those who were actually engaged in performing these behaviours.

Most participants recognized a link between diabetes and some of its complications (17/20, 85%). Hypoglycemia was the most feared complication and was cited by most participants (17/20, 85%). Retinal (12/20, 60%) and kidney damage (10/20, 50%) were the second mostly cited complications of diabetes. Some participants acknowledged other long-term complications of diabetes such as heart disease (6/20, 30%), foot complications (8/20, 40%), peripheral neuropathy (5/20, 25%) and delayed wound healing (5/20, 25%). The possibility of having stroke as a result of diabetes was cited only by one participant (5%).

Table 2.16 summaries participants' knowledge of diabetes complications, illustrating that not all participants were aware of diabetes complication/their seriousness.

As for the etiology of diabetes, some participants (6/20, 30%) reported hereditary factors to play a role in their diabetes. In addition, over half of participants (11/20, 55%) recognized the role of stress in causing, or worsening of diabetes. Participants' knowledge about diabetes/its treatment was mostly self-learnt through discussions and sharing experiences with family members or friends who had diabetes (17/20, 85%). Participants rarely reported a doctor or a healthcare provider as the source of their diabetes-related knowledge. Some participants (5/20, 25%) reported they took responsibility of educating themselves about their disease/its treatment through the internet, the media, and making use of whatever posters or leaflets they found available at clinics. Table 2.17 illustrates quotes supporting these findings.

Table 2.15: Participants who acknowledged the necessity of diet and exercise vs. those who were performing these behaviours

Participant	Acknowledging diet control necessity	Actual diet control engagement	Acknowledging exercise necessity	Actual exercise engagement
1	✔	⊘	✔	⊘
2	✔	✔	✔	⊘
3	✔	⊘	✔	✔
4	✔	✔	✔	⊘
5	✔	✔	✔	⊘
6	✔	⊘	✔	⊘
7	✔	⊘	✔	⊘
8	✔	✔	✔	⊘
9	✔	⊘	✔	✔
10	✔	⊘	✔	⊘
11	✔	⊘	✔	⊘
12	✔	✔	✔	⊘
13	✔	⊘	✔	✔
14	✔	⊘	✔	⊘
15	✔	⊘	✔	⊘
16	✔	⊘	✔	⊘
17	✔	⊘	✔	⊘
18	✔	⊘	✔	⊘
19	✔	✔	✔	✔
20	✔	✔	✔	✔

✔ Yes, ⊘No

Table 2.16: Participants' knowledge of diabetes complications

Participant	Hypo-glycaemia	Retinal damage	Kidney damage	Foot problems	Heart disease	Peripheral neuropathy	Delayed wound healing	Stroke
1	✔	✔		✔	✔	✔	✔	
2	✔	✔	✔	✔	✔	✔	✔	
3		✔			✔			
4	✔	✔	✔	✔				
5	✔	✔	✔	✔	✔		✔	
6	✔	✔	✔	✔			✔	
7	✔							
8	✔		✔					
9	✔							
10	✔					✔		
11								
12	✔	✔	✔			✔		✔
13		✔						
14	✔			✔	✔	✔	✔	
15	✔	✔	✔	✔	✔			
16	✔	✔	✔	✔				
17	✔	✔	✔					
18	✔	✔	✔					
19	✔							
20	✔							

✔ Patient demonstrated knowledge in the specific area.

Table 2.17: Quotes of participants' knowledge about the aetiology of diabetes, and sources of knowledge

Finding	Quotes	Patient, Line
Role of heredity in diabetes	*'Diabetes is mostly caused by heredity. As for myself, I know I had it because of heredity.'*	Patient 1, male urban area, line 107
	'In our family, we get it (diabetes) because of heredity. During our forties, almost all of my siblings, including myself, had diabetes.'	Patient 6, male, urban area, line 9
	'I don't know what causes it exactly, but they say it could be hereditary as my mum had it.'	Patient 17, female, urban area, line 33
	'It's genetic in our family. My mum had it, and three of my sisters as well as myself.'	Patient 18, female, urban area, line 33-39
Role of stress in initiating or worsening of diabetes	*'It seems that my blood glucose levels rise whenever I am stressed, very much so.'*	Patient 1, male, urban area, line 53
	'When I am stressed my blood glucose levels tend to rise even more than when I eat. Stress plays a major role.'	Patient 2, male, urban area, line 113-117
	'For sure, stress is the cause of diabetes and hypertension. I got diabetes as a result of an emotional stressful event... and the more stressed you are, the worse (diabetes) it will get.'	Patient 7, female, rural area, line 141
	'When I get stressed, I know it (blood glucose levels) will rise, so I check.'	Patient 5, male, urban area, line 219
	'It's when you worry too much about things... you see when Saddam Hussein invaded Kuwait, half the Kuwaitis got diabetes because of stress.'	Patient 3, male, urban area, line 147-149
	'....sometimes stress can also cause your diabetes.'	Patient 17, female, urban area, line 33
Knowledge of diabetes/its treatment usually gained from family, friends, or self	*'My family, i.e. sisters warned me about what diabetes can do to my body if left untreated... I got scared and now I am more careful about my tablets.'*	Patient 14, female, rural area, line 73
	'My sister is a nurse; she taught me how to inject my insulin... I usually turn to the media for knowledge about diabetes, you can learn everything from there.'	Patient 16, female, urban area, line 62-68
	'The doctor explained to me briefly about diabetes at first, but then I started to learn more from the leaflets, media, etc. Doctors don't tell you much.'	Patient 20, female, urban area, line 69-77
	'I learn a lot from my mother, and I also read a lot...I usually get my knowledge from friends and family who have the disease.'	Patient 19, male, urban area, line 41-135

2.4.4.1.2.2 Beliefs about medicines

The participants expressed a range of beliefs about medications. These beliefs were sometimes specific to their diabetes medications, and other times they were related to medications in general. Whether specific or general and depending on their nature, beliefs about medications appeared to influence patients' adherence to medications among the study participants. The following subthemes emerged in relation to beliefs about medicines:

2.4.4.1.2.2.1 Medications are necessary for the management of diabetes

All but one participant (19/20, 95%) acknowledged the necessity and importance of their medications as an essential part of their diabetes management, if not the only part. Twelve out of twenty (60%) participants spoke of the importance of their diabetes medications, giving them absolute priority over all their other medications:

> *'I give my diabetes medications the absolute priority. They are the most important to me so no matter what, I would always take them.'*
>
> *(Patient 5, male, urban area, line 96-103)*

> *'I am so careful about my diabetes medications, they are the most important to me and I would always take them no matter what. Even if I had to beg, I would always buy them.'*
>
> *(Patient 8, female, rural area, line 304-306)*

Some participants (7/20, 35%) perceived their medications to be even more important than other parts of their diabetes self-management behaviours:

> *'I think medications are even more important than diet or exercise as a treatment for diabetes.'*
>
> *(Patient 13, male, rural area, line 145-147)*

For one participant, it was particularly interesting to find that he completely believed in the necessity of his Diamicron® tablets (from the class of diabetic medicines called sulphonylureas), but not his Glucophage® tablets (from the class of diabetic medicines called biguanides). When this was further investigated, it was found that the participant had suffered severe diarrhea with his Glucophage® tablets previously, which might have led him to doubt the usefulness of this tablet. This was combined with his perception of his diabetes to be under control, especially since he was exercising daily:

> *'I don't appreciate the need for these Glucophage® tablets. I am supposed to take three a day but I only take two since I don't eat at noon. And, you know, I think my diabetes in under control, I don't wake up in the middle of the night to go to the loo*

for example... I take less because I exercise every day; I walk for like an hour, an hour and a half, something like that.'

(Patient 9, male, urban area, line 115, 117)

2.4.4.1.2.2.2 Medications are ineffective at controlling blood glucose levels

Despite having strong beliefs in the necessity of medications for the management of their diabetes, some participants (6/20, 30%) doubted the effectiveness of their medications at controlling their blood glucose levels. In this regard, one participant perceived a certain formulation of his tablets to be better than another:

'I find the newer type of Diamicron® tablets, you know the ones that you have to take all at once in the morning, less effective than the older type at controlling my blood glucose levels.'

(Patient 1, male, urban area, line 159-171)

With another participant, a lack of education may explain why he doubted the effectiveness of his diabetes medications as he demonstrated a great lack of understanding of how diabetes medications work, thinking that somehow diabetes medications were supposed to have a tangible effect, and that he should have been cured, had these medications been working effectively:

'These medications are useless! I've been taking them for years now and I still didn't feel anything; my diabetes was never cured!'

(Patient 11, male, urban area, line 191-193)

Having competing beliefs in effectiveness of herbal remedies was evident with a few participants (4/20, 20%), as illustrated in the following quote:

'I once read about an herbal remedy for lowering blood glucose from the internet, it's something like a tea infusion, you just have to boil it and drink it. So I tried it along with my Glucophage® tablets and I found it very useful. It lowered my blood glucose levels quite effectively.'

(Patient 8, female, urban area, line 45)

This might explain why some participants have doubted the effectiveness of their traditional diabetes medications, the following quote provided evidence for this:

'I sometimes use herbal remedies along with my diabetes medications, and believe it or not, I find herbal remedies better at lowering my blood glucose levels!'

(Patient 20, female, urban area, line 85-95)

2.4.4.1.2.2.3 Medications are harmful chemicals, and they have adverse effects

Almost half the participants (9/20, 45%) perceived traditional medications as harmful chemicals, too much of which can have devastating effects on one's health or can even be fatal:

'Medications are chemicals, if you take too much of these it's too much; too much for your stomach, too much for your heart veins! I know someone who died because of taking too many medications! The veins of her heart just got clogged and she died, all because of these medications and chemicals.'

(Patient 11, male, rural area, line 19)

'I feel like I am taking too much of medications and I am frightened of this. I had a friend who was a doctor himself who had developed liver cirrhosis because of taking too many medications. He was a colleague of mine as we used to work together in the Department of Preventive Medicine. When I asked him how he got his liver cirrhosis he said he might have messed up by taking too many medications.'

(Patient 15, male, urban area, line 79)

Some participants even believed that if you take too many medications your body might somehow lose its immunity and grow weaker; therefore they thought it might be wise to take less of these medications:

'I would like to take less of these medications because, as you know, if you take too much of these tablets and medications your body would lose its immunity.'

(Patient 14, female, rural area, line 93)

Potential or actual adverse effects of medications were a common concern shared by more than half of the participants (11/20, 55%) often resulting in patients deliberately stopping/taking less of their medications to avoid/alleviate these adverse effects (i.e., resulting in intentional nonadherence):

'For ten years now, I have been taking one tablet of Glucophage® instead of three because I don't eat much, and I'm afraid I might get hypoglycaemia if I take three tablets.'

(Patient 12, female, rural area, line 23)

'When I was on the 850 mg of Glucophage®, it gave me continuous diarrhoea so I just stopped it on my own, and consulted the doctor later on.'

(Patient 9, male, urban area, line 59)

Interestingly, a few participants (4/20, 20%) perceived themselves to be more sensitive to adverse effects of medications than others, and hence they deliberately took less of their medications (i.e., resulting in intentional nonadherence):

'I used to have duodenal ulcer so I have a sensitive stomach, I get a burning stomach all the time. I take one tablet of Glucophage® instead of two recommended by the doctor because I have a sensitive stomach so I can't take too many medications. I once tried two tablets and I had a burning stomach.'

(Patient 14, female, rural area, line 31-33, 93-94)

'I was prescribed three tablets a day but when I took them I felt dizziness. Maybe I am more sensitive to medications than others? I don't know, so I started taking one tablet instead of thee for a whole week, and you know what, it did help with the dizziness. I don't get dizziness anymore.'

(Patient 19, male, urban area, line 55-61)

Two participants (10%) perceived herbal remedies to have fewer or no adverse effects compared to traditional medicines:

'Some might say with herbal remedies, you might not get any benefit but you could never get harmed of it.'

(Patient 2, male, urban area, line 205)

'When I get sick I try to treat myself with herbal remedies as much as possible, because these are natural things that can never cause harm you know. Unlike traditional medications, they are chemicals and they are full of adverse effects!'

(Patient 11, male, rural area, line 21-23)

As for insulin, many participants (13/20, 65%) had reservations and concerns regarding its use (these included opinions expressed by those who were users and non-users of insulin). Pain and inconvenience of insulin use were amongst the biggest concerns among insulin users, reported by two thirds of them (4/6, 67%) as illustrated:

'Ever since I was put on insulin, I am afraid to travel...Insulin injections are so annoying. All my body is pierced now, it's very annoying.'

(Patient 10, female, urban area, line 41)

'I have to inject myself twice a day, sometimes three times, so I have pain all over my body. It feels like bruises, even when I rotate the site of injection.'

(Patient 2, male, urban area, line 243)

Hypoglycaemia was also a common concern shared by half of insulin users (3/6, 50%), which often lead to them taking less of their insulin to avoid it, as illustrated in the following quote:

'I take my Actrapid® twice instead of three times because I am afraid of getting hypoglycaemias at night, especially when I am also taking Lantus® at night. I already told the doctor about this.'

(Patient 6, male, urban area, line 69)

Weight gain as a result of insulin use was an issue for one participant, who refused to take more insulin as recommended by her doctor, to avoid it:

'The doctor wanted to increase my insulin dose but I told him I didn't want that, because insulin causes weight gain. He told me to take an extra tablet of Glucophage® instead.'

(Patient 12, female, rural area, line 33)

Another participant who was tablet-treated feared that once she had started insulin injections, she would have to use them for the rest of her life:

'I imagine once you are on the insulin injection, that's it! You're stuck with it for the rest of your life! Even if a new treatment comes out, they might say "you can't have this treatment because you're already on insulin."'

(Patient 14, female, rural area, line 103)

There was a general fear of insulin among non-insulin users reported by more than half of them (8/14, 57%):

'I am very concerned regarding insulin injections. I don't like them; it's something psychological I guess... I hope I don't ever have to use them.'

(Patient 19, male, urban area, line 37, 127)

However, once patients were already on insulin, they were less concerned about its use and often found it to be very useful at controlling their blood glucose levels:

'Ever since I was switched to using insulin, it worked really well for me and my diabetes seems to be under control, even better than when I was on the tablets.'

(Patient 4, female, urban area, line 23-37)

2.4.4.1.2.2.4 Doctors overprescribe medications

A few participants (4/20, 20%) perceived doctors to prescribe too many medications, without first checking whether patients really needed them, as illustrated in the following quotes:

'The doctor at the hospital prescribed me so many medications I ended up with a large bag full of medications. I am really afraid to use all of these. I just take the

diabetes and hypertension ones along with some vitamins. I don't use the rest to be honest.'

(Patient 11, male, rural area, line 82,100)

'When you go to the doctor, he would just immediately prescribe Amoxil® for you without even asking you anything or checking. I don't think it's good to do that, if doctors over-prescribe these antibiotics your body might get used to them building up immune bodies so they won't be useful to you when you really need an antibiotic. They (doctors) just write you one course of Amoxil® after another, it's like they don't have anything else! Our bodies got used to this antibiotic that it just doesn't work anymore.'

(Patient 18, female, urban area, line 175)

'When you go to the doctors they would just give you Panadol®. It's unbelievable how much they prescribe of it! That's not good. People got so addicted to it.'

(Patient 16, female, urban area, 136)

Doctors' overprescribing of insulin was a concern shared by a few participants (3/20, 15%), as illustrated in the following quote:

'My doctor is nice but he gives me way too much insulin and it's just not right, I mean, a doctor should understand the patient's circumstances first, right?...The doctor keeps giving me more and more insulin and I don't like that.'

(Patient 12, female, rural, line 143-149)

2.4.4.1.2.2.5 Brands/country of origin of medications influence their quality

An interesting belief which emerged was relating to certain brands of medications having a better quality. For example, a few participants (3/20, 15%) believed that Western brands of diabetes medications were somehow more effective than the local alternatives at lowering blood glucose levels:

'The German brand of Daonil® is the best. I have tried the Kuwaiti, Saudi and the

UAE brands and they were all no good, they made my blood glucose levels go high.'

(Patient 8, female, urban area, line 91-99, 351-354)

Conversely, another participant believed that local brands of medications were more effective than Western brands because they were "fresher":

'People often underestimate the effectiveness of the local brands of medications. They don't know that these are actually better than the ones imported from Western countries. I have tried the Kuwaiti brand once and it worked really well because it is freshly-made. Now, every time I go to the pharmacy I ask for this particular brand because it's great. I think local brands are fresher and more effective than Western brands.'

(Patient 3, male, urban area, line 197)

One other participant also preferred local brands of medications for another reason, which was a lack of trust in the West:

'I don't trust Western medications! Who knows who makes them, you know, and what do they put in them? They just bring these medications to us in packages which have English information written on them, so no one could understand because it's all in English. I don't trust these Western brands, who knows what do they put for us in these medications! They might as well dump in them rubbish from the sea and we wouldn't even know it.'

(Patient 11, male, rural area, line 60,118)

Conversely, one participant did not care about particular brands of medications:

'I don't care where the medications are from. It makes no difference to me.'

(Patient 19, male, urban area, line 147)

In terms of adverse effects, two out of twenty participants (10%) perceived Western brands of medications to have fewer adverse effects than local brands:

'Tablets from Julphar company (a local, UAE manufacturer) are so hard, they just stick onto the back of your throat and you have to drink a whole bottle of water to swallow it!'

(Patient 16, female, urban area, line 118)

'They used to give me a local brand of Glucophage® that would just stick onto my oesophagus and I could feel it reacting there and not getting swallowed even when I drink water...if you use the UAE brand, you could feel it causing cramps in your stomach! Now I make sure I don't take anything other than the Swiss brand. If it wasn't available, I would purchase it from a private pharmacy.'

(Patient 18, female, urban area, line 125)

2.4.4.1.2.3 Perceptions of social support

Participants actual/perceptions of social support they receive from family members or friends (whether in the form of physical assistance or emotional support) seemed to influence their adherence to their medications or other diabetes self-care behaviours. Those who reported some degree of social support (11/20, 55%) appeared to have an advantage over those who reported little or no social support (6/20, 30%) with regards to adhering to medications or other self-care behaviours as their family members often helped them remember to take their medications, to perform the SBGM, or made suitable meals for them to eat. Table 2.18 illustrates how social support helped participants carry out their diabetes self-care behaviours.

2.4.4.1.2.4 Attitude towards illness

Participants expressed different attitudes towards their diabetes, which may have also influenced their adherence to medications or other diabetes self-care behaviours. Some of these attitudes may have influenced adherence in a positive way (e.g. fear of diabetes, doctor-centered locus of control, and perceptions of self-efficacy), while others may have influenced adherence in a negative way (e.g. denial, down-playing severity of diabetes, fatalism/God-centered locus of control, social stigma, and perceptions of being an expert at one's own diabetes). This section describes subthemes relating to these attitudes.

Table 2.18: Quotes of impact of social support on participants' self-care behaviours

Finding	Quote	Patient, Line
Social support: providing physical assistance	*'My wife bought me a dosette box (special dosing device) as in a key chain to help me take my medications when I go to the desert with my friends.'*	Patient 3, male, urban area, line 105
	'My wife sorts out my medications for me; she prepares my doses for the next few days and puts the rest in the fridge. She brings out the nearly expired ones first, then she refills my doses. She's a great help to me, bless her!'	Patient 5, male, urban area, line 357, 123
	'My maid helps in giving me my insulin shots. I took her to the clinic and they showed her how to do it so sometimes she would inject me.'	Patient 6, male, urban area, line 167
	'I have a blood glucose meter at home so when I feel tired my daughters would test me, and if necessary take me to the doctor.'	Patient 7, female, rural area, line 193
	'My son and his family take a good care of me; they watch my diet, help me manage my medications, and even take me to a private pharmacy to check my blood glucose levels when I get tired and from time to time, if my blood glucose levels were high, they would give me an extra tablet at lunch time.'	Patient 8, female, rural area, line 124-140, 314-323
	'My daughters help me check that there are no air bubbles in my injection, because I have poor eye sight.'	Patient 12, female, rural area, line 230
	'My wife helps me a lot, she would remind me, and she would monitor my blood glucose levels herself.'	Patient 15, male, urban area, 143-147
Social support: reminding patients about medications	*'My kids at home even the little ones now know my medications, they would get my tablets for me to take at lunch or dinner and they remind me when I forget.'*	Patient 18, female, urban area, line 223
	'Sometimes at lunch time, my wife would get my tablets and put them next to me so that I would remember to take them after food... and sometimes when we're out for lunch she would remind me to take my tablets.'	Patient 5, male, urban, line 357, 367
	'My kids at home check on me and remind me to take my medications... I think family support plays a big part in patient's care, the family should remind patients to take their medication.'	Patient 7, female, rural area, line 61, 143
Social support: providing emotional support	*'My family give me the emotional support I need, they lift up my spirits to help me with my diabetes.'*	Patient 8, female, rural area, line 230
	'My family at home would prepare special meals for me and always ask me what I would like to eat.'	Patient 19, male, urban area, line 137

2.4.4.1.2.4.1 Denial

A couple of participants (2/20, 10%) described feelings of denial towards their diagnosis with diabetes. Up until the time of the interviews, they seemed to have failed to come to terms with their disease:

> *'I try to forget that I have diabetes. I don't like to think about it so that it doesn't get worse. I'm worried that if I think about it, my blood glucose levels would increase so it's better to skip it.'*
>
> *(Patient 14, female, rural area, line 133)*

> *'Deep inside, I just can't accept that I have diabetes. I still haven't come to terms with my diabetes, I'm in denial!'*
>
> *(Patient 18, female, urban area, line 139)*

It seems plausible that denial of the disease can lead to denying prescribed treatment (medications, diet plan, exercise, or self-blood glucose monitoring) resulting in patients' nonadherence to such behaviours.

2.4.4.1.2.4.2 Down-playing severity of diabetes

Other participants did not deny their diabetes, but yet did not pay careful attention to it, moving on with their lives as they would before their diagnosis (7/20, 35%). These participants showed evidence of down-playing the severity of their diabetes. Interestingly, this did not appear to be out of ignorance but rather a psychological defense strategy to avoid having to deal with the associated emotional and psychological pain. Table 2.19 includes quotes of participants down-playing the seriousness of their diabetes.

Table 2.19: Quotes of participants down-playing the severity of their diabetes

Finding	Quote	Patient, Line
Down-playing severity of diabetes	*'I don't care about my diabetes or think about it at all. I just skip it.'*	Patient 3, male, urban area, line 251
	'It's nothing to worry about. I just take my medications and everything is okay. I wasn't even scared of having my caesarean operations. I'm not scared of diabetes.'	Patient 4, female, urban area, line 203-207
	'Diabetes is just an increase or decrease of blood glucose levels, that's it! ...you have to simplify things; diabetes is not a disease at all. You see, even kids can have it once the pancreas fails.'	Patient 8, female, rural area, line 263,220
	'You know most people in Kuwait have diabetes'	Patient 17, female, urban area, line 47

It seems reasonable that people who do not think of or treat their diabetes as a serious condition may also overlook the necessity of adhering to its prescribed treatment, potentially resulting in nonadherence.

2.4.4.1.2.4.3 Fear of diabetes

Fear of diabetes or its complications was a common theme which might facilitate medication taking or other diabetes self-care behaviours. Many participants (14/20, 70%) reported fear of diabetes and what it could do to their bodies if left untreated. Those who recognized a link between diabetes and its complications feared that missing doses or not adhering to their medications might speed-up the development of diabetes complications. Table 2.20 illustrates quotes of those who feared their diabetes and subsequently thought more highly of their medications.

2.4.4.1.2.4.4 Fatalism and God-Centered locus of control

Whether participants felt the ability to perform diabetes self-care behaviours was in their own control or was controlled by external factors (e.g., God, doctors, weather, etc.) may have influenced of their actual adherence to these.

God-centered locus of control was one of the most reported among the study participants, with six out of twenty participants (30%) describing it. Those who had a God-centered locus of control described fatalism, helplessness and a tendency to leave everything up to God's will, which might have a negative impact on their adherence. God was perceived as the only saviour and protector against diabetes or its negative consequences. Participants communicated that "what is meant to be will be" regardless of self-care behaviours:

> *'Healing comes from God not the doctor. If God wants to cure you, you will be cured, and if he wants to harm you, you will be harmed... If God wants you to live you will live, and if he wants you to die, you will die. It's all up to God, not the doctor... what is meant to be will be.'*
>
> *(Patient 11, male, rural area, line 50, 74)*
>
> *'God is our saviour and protector... I have faith in God; he is to decide what's going to happen to me, whether good or bad... life and death is something that only*

God can control. Sometimes you see someone dying despite being completely healthy, and sometimes you see someone living despite being very ill... No one can tell what's going to happen to you other than God, whatever he wants, will happen.'

(Patient 8, female, rural area, line 221, 262, 296-299, 336)

Table 2.20: Quotes of participants illustrating fear of diabetes as a facilitator to medication taking

Finding	Quote	Patient, Line
Fear as a motivator to take medications	*'I don't think I would ever forget or skip to take my medications, especially after I had developed eye bleeds.'*	Patient 4, female, urban area, line 77
	'I take my medications because if I don't I might get diabetes complications prematurely, prophylaxis is good you know.'	Patient 5, male, urban area, line 105
	'Had I been careless, I would have been dead a long time ago.'	Patient 6, male, urban area, line 93
	'I continued to take my tablets despite the fact they were giving me stomach pain because I was afraid of diabetes.'	Patient 7, female, rural area, line 27
	'If I don't take my tablets my diabetes would get so much worse, even if I don't eat much.'	Patient 8, female, rural area, line 294
	'If I was out and I don't have my insulin with me I would not eat anything until I get back home and take my insulin, because I would be afraid.' *'I would never skip a dose of my insulin, I'd be terrified, oh I wouldn't, never.'*	Patient 10, female, urban area, line 47, 145
	'I am especially careful about my diabetes and hypertension medications because I am worried the doctor had told me they were high.'	Patient 11, male, rural area, line 50
	'You know if I don't take my medications I might get a stroke, I might become disabled, and I could get a whole range of diseases because of diabetes, God forbid... that's what makes me committed to these medications.' *'I would never stop or alter the use of my medications because I am so afraid to do so. I am an old woman but I am so scared to make such decisions.'*	Patient 12, female, rural area, line 197,199,219-221
	'People, especially my family and sisters warned me that if left untreated, diabetes can damage my nerves, and many things in my body so I got scared...once you're afraid of something, you would be committed to whatever that is needed to treat it.'	Patient 14, female, rural area, line 73, 192
	'I take my medications because I am afraid. I don't want it (diabetes) to get so out of control I might get into a coma. I try to protect myself from all of that.'	Patient 17, female, urban area, line 29
	'I take my medications because I am afraid of the complications... I saw diabetes causing eye damage, kidney failure, gangrenes for people in my family.'	Patient 18, female, urban area, line 239, 43-45
	'I take my medications because I want to protect myself, and because I am concerned for the sake of my children. Who would care for them if I had died?'	Patient 20, female, urban area, line 59-61

2.4.4.1.2.4.5 Doctor-centered locus of control

Doctor-centered locus of control was also common among the study participants, described by more than half of participants (11/12, 55%). Participants who reported this pointed out that doctors have control over their illness and treatment decisions, and there was little they could do as they perceived everything to lie within the doctor's hands:

'Whatever the doctor tells you to do you have to follow, what else can you do?'

(Patient 7, female, rural area, line 133)

'I don't know anything, I can't read and I can't write! Whatever the doctor tells me I just have to do it, what else can I do?'

(Patient 11, male, rural area, line 66)

'Whatever the doctor tells me to do I have to follow....You and the doctor both have experience with medicines, but I don't. You see I can't change the way I use my medications on my own, I have to follow the doctor's advice because he knows best.'

(Patient 5, male, urban area, line 73, 321)

In that way, having a doctor-centered locus of control might positively influence adherence (unlike a God-centered locus of control), it appeared that those who had a doctor-centered locus of control were more likely to be willing to take their medications as prescribed:

'It's definitely wrong to make changes in the way you use your medications on your own. People should consult their doctor frequently to ask them about things. They should always follow the doctor's advice and not act based on their own judgment. Otherwise, they will suffer.., the most important thing is to stick to the doctor's advice.'

(Patient 7, female, rural area, line 83-87, 109)

'I don't change anything and I don't take less of my medications. I would never do

that unless the doctor tells me to.'

(Patient 5, male, urban area, line73-75)

2.4.4.1.2.4.6 Perceptions of self-efficacy

Perceptions of self-efficacy, or ability to adhere to medications/other diabetes self-care behaviours, also emerged among study participants. The external types of loci of control described above (i.e. God-centered or doctor-centered) denoted participants perceptions that management of their diabetes was dependant on something which is outside their control (e.g., God or doctors). In contrast, perceptions of self-efficacy denoted participants' perceptions of having the skills and ability to manage their own diabetes (i.e., having a can-do attitude). In that way, perceptions of self-efficacy might facilitate adherence to medications/other diabetes self-care behaviours.

All participants (20/20, 100%) reported a high medication self-efficacy, while some reported a high self-efficacy to diet (7/20, 35%), and exercise (5/20, 25%). Therefore, participants were more confident in their ability to take their medications than to perform the other diabetes self-care behaviours such as diet or exercise. Table 2.21 illustrates participants who reported evidence of medication, diet, or exercise self-efficacy (SE).

Table 2.21: Participants reporting evidence of medication, diet, or exercise self-efficacy (SE)

Participant	Medication SE	Diet SE	Exercise SE
Patient 1	✔	⊘	⊘
Patient 2	✔	✔	⊘
Patient 3	✔	✔	✔
Patient 4	✔	✔	⊘
Patient 5	✔	✔	⊘
Patient 6	✔	⊘	⊘
Patient 7	✔	⊘	⊘
Patient 8	✔	✔	⊘
Patient 9	✔	⊘	✔
Patient 10	✔	⊘	⊘
Patient 11	✔	⊘	⊘
Patient 12	✔	✔	⊘
Patient 13	✔	⊘	✔
Patient 14	✔	⊘	⊘
Patient 15	✔	⊘	⊘
Patient 16	✔	⊘	⊘
Patient 17	✔	⊘	⊘
Patient 18	✔	⊘	⊘
Patient 19	✔	⊘	✔
Patient 20	✔	✔	✔

✔ Yes, ⊘No

One interesting finding with regards to medication self-efficacy was that for some participants (6/20, 30%) medication self-efficacy seemed to decrease in case of travelling or being away from home:

'When I travel it gets a bit difficult to inject my insulin. You know, it depends on the journey time, whether it was short or long. It affects my medication taking.'

(Patient 4, female, urban area, line 79-81)

'I travel a lot, and sometimes when I do I don't take my medications during my journey. I'd be tired so I sometimes skip my medications.'

(Patient 9, male, urban area, line 55-65)

'Sometimes when I'm outside the house, I can't take my insulin with me so I have to wait until I get back home so I could eat and inject my insulin.'

(Patient 16, female, urban area, line 26)

2.4.4.1.2.4.7 Perceptions of expertise with the disease and body awareness

Perceptions of expertise with the disease and body awareness is another factor which emerged and might have interfered with patients' adherence to their medications or other diabetes self-care behaviours. Some participants (8/20, 40%) reported that they were able to skip and alter doses of their medications because they became experts at their diabetes and became aware of their own bodies which allowed them to sense what to do in certain situations based on their own feelings, rather than the advice of a health professional. They reported that they can feel when they need to reduce or increase their doses of their medications as their own body would provide cues for action:

'When I have frequent urinations that would disrupt my sleep at night I know that I need to take an extra 20-30 units of insulin. I just know, you kind of become an expert with time.'

(Patient 2, male, urban area, line 53)

'You know after years of having the disease, a person would just know what to do

and how to treat himself.'

(Patient 5, male, urban area, line 142)

This was more common with people who had been diagnosed with diabetes for longer periods of time. Indeed, all participants who reported this sub-theme had been diagnosed for 8 or more years.

2.4.4.1.2.4.8 Social stigma

Social stigma associated with the diagnosis of diabetes appeared to influence participants' adherence to their medications. A couple of participants (2/20, 10%) reported that they would never take their medications in front of others in fear of being stigmatised for having the disease. These participants were among the three youngest participants of the sample (35 and 43 years old) and perceived diabetes to be often associated with older people and so did not want people to find out they had it:

'I wouldn't take my medications when I am with a group of people because they would get surprised that I had it at this age, and they would make it sound like a big deal so I just don't take my medications in front of people.'

(Patient 13, male, rural area, line 189)

'Sometimes when I'm over at my friends' place and it's time for my dose I try to hide the box and pretend that it is just Panadol® or something so that they won't know what it is. I don't want to be known as a diabetic. It's for older people (laughing).'

(Patient 18, female, urban area, line 119-123)

Thinking of the lifestyle of young patients with diabetes, one can imagine that situations whereby the patient would be surrounded by a group of friends are not rare. Therefore, this might be an issue that can influence adherence to their medications in this particular group of patients.

2.4.4.1.2.5 Impact of illness on patient's life

Whether or not diabetes had a great impact on participants' lives seemed to influence their adherence to their medications/other diabetes treatment regimens. For

example, a few participants (4/20, 20%) reported that they had suffered eye damage as a result of their diabetes:

'Diabetes had damaged my eyes gradually.'

(Patient 2, male, urban area, line 15)

'I had eye bleeds because of diabetes. I had a laser surgery for it once, and now they say I have to do it again.'

(Patient 4, female, urban area, line 163)

'Having diabetes for a long time had ruined my eyes. I had to undergo two operations. My left eye had oedema so they drained the water out of it, and I had a laser surgery for the other eye. I had both operations done in Liverpool in the UK'

(Patient 6, male, urban area, line 173)

One participant (1/20, 5%) acknowledged that he had suffered kidney damage as a result of their diabetes:

'I had developed kidney disease, you know, diabetes slowly damages everything in the human's body.'

(Patient 2, male, urban area, line 15)

Other participants (4/20, 20%) reported limitations in performing their daily activities because of their diabetes. One participant reported he could not drive anymore and had to hire a chauffeur to drive him to his daily trips:

'I can't even drive anymore, I can't see properly so people have to drive me everywhere... I got my own chauffeur now who takes me everywhere.'

(Patient 6, male, urban area, line 264)

Two other participants (2/20, 10%) reported they could not do their house work or clean their houses anymore because of their diabetes, which left them constantly exhausted:

'I used to be able to do the house work all by myself, but now my diabetes has

drained my energy levels and caused me pain in the arms. I feel like my bones are so fragile now and not as strong. That's because of diabetes, right?'

(Patient 7, female, rural area, line 119)

'My arms feel so numb. When my daughter puts her head on my arm they go completely numb. I feel like I can't carry anything, like when I'm doing the dishes I feel pain especially in my right arm, so I can't finish the work.'

(Patient 7, female, urban area, line 101)

One other participant (1/20, 5%) reported that prior to his confirmed diagnosis with diabetes; he suffered constant headaches and loss of concentration which hindered his academic performance:

'In 1997 when I was doing my dentistry diploma I felt loss of concentration and constant headaches that hindered my performance. I took loads of Panadol® but it didn't do me any good... So I went to the clinic and they told me I had diabetes. They prescribed me medications; I got better when I used them.'

(Patient 13, male, rural area, line 21)

In general, participants who had developed diabetes complications or diabetes-related limitations in their lives seemed to be more careful about their medications, diet or exercise regimens than those who had not.

2.4.4.1.2.6 Irregular meal patterns

Not having a regular meal pattern emerged as a barrier to medication adherence among participants. Some participants (7/20, 35%) reported that they would never take their insulin or tablets if they had missed their meal(s). Participants seemed to lack the knowledge or education about what to do and acted based on their own judgement in such situations:

'My doses are a complete mess because I don't have regular meals, I delay or take my insulin earlier than I should according to when I had my meals.'

(Patient 10, female, urban area, line 123)

'I associate taking my tablets with meals, so for example if I woke up late and missed breakfast I would just miss the morning tablet and take my next dose at lunch time.'

(Patient 13, male, rural area, line 61)

'I usually don't have breakfast so I just skip the morning tablet of Glucophage®. I don't know if that's the right thing to do. I think that's the right thing to do because the doctor said I should take it after food.'

(Patient 18, female, urban area, line 101-105)

2.4.4.1.2.7 Poor glucose control

Having a history of poor diabetes control was reported by many participants (13/20, 65%) and might be a possible facilitator of their adherence to their medications or an indicator of past or current nonadherence. Participants who reported a history of poor diabetes control appeared to be keener to adhere to their medications in an effort to improve their diabetes control:

'My diabetes was way out of control so I was prescribed many different medications and dosages to try to control my diabetes... now I am on Actrapid® insulin plus Lantus® at night and Glucophage®. It's been working well at controlling my diabetes so I will keep on the same regimen.'

(Patient 6, male, urban area, line 25-67)

'As you can see my blood glucose levels are very high, so the doctor has just increased my dose. I will start taking an extra tablet starting from Sunday to try to bring my blood glucose levels down.'

(Patient 12, female, rural area, line 27-37)

'I was prescribed twice a day, but since there was no control the doctor have added another tablet so I started using three tablets now. I will adhere to this regimen and we shall see how this will work.'

(Patient 19, male, urban area, line 7)

2.4.4.1.3 System/policy related factors

Several themes emerged with regards to the health care system or policy. This section describes subthemes related to the healthcare system or policy which might have influenced adherence to medications (or other diabetes self-care behaviours) among study participants.

2.4.4.1.3.1 Unavailability of medications

Unavailability of medications or unavailability of the required dosage/strength of medications in governmental pharmacies at the time of prescription refills was reported by a quarter of participants (5/20, 25%) and may present barriers to medication adherence:

> *'Glucophage® is not available every time at the pharmacy, so I have to purchase it. This happened only once to be honest.'*
>
> *(Patient 1, male, urban area, line 238)*

> *'Glucophage® is always available, although sometimes in 850 mg and other times in 1000 mg.'*
>
> *(Patient 7, female, rural area, line 97)*

> *'The doctor told me to take two tablets of Glucophage® but I only take one because it's 850 mg. You know, I am supposed to take two of the 500 mg tablets, but sometimes it's not available and they give me the 850 mg instead.'*
>
> *(Patient 14, female, rural area, line 31)*

Although participants in this study reported that when the required medications/dosage forms were unavailable at government pharmacies they purchased them from private pharmacies, this might not be possible or convenient for other patients in reality and might present a barrier to medication adherence.

2.4.4.1.3.2 Perceptions of access difficulties

Access to doctors for diabetes follow-up was perceived as not satisfactory. Seven participants (7/20, 35%) reported that they got the chance to see their doctor only once every two months, a time-gap perceived by one participant to be too long and potentially dangerous:

'You come one month to collect your medications and the next month to see your doctor. TWO MONTHS! That's way too long! It can be dangerous...What if something happens in between that time?'

(Patient 16, female, urban area, line 168-179)

Participants reported difficulties in accessing medications. One common complaint was that some diabetes medications were unavailable for dispensing at polyclinics (4/20, 20%); patients had to go to hospitals to collect some of their diabetes medications which was inconvenient and cumbersome:

'...for example things like Diovan® and insulin you don't get at the polyclinic, you have to come to the hospital. There are more medications here.'

(Patient 4, female, urban area, line 131)

'Some of my medications are unavailable at polyclinics and I have to go to Mubarak Hospital to collect them so, what's the point of going to the polyclinic then? I better come to the hospital directly...you get better availability at hospitals.'

(Patient 10, female, urban area, line 71, 179)

'The real disaster is that Lantus® is only available at hospitals; polyclinics are deprived of it. Why? It's a real disaster.'

(Patient 6, male, urban area, line 49)

Having to wait for a long time for prescriptions to be filled or dispensed at the pharmacy was also a troublesome issue for a few participants (4/20, 20%) who complained of terribly long queues which made them dread and sometimes avoid coming to the pharmacy to collect their medications. Two participants (2/20, 10%) did not come to pharmacies at the Ministry of Health for years because of this issue:

'Medication access became a problem, when you reach the pharmacy it's like you're begging for your medications! The queues are just unbelievable, people have to come from 6.00 AM to take their medications. Why do we have to wait all that long?... I think one of the biggest problems preventing people from taking their

medications is these ridiculous queues at the pharmacy. I for one don't come here anymore because of it. I take my prescription to the Amir's Office Pharmacy, which I am entitled to use because of my job, I've been filling it there for years.'

(Patient 3, male, urban area, line 27, 218, 67)

'You have to come to the pharmacy every month to take your medications, and it's really crowded there so I stopped coming here for a long time. I've been buying my medications from private pharmacies for five years now to avoid this crowdedness.'

(Patient 13, male, rural area, line 109-119)

One of the concerns reported by a couple of participants (2/20, 10%) with regards to access to the health care system was that in case of diabetes emergencies, there was no practical place to go to that was within patients' reach. Participants had no choice but to go to hospitals which were far away and inconvenient:

'Suppose I had a diabetes emergency at night, where shall I go? Do I HAVE TO go all the way to the Emergencies at Al-Amiri Hospital! That's really the closest point of care and it's too far.'

(Patient 16, female, urban area, line 174)

A few participants (3/20, 15%) complained there was no specialized diabetes centre where all diabetes-related services were provided. Participants reported having to go to a number of different places to carry out routine diabetes tests and investigations which was cumbersome and inconvenient, as one participant explained in the following quote:

'Every time you come here the doctor gives you a load of referral papers to do your routine lab tests. We have to go to many different places. Why can't we have a specialised diabetes centre at each residential area so that people don't have to go through all the trouble?'

(Patient 13, male, rural area, line 91-93)

2.4.4.1.3.3 Perception of inequalities of medication supply and services

A quarter of participants (5/20, 25%) perceived there were inequalities in care provision and supply of medication at different clinics or hospitals. One participant complained of inequality at dispensing medication supplies in different health districts, with patients receiving more quantities of their medications at some districts:

> *'When I come here they just provide me with a month's supply of medications, when I ask for more they won't give me. You know my sister in law gets a three month's supply every time at Al-Adiliya clinic! (a polyclinic in a different health district)'*
>
> *(Patient 9, male, urban area, line 147-149)*

Another participant perceived an inequality in availability of medications at different hospitals:

> *'At Mubarak hospital you get a good availability of medications, whereas at Al-Amiri Hospital you get a lot of missing items, especially Lipitor® and stuff.'*
>
> *(Patient 6, male, urban area, line 251)*

One other participant perceived there was a disparity in the quality of medical services provided for patients at different health districts, and considered people living in rural areas as disadvantaged compared to people living in inner cities of Kuwait:

> *'People in Al-Jahra district have no access to good quality medical services like people in the city, so they often travel to get treated at city hospitals, where there are better services and where people treat them better. Why can't they have a place which includes all the clinics and specialized medical services they need there at their convenience?'*
>
> *(Patient 3, male, urban area, line 183)*

2.4.4.1.3.4 Lack of trust in the government health care system

A few participants (4/20, 20%) reported a lack of trust in the government health care system as a whole. One participant accused the Ministry of Health of corruption and not acting in the interests of patients. He explained this with the example of Avandia® (a relatively new diabetic medicine that was associated with serious side effects):

'I think the whole system is built on corruption and not taking the interests of patients as the priority. Like in the case of Avandia®, when it was found to be harmful it was supposed to be taken off the market immediately, just like in other countries, but instead they decided to go on dispensing the remaining stock to patients so the drug agent won't incur any financial loss. Even though technically the mother company would incur the financial loss in that case, the ministry continued to prescribe it. It's all about politics and satisfying personal interests of the people in charge; no one really cares about the interest of patients.'

(Patient 6, male, urban area, line 283)

Another participant accused employees of the Ministry of Health of not having a genuine care for patients; she perceived the reality to be far from the image they try to convey in front of the media and the ministry's management leaders:

'It's too bad, and no one would ever know how they (clinic staff) really treat patients. When a minister or a manger shows up, they would spread flowers everywhere, and they would be all smiles treating us right. But when no one is watching, they go back to their normal selves. You can't tell how a doctor treats patients unless you're the patient and you go into that room alone with the doctor.'

(Patient 8, male, rural area, line 382)

Two participants had no trust in the medications provided by the Ministry of Health. They perceived medications provided to be of the low quality, which might cause or complicate other problems to patients, as in the following quote:

'I don't know whether this is true or if it's just my own belief, but I think that the tablets they provide for us here are no good. You know a friend of mine had a father who had diabetes and a heart condition. I remember they took him for treatment outside the country, and doctors told him that the tablets he was prescribed in Kuwait were not good, that somehow they were complicating his other conditions.'

(Patient 18, female, urban area, line 187)

Due to all of the above, a few participants (3/20, 15%) turned to the private sector which they perceived to provide them with better care, better services, and better medications:

'I always take my kids to private doctors because they diagnose and treat them way better than in the government sector.'

(Patient 18, female, urban area, line 173)

'I have been following up for my diabetes at a private pharmacy rather than at the polyclinic, I have come to know a pharmacist who is very good and very respectful and provides me with good advice and a good service, because I am paying him, you know.'

(Patient 8, female, rural area, line 130, 250)

'If you catch the flu for example here at government sector they would typically give you a medication that won't work, even if you finish the whole bottle. If you go to the private doctor however, he (the doctor) would prescribe you the best medication out there, you just have to take a tablet or two and you'd be all better already. Medications at the Ministry of Health are not that effective.'

(Patient 16, female, urban area, line 123)

2.4.4.2 Barriers to other diabetes self-care behaviours

Although medication adherence was the main focus of research, participants were also asked whether they performed other diabetes self-care behaviours including: (1) adherence to diet plans, (2) adherence to exercise, (3) adherence to self blood glucose monitoring (SBGM), and (4) adherence to foot care. Those who reported not being involved in a particular behaviour were asked for particular barriers preventing this. This section will discuss the findings related to barriers to performing other diabetes self-care behaviours.

2.4.4.2.1 Diet

Only some participants (7/20, 35%) reported that adherence to dietary advice was provided by their doctors, although none of them had a specific healthy diet plan to follow.

Adherence to dietary advice among participants manifested mainly as avoiding or cutting back on sweets and desserts, eating in moderation, having more fruits and vegetables, avoiding fatty foods, avoiding snacks in between meals, incorporating healthy alternatives such as artificial sweeteners, and barley bread instead of white bread. As for the barriers preventing participants from adhering to diet plans, six themes emerged. According to their recurrence these were: (1) food cravings (13/20, 65%), (2) social gatherings (10/20, 50%), (3) lack of dietary awareness (5/20, 25%), (4) lack of motivation (3/20, 15%), (5) eating like rest of family members (3/20, 15%) and (6) lack of time (2/20, 10%). Table 2.22 lists some quotes which illustrates the above themes as barriers preventing diet adherence.

Table 2.22: Quotes of participants illustrating barriers to diet adherence

Finding	Quote	Patient, Line
Food cravings/ temptations	*'Ever since I was diagnosed with diabetes, I started to crave for chocolates... my biggest problem I think is that I'm crazy about rice, I just love to have rice! I can't live without rice and that's what spikes my sugar levels.'*	Patient 14, female, rural area, line 15-19
	'The biggest problem I face with regards to diet is hunger. I constantly feel hungry, all the time so it's hard for me.'	Patient 15, male, urban area, 131
	'Sweets are so tempting to me, I can't resist them when I see them'	Patient 19, male, urban area, line 27
Social gatherings	*'I am usually very careful about my diet, except at family gatherings which are once a week. I let myself have whatever they're having.'*	Patient 19, male, urban area, line 23-29
	'When I go to the desert with my friends, we would eat lots of meat and stuff.'	Patient 11, male, rural area, line 247
Lack of dietary awareness	*'The doctor hasn't told me what to eat and what not to eat, so I eat normally.'*	Patient 9, male, urban area, line 77
	'You should eat whatever you desire; otherwise your body will grow weak. Your body needs it, your blood need it. If you don't eat well you'd die. Food is health, you shouldn't deprive yourself.'	Patient 11, male, rural area, line
	'At the beginning of my diagnosis, I did not know anything about diet control. I was unaware of what to eat and what to avoid. I used to eat things I shouldn't have like sweets, creamy desserts, you name it!'	Patient 4, female, urban area, line 39, 59, 219
Eating like rest of family members	*'You know, we eat whatever the family is eating, rice.. fish.. stew..whatever.'*	Patient 4, female, urban area, line 189
	'I eat normally, like anyone else in the family.'	Patient 9, male, urban area, line 71
Lack of motivation	*'I should take a firm decision about it (diet) but I still haven't. I always say I'll start tomorrow, it's always tomorrow, tomorrow, tomorrow.'*	Patient 18, female, urban area, line 153
	'You stick to a diet plan just for a little while and then you get sick of it, you know.'	Patient 14, female, rural area, line 15
Lack of time	*'I was too busy taking care of my kids to be thinking about my own diet.'*	Patient 4, female, urban area, line 189

2.4.4.2.2 Exercise

As for exercise adherence, only a quarter of participants (5/20, 25%) reported they were exercising regularly. Walking was reported as the most common exercise (reported by 4/5, 80% of those who exercised). One participant reported swimming, and another reported going to the gym for exercise. As for the barriers preventing participants from adhering to exercise, seven themes emerged. According to their recurrence these were: (1) comorbidity (9/20, 45%), (2) laziness/lack of motivation (6/20, 30%), (3) weather (4/20, 20%), (4) considering activities of daily living enough exercise (4/20, 20%), (5) social/cultural restrictions (3/20, 15%), (6) fear of hypoglycaemia (1/20, 5%), and (7) no time (1/20, 5%). Table 2.23 lists some quotes which illustrate the above themes as barriers preventing exercise adherence.

Table 2.23: Quotes of participants illustrating barriers to exercise adherence

Finding	Quote	Patient, Line
Comorbidity	*'I have a bad asthma so I can't go out for walking if the weather was dusty.'*	Patient 5, male, urban area, line 193
	'I can't walk because I have varicose veins...some people have health problems which prevents them from exercising.'	Patient 7, female, rural area, line 73, 159
	'I can't walk because of my knee problem...it's too painful to walk.'	Patient 10, female, urban area, like 107-113
Laziness/lack of motivation	*'My wife has a jogging machine at home but I don't use it, I would use it maybe once or twice and then I'd get bored.'*	Patient 5, male, urban area, line 345
	'I signed up with a gym with my friend but when she cancelled I cancelled too. I needed someone to encourage me.'	Patient 18, female, urban area, line 65
	'There is no excuse for me, it's just laziness and carelessness'	Patient 14, female, rural area, line 27
Weather	*'I don't exercise often because of the weather. I can't stand the heat, so I go for walking rarely when the weather is nice.'*	Patient 6, male, urban area, line 103,113
	'How could I exercise in this weather? It's too hot in the summer and too cold in winter.'	Patient 16, female, urban area, line 97
Considering activities of daily living enough exercise	*'I don't exercise but you see, when I go out I'd park the car as far as possible so I would walk a bit more.'*	Patient 6, male, urban area, line 109
	'I don't exercise but I would walk every day to the mosque, it's not that far from the house though.'	Patient 11, male, rural area, line 139
	'Well I don't exercise per se but I do the housework on my own which involves going up and down the stairs, cleaning and so on, so I am always moving. I think that counts!'	Patient 17, female, urban area, line 67
Social/cultural restrictions	*'I would love to go out for walking but my husband doesn't really like it.'*	Patient 14, female, rural area, line 113
	'I used to walk but now I have a little daughter to take care of so I don't get the time to do any exercise.'	Patient 17, female, urban area, line 69
	'I usually go walking everyday but I have been busy lately, helping the kids prepare for their exams.'	Patient 20, female, urban area, line 37
Fear of hypoglycemia	*'I am afraid to go walking these days because I am afraid to get a hypoglycemia... especially after they had added my Actrapid®*	Patient 6, male, urban area, line 105,165
No time	*'I have a little daughter to take care of so I don't get the time to do any exercise.'*	Patient 17, female, urban area, line 69

2.4.4.2.3 Self Blood Glucose Monitoring (SBGM)

Although many participants (13/20, 65%) reported they were self-monitoring their blood glucose levels at home using a glucometer, only three (15%) did this on a regular basis. Ten participants (50%) reported they monitored their blood glucose levels only occasionally: (1) when they felt it was needed (i.e. feeling tired, dizzy, increased frequency of urination, numbness of limbs, etc.), (2) when the doctor requests it, (3) after medication/dose changes, and (4) just prior to appointments. Table 2.24 lists the frequency with which participants self-monitored their blood glucose levels. As for the barriers which prevented patients from self-blood glucose monitoring six themes emerged. These were, according to their recurrence: (1) fear of becoming stressed about it/obsessed with it (2/20, 10%), (2) fear it might not give accurate results (2/20, 10%), (3) fear of not liking the results (1/20, 5%), (4) monitoring strips no longer supplied to patients by the Ministry (1/20, 5%), (5) lack of awareness regarding necessity of SBGM (1/20, 5%), and (6) no time (1/20, 5%). Table 2.25 lists some quotes illustrating the above themes.

Table 2.24: Frequency of self-monitoring blood glucose levels among participants

Participant	Performs SBGM
Patient 1	When feels needed- After medication or dose changes
Patient 2	When feels needed- After medication or dose changes- When doctor requests
Patient 3	-
Patient 4	When feels needed
Patient 5	-
Patient 6	-
Patient 7	When feels needed
Patient 8	-
Patient 9	Once a week
Patient 10	When feels needed- When doctor requests
Patient 11	-
Patient 12	When feels needed- After medication or dose changes- When doctor requests
Patient 13	When feels needed (once a month)
Patient 14	When feels needed
Patient 15	When feels needed
Patient 16	Twice a day every day- When feels needed
Patient 17	When eats a lot- Just before appointments
Patient 18	-
Patient 19	-
Patient 20	Twice a week

Table 2.25: Quotes of participants illustrating barriers to SBGM

Finding	Quote	Patient, Line
Fear of becoming stressed about it/obsessed with it	*'I don't want to get used to the thing (glucometer) because I don't want to become obsessed about it. People who use it tend to panic and get obsessed about it they might monitor every 5 minutes! If you get used to it, it might elevate your blood glucose levels, because of the stress it creates.'*	Patient 5, male, urban area, line 243-253
	'I don't want to be stressed, over-doing it (SBGM) makes me stressed and worried.'	Patient 20, female, urban area, line 136-141
Fear of not liking the result	*'Last time I monitored myself it (blood glucose level) was high so I didn't like the result. I don't want to do it because I'm afraid I might not like the results (laughing).'*	Patient 18, female, urban area, line 205
Fear it might not give accurate results	*'I am afraid to do it (SBGM) at home because I am worried it might not be accurate. I prefer to do it at the private pharmacy, it's cheap and convenient. '*	Patient 8, female, rural area, line 195
	'I don't want to get a home monitor, I prefer to do this at the clinic because I am worried the home monitor might not be accurate and might give faulty readings.'	Patient 19, male, urban area, line 1487-157
Monitoring strips no longer supplied by the Ministry	*'I don't test my blood sugars at home because the Ministry no longer provides us with the testing strips. Now I go to the clinic to do the test.'*	Patient 6, male, urban area, line 209-211
Lack of awareness regarding necessity of SBGM	*'I think it (SBGM) is all useless! I don't want to do it. Like some people would stick themselves with needles and so on. I don't want that, even if the doctor gave me the strips for free. I won't do it because it's useless. I don't believe in testing blood glucose levels, not even at the clinic.'*	Patient 11, male, rural area, line 249-253
No time	*'I don't monitor myself at home anymore to be honest because I don't have the time, I am always in a rush going to work and so on.'*	Patient 18, female, urban area, line 25-27

2.4.4.2.4 Foot care

Only some participants (6/20, 30%) reported taking care of their feet and performing foot checks and related activities (e.g., washing the feet regularly, drying carefully, moisturizing feet, wearing socks, wearing loosely-fitted closed shoes, going to

the hospital for wound treatment when necessary, and/or having professional pedicure sessions periodically):

'I take a good care of my feet. For example when I notice something wrong with it I would immediately go to Al-Amiri Hospital to have it cleaned and wrapped before it gets worse and turn into gangrene... I know what to do because the doctor told me to wear closed loose-fitted shoes, wash my feet regularly, check them for any wounds by placing a mirror underneath my feet so I always do that. I also wear healthy pairs of shoes which are loosely-fitted.'

(Patient 2, male, urban area, line 215-220)

'I take care of my feet. I would wash them thoroughly, especially for prayers. I don't wear my socks unless I'm sure my feet are dry. I always sterilise them with Dettol® and that orange disinfectant. I don't want to have foot problems.'

(Patient 5, male, urban area, line 163-179)

'I take care of my feet. Look at me, wearing these thick pair of socks like an old lady! (laughing). My daughter is embarrassed of me but I don't care if it doesn't look nice, I just do it to protect my feet because I'm worried about it. I always wear a comfy pair of shoes; I don't wear high heels anymore.'

(Patient 14, female, rural area, line 126-130)

'I sometimes have professional pedicure sessions done for my feet at private clinics. I had one here in Kuwait, and another in Jordan. I will do another one when I visit my son in Jordan.'

(Patient 6, male, urban area, line 195)

Participants who did not perform foot care activities did not describe any barriers preventing them from performing these. Table 2.26 summarizes the different diabetes self-care behaviours and whether they were performed by each patient.

It is clear from Table 2.26 that adherence to SBGM was most common among study participants followed by adherence to diet, foot care, exercise then medications (respectively).

Table 2.26: Participants' performance of different self-care behaviours

Patient number	Medication adherence	Diet adherence	Exercise adherence	SBGM Adherence	Foot care Adherence
1	⊘	⊘	⊘	✔	?
2	⊘	✔	⊘	✔	✔
3	⊘	⊘	✔	⊘	?
4	⊘	✔	⊘	✔	?
5	⊘	✔	⊘	⊘	✔
6	⊘	⊘	⊘	⊘	✔
7	⊘	⊘	⊘	✔	?
8	✔	✔	⊘	⊘	?
9	⊘	⊘	✔	✔	?
10	⊘	⊘	⊘	✔	?
11	⊘	⊘	⊘	⊘	?
12	⊘	✔	⊘	✔	?
13	⊘	⊘	✔	✔	?
14	⊘	⊘	⊘	✔	✔
15	⊘	⊘	⊘	✔	✔
16	⊘	⊘	⊘	✔	✔
17	✔	⊘	⊘	✔	?
18	⊘	⊘	⊘	⊘	?
19	⊘	✔	✔	⊘	?
20	✔	✔	✔	✔	?

✔ Yes, ⊘No, ? Not mentioned.

2.4.4.3 Information/service needs

All but one participants (19/20, 95%) offered recommendations for improving diabetes care in Kuwait. Recommendations involved the need for; (1) services, (2) supply, and (3) information.

2.4.4.3.1 Required services

A few participants (3/20, 15%) requested specialized diabetes centers where diabetes care could be provided to them at their convenience. These centers would be inclusive of all the necessary services a diabetic would typically need:

> *'We need to have a diabetic foot clinic, a dental check clinic, a cardiovascular clinic all here at one place...We have to go to different places at different days to do all of the necessary routine checks...For example why should I have to go all the way to Al-Amiri Hospital to do this? It is a must to have all of these services at one*

place, we also need a consultant and a psychologist at the clinic, it is very essential.'

(Patient 16, female, urban area, line 56)

'I see a lack of planning on part of the Ministry of Health; there are no specialized centres which provide special care for example for skeletal diseases, diabetes, etc. Patients need to have everything at one place so they don't get lost trying to find where to go! ... The government should look into that; building specialised fully equipped hospitals.'

(Patient 3, male, urban area, line 23, 31)

Two participants (2/20, 10%) recommended emergency points of care, which would be available to patients at their convenience, and covering hours outside of the typical working day:

'Say you had a diabetic crisis after 10.00 PM, what shall you do in that case? Polyclinics would be closed, you see.'

(Patient 8, female, rural area, line 206)

'We must have emergency points of care which are close by and convenient. It is very important.. especially for school kids. There is nowhere close by to go to in case you had a diabetic emergency.'

(Patient 16, female, urban area, line 174-181)

As reported in Section 2.4.4.1.1.2, a quarter of participants (5/20, 25%) complained that doctors sometimes missed performing essential checks at outpatient clinic appointments, and therefore they requested a more comprehensive care at outpatient appointments:

'Doctors are supposed to check on our feet. A foot clinic and a dental clinic must be available for us on site. I know they have just opened these vascular clinics (pointing to the rooms in front of us), but look at them now, they are all closed! Lately I have been transferred to the heart clinic to have my heart checked, but they

only checked on my heart rate! It shouldn't be just about that! They were supposed to let me do the treadmill test...These things are important for a diabetic person but they are still unavailable.'

(Patient 16, female, urban area, line 56-58)

A couple of participants (2/20, 10%) considered necessary more flexibility in outpatient appointments in case patients were unable to attend their appointments for any reason:

'Appointments are set in such a way that there are days for ladies, and days for gentlemen. For some reason occasionally some ladies show up on gentlemen's days and vice versa, and they (clinic staff) turn them away. Doctors need to be more flexible about appointments.'

(Patient 1, male, urban area, line 261)

One participant also required more frequent appointments in order to avoid or decrease potential problems that might arise in the long time-gaps between current appointments:

'You get to see the doctor only once every two months! That's way too long! It can be dangerous...What if something happens in that time? Diabetics and hypertensive patients must see their doctor more frequently.'

(Patient 16, female, urban area, line 168-179)

A couple of participants (2/20, 10%) requested provision of proper diet and exercise plans, so that it would be easier for them to undertake such demanding behavioural changes:

'It would be great if dieticians would provide us with proper dietary advice, and then provide follow-up to make sure we are on the right track.'

(Patient 2, male, urban area, line 149)

'I would have loved it if the doctor would give me specific instructions on what to

do in terms of diet or exercise so I could lose some weight and improve my blood sugar levels.'

(Patient 12, female, rural area, line 149)

Another couple of participants (2/20, 10%) suggested the Ministry should provide special services for the elderly who need special care and attention. One participant suggested preparation of special packaging of medications by pharmacists:

'Older people often have trouble taking their medications because some of them can't read so it's hard for them to follow instructions. It would be good if pharmacists would do something like arranging their medications for them...like putting all the morning medications together in one sleeve and telling them that these are for the morning, and those are for the evening, you know, classifying and preparing them in such a way to make it easy for the older patients to take their medications correctly.'

(Patient 1, male, urban area, line 317-324)

Another participant suggested offering home-visits to those who are immobile:

'Some of the elderly patients are immobile so it's very hard for them to come to the clinic for follow up. It would be helpful if doctors could go to their homes to check on them. I know this service is available now by some companies who offer nursing services to the elderly at their homes, but I'm not sure if doctors are involved.'

(Patient 5, male, urban area, line 309-318)

2.4.4.3.2 Required supplies

Participants had many recommendations with regards to their medication supply. A couple of participants (2/20, 10%) requested vitamins to be reauthorized as standard care for diabetics. The Ministry had stopped its supply of vitamins for diabetics for a while in order to cut down costs, a change perceived as neither reasonable nor welcome by some participants:

'I would like to suggest bringing back the vitamins because these are very important for people with diabetes, especially vitamin E. I don't understand why

they stopped our vitamins... we need our multivitamins.'

(Patient 1, male, urban area, line 265, 289)

'I would like to suggest for the Ministry to provide us with vitamins. People over 40 years of age need things like Omega 3 and so on. They (the Ministry) even stopped our normal multivitamins! Now we are buying ¾ of our medications from the private pharmacies.'

(Patient 16, female, urban area, line 118)

As reported in Section 2.4.4.1.2.2.5 Western brands of medications were perceived by some as more effective and palatable, and therefore a few participants required the Ministry to import these brands instead of the local alternatives (3/20, 15%):

'I would like the Ministry to provide us with the best medications out there, not those of Julphar (local, UAE manufacturer) and so on! They're no good, you can't even swallow their tablets.'

(Patient 16, female, urban area, line 118)

One participant complained that medications provided by the Ministry were of a very low quality, hinting a desire for access to better quality medications:

'Let me tell you something, the Ministry provides us with the worst, cheapest, lowest quality of medications. Worst.. worst..worst.. nastiest.. cheapest... medications. That's what they bring to us.'

(Patient 11, male, rural area, l81)

As for the logistics of medication supply at the Ministry, a few participants (4/20, 20%) dreaded the fact that some diabetes medications were only available for dispensing at hospitals, and requested, for their convenience, that the Ministry make these available at the clinics too:

'I don't know who is that genius who set that stupid strategy to dispense our diabetes medications only at the hospitals! Why can't we collect our medications from polyclinics?! They can put some medications at the hospitals but not all! Why

do I need to drive all the way from my home to Ahmadi to collect my medications! They need to make it easy for us, make medications available at polyclinics. It will also decrease the crowdedness at the hospitals.'

(Patient 3, male, urban area, line 219)

Some participants (5/20, 25%) were not happy about the quantity of medications prescribed at refills and requested more "generosity" in dispensing so that they would not have to come to the pharmacies often:

'When I come to the pharmacy they would give me the exact number of tablets written by the doctor, not even a single more tablet. They should be more generous!'

(Patient 11, male, rural area, line 175)

'I don't want to have to come to the pharmacies often so I usually ask the doctor to prescribe me a 3-month supply but when I go to the pharmacy they would only dispense me a one month's worth of supply. I argue with them often about that, but they say they don't have enough stock'

(Patient 1, male, urban area, line 279)

A few participants (3/20, 15%) required the Ministry to keep up to date with the latest advances of diabetes treatment and to make them available in Kuwait as soon as possible once they become available in the international market:

'I wish that the Ministry would bring the latest advances in diabetes treatment such as that nasal insulin and so on to Kuwait as soon as possible. For example, insulin pens became available to us years after they came out, you know.'

(Patient 2, male, urban area, line 163)

One participant also needed the Ministry to supply blood glucose monitoring strips to patients so they could perform SBGM at home:

'I don't monitor my blood glucose levels at home because I don't have the strips. The

polyclinic used to provide us with these strips before but now they don't and it's a problem really, a big problem.'

(Patient 6, male, urban area, line 211)

2.4.4.3.3 Information needs

As described in Sections 2.4.4.1.1.2 and 2.4.4.1.2.1 participants demonstrated a lack of knowledge about diabetes medications, diabetes complications/anticipated problems, or diet/exercise advice. Recognizing these deficiencies, many participants (12/20, 60%) requested that clinicians provide more education about such important issues. Table 2.27 illustrates quotes associated with this.

Table 2.27: Quotes of participants highlighting their information needs

Recommendation	Quotes	Patient, Line
Information regarding diabetes/potential problems	*'It is very important to raise awareness about the harmful impact of smoking on patients with diabetes. If a patient smokes, chances are he would get worse gangrenes so people must be made aware of this.'*	Patient 6, male, urban area, line 304
Information regarding diabetes/ medications	*'I would like to know more about diabetes and I know it's not just me, many people need it too. For example what is Glucophage®, what does it do, how long does it take to work, and for how long does it last? It's important. We need these kind of information.'*	Patient 15, male, urban area, line 157
Information regarding diabetes complications/potential problems	*'Some people are unfortunately ignorant and would do harmful surgical procedures to their feet thinking it might cure their diabetes. Unfortunately most of them end up having gangrenes, it's very important to educate people and raise their awareness regarding this.'*	Patient 6, male, urban area, line 284-289
Information regarding medication use	*'We don't get enough instructions about how to take our medications; they are supposed to tell us.'*	Patient 13, male, rural area, line 183
Information regarding diet advice	*'Dieticians would just look at your tests and tell you whether they were OK or not. They don't tell much, and they don't provide ongoing education and support.'*	Patient 2, male, urban area, line 153
Information regarding complications, diet advice	*'Doctors are supposed to tell you about the complications of diabetes early on so that you could try to avoid them. I never realized it could affect the eyes and kidneys.. I didn't even know I should control my diet until years after.'*	Patient 4, female, urban area, line 153-159, 217-219

A quarter of participants (5/20, 25%) suggested useful educatory material/channels to deliver the needed information such as posters, brochures, TV shows or programs:

'Brochures with pictures are very handy and make it easy for the elderly to follow instructions... or posters on the walls at the polyclinics, with big pictures and preferably brief or no writing makes it very easy to spot and learn from.'

(Patient 1, male, urban area, line 267,273)

'I find posters and little leaflets with all the necessary information very useful and handy'

(Patient 4, female, urban area, line 173)

'I find the media, such as TV programs and shows very useful to raise the public's awareness about diabetes.'

(Patient 16, female, urban area, line 68-72)

A few participants (4/20, 20%) were also very keen to learn about latest advances in the treatment of diabetes, and considered it the responsibility of their doctors to provide them with such important information:

'If there was anything new with regards to diabetes, it is the responsibility of the doctor to let us know about it, to keep us up to date you know.'

(Patient 1, male, urban area, line 255)

'I think the doctors should tell you about the latest advances in treatment of diabetes, even if these were still not available at the Ministry, so that you would know and buy it on your own if you wanted to. They must give you the choice to do that, especially if the new unavailable treatment is the better option.'

(Patient 2, male, urban area, line 163-167)

2.5 Personal reflections about the research

In qualitative research, it is important for researchers to understand and be aware of their own positions in the research process and how their personal characteristics and/or

experiences might have influenced choices made in the research process, their understanding of the research participants, the phenomenon under study, or both, and ultimately, the knowledge constructed. It is now accepted that cultural, social, professional, biographical, and personal characteristics influence what is perceived, experienced, interpreted and reported. Consequently, reflexivity about the research process is considered an important task of qualitative researchers:

> *"Without such reflection the outcomes of the research process are regarded as "characteristics of objects," as "existing realities," despite their constructed nature that originates in the various choices and decisions researchers undertake during the process of researching".*
>
> (Mruck and Breuer, 2003)

In this section I will reflect on how my personal characteristics and background may have influenced the research process and findings. I believe that my personal characteristics, in terms of nationality, gender, professional background have put me at a distinctive place, which proved advantageous in terms of facilitating the research process, although at times, it proved otherwise.

As a Kuwaiti national, I felt that I was perceived by the research participants as an "insider", someone who shared the same cultural norms and belief system of the Kuwaiti community. I believe that this has placed me at an advantageous position which facilitated the research process in so many ways. I felt that, as a result of my nationality, participants felt an immediate connection and were happy to disclose and share information with me. This was evident as some participants made their feelings explicit in terms of my nationality:

"You are our Kuwaiti daughter, we have to help you"

"You make us and the country very proud. God bless you!"

In addition, it might have also made it particularly easier for participants to disclose their feelings about particular non-Kuwaiti doctors, whom they perceived as uncaring and insensitive. Had I been a non-Kuwaiti, it is unlikely that participants would disclose their

negative views in this regard, especially if I had shared the same nationality of these doctors.

Despite being an "insider" as a Kuwaiti national, I was also "an outsider" to the research participants, as I was unfamiliar with the life and contexts of patients who had T2DM. This might have had an influence on how they might have perceived me, and consequently, behaved towards me. Therefore, I had to find a balance between being sensitive and responsive to the issues and concerns participants raised in a way to allow them to share their stories, and yet not influencing what they had to say in any way.

My gender role as a female had a potential influence on the research process. In Kuwait, and as any other country in the Middle East, there are defined gender-roles, which people are supposed to play and live by. Females are not supposed to mix with or talk to males, unless extremely necessary. I was aware of that issue from the outset of my research and wondered whether there would be a problem recruiting and talking to male participants. I was afraid that males may not welcome or feel comfortable talking to me (as a female) about their disease, medications, etc. in sufficient depth and sincerity to allow the aims of the research to be achieved. However, after the pilot study with the first three participants (who were male), my worries resolved as I was able to engage with male participants in a professional way that it was easy for them to share their stories with me. At the end of data collection, the analysis of interview transcripts showed that I was able to gather data of similar quality and depth from the male participants as that of female participants.

Nevertheless, there was an issue which might have been brought about due to my gender as a female and might have been disadvantageous in the research. Specifically, when I asked participants about the impact of diabetes in the context of their daily lives, I have noticed that none of the male participants discussed having sexual dysfunction as a result of their diabetes. This is possibly due to the intimacy of the issue, complicated by my gender as a female. Discussing sexual problems is considered culturally inappropriate and embarrassing, particularly with someone of the opposite sex, even if that person is a healthcare provider.

In terms of my identity as a researcher, I chose to introduce myself as a PhD student

and a pharmacist. Therefore, participants might have suspected an association between myself and their healthcare providers. Consequently, they might have concealed critical information fearing that I might share it with their healthcare providers, ultimately influencing the care they would receive. However, participants were assured that the information they provide was confidential and would not be shared with their healthcare providers. I believe this helped to put participants at ease and the amount of criticism to healthcare providers (as shown in the results section of this chapter) assured me that, to some degree, participants trusted in me and provided me with their true accounts of how they felt about their healthcare providers.

Another issue that became apparent, especially with participants of the rural areas, is their perceived class difference. Some participants clearly stated their disadvantaged position compared to me (as an educated person who can read and write, and who is also a pharmacist):

> *'You are a pharmacist, you can read and write, so you could easily understand these things (meaning detailed information about medicines), whereas I don't. I am just a simple person, I cannot read and I cannot write'*

However, despite the perceived difference, participants were incredibly willing to me talk freely, and I did not feel they had reservations or intention to withhold information. In fact, I felt that participants were actually happy to have had the chance to speak for themselves and to be heard. They somehow thought of this research as an opportunity to raise their issues and concerns, hoping that findings from this research would help to solve at least some of these problems.

Finally, I believe that my Muslim faith had an influence on the research process. Sharing the same faith with my participants I felt helped to create an instant connection between us, and the talk of God and Islamic values and beliefs painted most interviews. Nevertheless, the expectations of being a practiced Muslim had a minor drawback with respect to participants revealing practices that might be judged as sins in the Muslim faith, such as the intake of alcohol and its relevance to lifestyle changes influencing diet plans. Only one participant admitted to consumption of alcohol, and I felt from the tone and facial expressions that he was not at ease to disclose such information.

2.6 DISCUSSION

This chapter presented the first study exploring nonadherence to medications and other diabetes self-care behaviors such as diet restriction, exercise, SBGM, foot-care and smoking cessation advice among Kuwaiti T2DM patients, providing novel evidence that nonadherence to diabetes medications and its treatment among this particular population is problematic. The main aim of the study was to explore how diabetes medications were being taken and what barriers existed which prevented adherence to medications among this particular population. Nevertheless, participants were also asked to discuss whether they adhered to other diabetes self-care behaviours, and in cases where they did not, to provide reasons for their nonadherence.

An exploration of barriers to adherence to diabetes medications and self-care behaviours among study participants revealed many similarities with evidence from the Western literature, although some differences were also found which appeared specific to the Kuwaiti population. For example, in line with the Western literature, patients' lack of knowledge about diabetes or its treatment, little or no patient education or counseling by healthcare providers, and their paternalism and lack of compassion towards patients were all found to interfere with participants' adherence to their diabetes medications and other self-care behaviours. In terms of barriers specific to this particular population, the current study identified some beliefs about medicines which have not been adequately described in the literature, although participants also held beliefs which were in common with the Western literature. In addition to these beliefs, perceptions about health care providers such as favouritism and inequality of care provision, and perceptions about the healthcare system such as lack of trust, issues relating to the organization of the healthcare system and the impact of this on access to healthcare services or medication supply appeared to be findings specific to the Kuwaiti population. In addition, a number of personal factors such as perceptions of social support, fatalism/having a God-centered locus of control, and social issues highlighted some differences to findings from the Western literature. These will all be discussed in more detail the following section, similarities or differences in reference to the current literature will be highlighted. The section will discuss separately: (1) Key findings, (2) Methodological limitations, (3) Summary of findings.

2.6.1 Key findings

Twenty patients with T2DM participated in this study, and the results showed that

most participants (all except for three) were nonadherent to their medications. In terms of intentionality, nonadherence to medications was both intentional and unintentional, and unintentional nonadherence was slightly more frequent than intentional nonadherence. Forgetting was the most frequently quoted reason for unintentional nonadherence, often resulting from distractions, being away from home/travelling, having too many medications, etc. Intentional nonadherence manifested in the form of altering or stopping medication-taking in travel or when away from home (mostly due to a lack of awareness, otherwise for convenience), when feeling better (to relieve the body) or worse (to alleviate adverse effects), taking drug holidays or skipping doses occasionally to relieve the body/to avoid potential for adverse effects, or to test being without the medication. This shows that patients are not passive recipients of medical advice. Rather they sometimes process this advice and develop their own way of taking their medications based on their circumstances or what makes sense to them.

In another classification looking at whether nonadherence was continuous, contextual (i.e., only within certain contexts), or one-off nonadherers (occurring at a one particular point or period of time but never again), the study showed that most participants were contextual nonadherers, i.e., being nonadherent to their medications in certain contexts or situations such as travelling or being away from home, during social gatherings, when tired, when distractions occur, when experiencing adverse effects, etc.

A particularly interesting finding in this study was relating to the use of different self-reported methods for the assessment of medication-adherence. In this study, the Morisky scale as well as interview data were both used for the assessment of adherence to medications, and for identifying the types of nonadherence among study participants. Comparison of data from both methods revealed that what one method suggested was sometimes different or even conflicting to the other. Even when the two methods agreed, it occurred due to chance as participants appeared to have different incidents in mind when reporting their nonadherence behaviour using these different methods. This implies that the usefulness of both methods for the assessment of nonadherence to medications is limited when used solely. It is therefore recommended that data from one method should be assessed with reference to the other. What is missing from one method can be completed by the other. For example, if a patient mentioned in interviews that he decreased his

medications intake to reduce adverse effects this means that he is intentionally nonadherent. If the same patient indicated that he forgets to take his medications through his responses to the Morisky then this patient can be said to have combined intentional and unintentional nonadherence.

Compared to interview data, the Morisky scale was of limited use at detecting intentional nonadherence in this study. This finding may be related to the wording of the scale's items which did not capture all possible forms of intentional nonadherence. In contrast, with interview data participants could easily report and justify their intentional nonadherence, rendering interviews better at detecting the intentional form of nonadherence to medications. When assessing unintentional nonadherence this study provided evidence that the Morisky scale was more useful than interview data for detecting unintentional nonadherence. With three of its eight items specifically worded to assess forgetfulness, it may have been easier for participants to recall particular incidents of forgetting to take their medications with the Morisky scale.

In terms of whether nonadherence was continuous, contextual, or a one-off behaviour, the study showed that interview data was more useful than the Morisky at detecting this aspect of nonadherence. Wording of items in the Morisky scale may have limited the detection of continuous and one-off forms of nonadherence, with most items specifically worded to detect contextual forms of nonadherence (e.g. in travel, when feeling better or worse, etc.).

This study provided evidence that diabetic patients had insufficient knowledge about diabetes and its treatment. Although diabetic patients feared diabetic complications, they did not know how these occurred and how to manage or avoid them. The insufficient knowledge about diabetes and treatment translated into nonadherence to medications and deficient implementation of dietary changes, exercise, blood glucose monitoring, and preventive measures necessary to avert diabetes complications. Studies from other parts of the world including the UK, Belgium, and Canada reported similar knowledge deficits among diabetic patients (Adams, 2003; Vermeire et al., 2003; Hernandez et al., 1999). It has been argued that knowledge is a prerequisite of preventive health behaviour and can motivate patients to take an active role in treatment of their disease (van, I et al., 2000). However, a complicating factor which hinders motivating T2DM patients is the

discordance between metabolic parameters and symptoms of complications. This has been attributed to the fact that changes in lifestyle behaviours do not produce an immediate result as the benefits in reducing the development of complications are long-term. Conversely, inappropriate lifestyle behaviours do not immediately lead to worsening of disease or perceived health (van, I et al., 2000).

The insufficient knowledge about diabetes among participants could be related to the lack of education and counseling by healthcare providers. Participants reported that healthcare providers, most specifically doctors, provided little or no education about diabetes and its management. This is a cause of concern as many participants showed evidence of underestimating the severity of diabetes, altering their medication intake on their own, and not incorporating lifestyle changes needed to manage their diabetes properly. Most participants in this study felt that doctors' education and support were essential, but lacking. Previous research highlighted that diabetic patients require ongoing supervision, direction and education from their general/family practitioners (O'Connor et al., 1997). In the current study, participants particularly wanted more education about new treatments for the management of diabetes.

When speaking of healthcare providers, participants spoke mostly about their doctors, illustrating that doctors were the key players in delivering diabetes patient care in Kuwait. Nevertheless, participants reported a vast amount of criticism about their doctors which have potential implications on their adherence to diabetes medications or treatment regimens. Paternalism and ignoring the patient's perspective during medical consultations was frequently evident throughout most interviews. This is in line with qualitative studies from other parts of the world such as the UK, Belgium and Croatia which reported similar findings (Greenhalgh et al., 1998; Vermeire et al., 2003; Vinter-Repalust et al., 2004). The current study provided evidence that a lack of time may be one possible reason for healthcare providers' adoption of a paternalistic approach. In addition, some participants' personal support for this approach could be another reason for the wide use of this approach by doctors. This became apparent as some participants reported never questioning treatment options, blindly following doctors' advice and considering it inappropriate to question or challenge the doctor's decisions. Low educational level or older age, with most participants growing-up at a time when a doctor's influence was accepted as authoritarian,

may be possible explanations for this attitude and have been reported in the literature (Dietrich, 1996). Nevertheless, the current study showed that some participants wanted more involvement in making decisions about their own treatment and wished for doctors to consider their perspectives. Ignoring patients' perspective may lead them not to follow the instructions provided. It was highlighted that better provider-patient communication may help build trusting relationships and lead to common ground for promoting diabetes self-care behaviours, including medication-taking (Xu et al., 2008).

The current study highlighted a very limited role for healthcare providers other than doctors in providing diabetes care for patients with T2DM. Pharmacists, nurses or dieticians were often criticized for their lack of involvement, impersonal communication or lack of respect for patients. In fact, other healthcare providers' involvement was so little that performing their expected duties was seen as an extraordinary service which was highly appreciated by participants. This implies that great satisfaction was linked to low expectations.

Of all other healthcare providers, this study revealed that pharmacists in particular received a great amount of criticism. Due to their lack of involvement in patient care, pharmacists were mainly perceived as suppliers of medications. Unfortunately, pharmacists even failed to perform this role properly, as basic tasks of labeling and providing clear instructions on the medications packages were often overlooked. Pharmacists used a quick swipe of the pen across medication packaging to indicate how many times the patient should take the medication. This finding has been previously reported in an editorial, and was attributed to the lack of legal requirements to label prescription medications in many countries in the Middle East (Fahey, 2005). The same editorial highlighted that patients' illiteracy and being in a rush were excuses often reported by pharmacists to justify their use of such approach to labeling. The International Pharmaceutical Federation guidelines clearly state that generic name of the medicine, strength and individual dosage instructions are an absolute minimum of information for labels of prescribed medicines (International Pharmaceutical Federation, 2001). However, the current study showed that these were not always be provided by pharmacists when labeling medications. Ensuring that the patient knows how to take their medications is a basic responsibility of the pharmacist, regardless of the patients' literacy level. In fact, pharmacists should make a bigger effort to help

illiterate patients as they may need more support to know how to take their medications properly. Both spoken and written information should be tailored to accommodate patients' literacy. The use of pictograms (small pictures used instead of words) have been found helpful in labeling for people with low literacy (Fahey, 2005). Nevertheless, it is important to note that labeling or any written information provided should reinforce oral discussion, but not substitute it.

The current study revealed perceptions of inequality and favouritism in health care provision among participants. There was a notion that "better" medications and treatment were provided for certain people, such as friends or acquaintances of healthcare providers. This finding has not been adequately described in the literature and may be specific to the Kuwaiti culture. It suggested a lack trust in healthcare providers or the healthcare system in general, which may lead not only to medication nonadherence, but also to patients' stopping their follow-up appointments at the government health sector and seeking help from the private health sector. Indeed, the current study revealed that some participants had more regard to the private healthcare sector, where they felt they were provided with better care and treated with more respect. The literature reported that patients appreciated healthcare providers who were respectful and who gave them the time they needed (Devlin et al., 2006).

Other issues related to healthcare providers identified in this study which might have implications for patients adherence to medication include discontinuity of care (i.e., having to see different doctors at each appointment), inflexibility of doctors about their appointments (i.e., being inconsiderate to patients if they missed their appointments), and having extended time gaps between appointments. These issues all need to be addressed to ensure patients' adherence to medications as they may constitute missed opportunities for intervention to resolve medication-related problems that could arise. Continuity of care, integration of education in healthcare and encouraging patients' attendance have been highlighted as the cornerstones of healthcare to support active patient participation in the management of their diabetes (van, I et al., 2000).

In line with current adherence literature in which beliefs about medicines were found to be strong predictors of medication adherence (Horne and Weinman, 2002b; Hunot et al., 2007; Horne et al., 2007), the current study showed that beliefs about medicines

influenced how patients made sense of their medications, and ultimately their medication-taking behaviour. In this regard, a particularly interesting finding of this study was relating to the range of beliefs participants held about Western brands of medications. Some participants perceived Western brands of medications to be more effective, to be of better quality, or to have less adverse effects compared to local brands. This finding is not adequately reflected in the literature. However, one study using in-depth interviews with 32 British Pakistani and British Indian patients with T2DM reported similar findings as participants perceived that their oral hypoglycaemics to be essential, more effective and of better quality than those that could be obtained from the Indian subcontinent (Lawton et al., 2005).

Interestingly, in the current study, a number of participants held the opposite view about Western brands, believing that they were "poisons" imported from the West, while others simply preferred local brands for their "freshness". Although it is hard to isolate factors that created these opposite perceptions, this finding has implications for healthcare providers. Not eliciting patients' perceptions or preferences relating to specific brands of medications before prescribing may lead to patients' nonadherence which would result in waste of medications and/or failure to reach the therapeutic targets if patients do not receive their preferred brands. It has been argued that the solution to the waste of resources inherent in nonadherence lies perhaps not in attempting to increase adherence per se, but in the development of a more open, cooperative doctor/patient relationship (Vermeire et al., 2003). This kind of relationship allows for patients to be full partners with healthcare providers in decisions about their medications, and once this is achieved, they are more likely to follow the agreed treatment (International Pharmaceutical Federation, 2003).

Findings of the current study also revealed other beliefs about medicines among participants such as the necessity of medications for the management of diabetes, ineffectiveness of medications for controlling blood glucose levels, over-prescribing of medications by doctors, harmfulness of medications and their potential for serious adverse effects. Healthcare providers need to elicit these beliefs and address them to ensure patients adherence to their prescribed medications. Patients who do not believe in the necessity of medications for managing their diabetes may not adhere to their medications, and may benefit from education and counseling from their healthcare providers to address this

concern. Similarly, patients who believe that medications are harmful chemicals that can cause serious adverse effects may also benefit of reassurance and education by their healthcare providers. An explanation of the consequences of not taking the prescribed medications may also resolve these beliefs. However, it is important for this to be achieved in a subtle way to avoid raising patients' anxiety. This study showed evidence that patients may get frustrated and become anxious when doctors used scaring tactics to deliver such information, a finding which is in line with the literature. In a study exploring doctors' perceptions of their diabetic patients' adherence to treatment, doctors assumed that the best method to promote patients' adherence was shocking patients, pressuring and threatening to send them to the hospital (Wens et al., 2005). In another study of urban Latinas with T2DM, patients reported incidents where scare tactics were used by their doctors to promote adherence (Adams, 2003).

A few participants reported taking additional remedies such as teas and herbal supplements to help manage their diabetes. These were perceived to have fewer or no adverse effects compared to diabetes medications. Although the use of such remedies was not associated with nonadherence to diabetes medications among the study participants, this has implications for healthcare providers as patients who use these remedies may not inform their healthcare providers about it, and thus run the risk of potentially serious interactions with prescribed medications which may adversely impact patients' health. To avoid this, it is therefore pivotal for healthcare providers to ask patients about their use of such remedies.

In relation to attitudes towards diabetes or its medications, there was evidence that participants exhibited several attitudes which may have implications on medication or treatment adherence. For example, some participants met the diagnosis of their diabetes with denial. This finding has been reported in qualitative studies (Hernandez et al., 1999; Lautenschlager and Smith, 2006; Dietrich, 1996) and may adversely impact patients' adherence to their medications or treatment. Acceptance of diabetes diagnosis, among other factors, has been documented as a key factor in facilitating management of T2DM (Brown et al., 2002). It has been argued that patients newly diagnosed with diabetes may take months to decades to come to terms with the reality of their disease and the fact that it may represent a serious threat to their health (O'Connor et al., 1997). The authors further argued

that patients were more likely to incorporate changes in their daily routines needed to accommodate diabetes and its treatment once they have realised the seriousness of their diabetes.

While some were in denial, other participants faced the diagnosis of diabetes with downplaying the severity of illness, i.e., minimize the severity of their disease by not paying too much attention to it. To these participants, life was still normal and should be lived as prior to their diagnosis. This attitude have been reported to decrease adherence to medications (Hernandez et al., 1999).

Perceptions of body awareness, i.e., participants' feeling that they were able to sense what was going on in their bodies as it would provide them with specific cues for action (e.g., frequency of urination, thirst), were reported and resulted in participants taking actions based on these cues (e.g., increasing or decreasing their doses of medications). This finding has been reported in the literature and was found to influence patients adherence to their diabetes treatment regimens (Vermeire et al., 2003; Hernandez et al., 1999). It is worth noting here that nonadherence as a result of body awareness does not necessarily result from poor knowledge but rather from a desire to maintain control over the body and to observe how one's own body would function without medications. This method of "trial and error" was cited in the current study, and has also been reported in the literature (Vermeire et al., 2003)

Social stigma was also evident, with participants reporting feelings of embarrassment and unease about having to take their medications in situations where they were overseen by others. This often led patients to avoid taking their medications in such situations. Patients who feel stigmatized by their diabetes may delay their doses or skip them altogether in situations where they can be overseen by others. This finding suggests a room for education and reassurance by healthcare providers about the nature of the disease. The media may also play important role in terms of raising the public awareness about diabetes.

Participants in this study reflected an attitude of fatalism and God-centered locus of control which might have an impact on their adherence to medications or other diabetes self-care behaviours. According to many participants, although medicines may control

diabetes, only God can cure it. This finding is in line with the literature where spirituality was reported and often shaped diabetes experiences and self-care practices (Greenhalgh et al., 1998; Utz et al., 2006; Monnier et al., 2004; Devlin et al., 2006; Adams, 2003; Puavilai and Stuifbergen, 2000). Self-efficacy was another closely related attitude reported in this study. Participants' perceptions of their ability to perform diabetes self-care behaviours appeared to influence their adherence to medications or other diabetes self-care behaviours in a positive direction.

In line with other qualitative studies of diabetic patients (Adams, 2003; Vermeire et al., 2003; Grams et al., 1996; Parker, 1994; Blanchard et al., 1999), fear of diabetes, or its complications was reported by the study participants and may have increased or decreased their adherence to medications. For example, fear of hypoglycemia led some participants to decrease their medication intake whereas for other participants, a fear of diabetes complications such as kidney damage and foot amputations led them to strictly adhere to their medications as directed by their doctors. Participants who had already developed the diabetes complications (e.g., kidney damage, retinal damage) or diabetes related limitations in their daily lives appeared to be more careful and keener to adhere to their medication or other diabetes self-care behaviours.

This study also identified the considerable role of patients' families in their disease management in general and in medication-taking in particular. Families were frequently quoted as an important source of support, providing moral as well as physical assistance to participants. In line with diabetes studies in other cultures (Lohri-Posey, 2006; Xu et al., 2008; Puavilai and Stuifbergen, 2000), Kuwaiti people value family intimacy and have the advantage of cohesive and supportive family networks. The spouse and children act as the major sources of support for patients with diabetes. In this study, all but one participant were living with their families. This suggests that a family-centered approach to education by healthcare care providers may be more beneficial.

In addition to providing support, participants' families constituted a major source of knowledge about diabetes and its medications or its treatment and might have influenced patient's behaviour. Studies from the literature showed similar findings (Stone et al., 2005; Adams, 2003; Greenhalgh et al., 1998). Healthcare providers need to be aware of this as

some patients may obtain false or inaccurate information from their families and initiate changes in their medication intake or other treatment accordingly.

In relation to performance of lifestyle changes, participants rarely incorporated these into their life due to several barriers. It is worth noting that barriers to lifestyle changes were generally similar to barriers to medication-taking (e.g. lack of education and counseling by healthcare providers, paternalism, low self-efficacy, fatalism/God-centered locus of control, perceptions of social support or lack of it, etc.). However, some barriers reported were relevant to specific lifestyle changes (e.g., social gatherings or food cravings preventing diet adherence, and weather or comorbidity preventing exercise adherence).

In line with barriers to medication adherence, a lack of education and counseling by healthcare providers was reported by most participants and may have led to nonadherence to lifestyle changes. It is generally accepted that diabetic patients should implement lifestyle changes in addition to medication-taking to manage their diabetes. To fully succeed in this, it is important for patients to have support from healthcare providers. In this study, there was evidence that instructions provided were insufficient. For example in terms of dietary advice, it was mostly given in the form of written instructions at the beginning of diagnosis. It has been reported that personal interaction in the form of counseling or group sessions might be more successful than simply handing out pamphlets; these may be useful as a reference or refresher of patients' knowledge but should not substitute ongoing patient education and follow-up (Dietrich, 1996). In addition, providing written material may be particularly problematic for patients in this population due to illiteracy, poor eyesight, or little formal education which were evident in the current study.

Although participants reported many barriers which prevented their adherence to diet, social gatherings were one barrier of particular importance and relevance for the Kuwaiti population. In the Kuwaiti society, feasts, social gatherings or occasions are common and culturally important. It is part of the Kuwaiti hospitality to offer sweets and rich foods during these gatherings, and people accepting and eating what is offered is a social obligation and a sign of appreciation. Participants reported it was difficult to adhere to healthy diet plans during such occasions. This finding was also reported in a qualitative study of British diabetics of Bangladeshi origin (Greenhalgh et al., 1998).

Exercise as a means of a health and fitness appeared to have little cultural meaning for Kuwaiti patients. Although some participants reported that doctors touched on the importance of exercise during consultations, exercise was perceived as difficult or potentially exacerbating illness. Reported barriers for exercise adherence varied but those which were particularly relevant for the Kuwaiti culture include social restrictions and extreme weather conditions. Healthcare providers need to explore specific barriers to exercise among patients so they could deliver tailored advice which would be useful and applicable.

Self-blood glucose monitoring is an established part of diabetes management, providing information about current blood glucose levels so that patients can make necessary adjustments in diet and exercise to help control their blood glucose levels in order to prevent the diabetic complications (Saulter, 2001; Capps, 2006). Nevertheless, the current study showed that self-blood glucose monitoring was not optimal among study participants. There was evidence that patients lacked the knowledge and education by healthcare providers regarding the importance of this self-management behaviour. In addition, even those who recognized the importance and performed SBGM did not do so regularly. Although the International Diabetes Federation recommends that frequency of SBGM should be tailored to individual circumstances (International Diabetes Federation, 2009), others recommend performing a 3-point daily glucose testing in poorly controlled diabetes, and a once daily testing in T2DM patients with tightly maintained levels (Monnier et al., 2004). In addition to the lack of awareness, fear of becoming stressed about SBGM, concerns regarding its accuracy, fear of not liking the results, lack of supply of monitoring strips by the Ministry and lack of time were all reported as barriers to performing SBGM in the current study. Healthcare providers need to address these barriers to improve patients' adherence to this aspect of the diabetes self-care behaviours.

In terms of the healthcare system, the findings of this study highlighted a number of important factors which might interfere with patients' adherence to their diabetes medications or other self-care behaviours. Access and organization of the healthcare system were of particular relevance and importance to participants in the current study. For example, access to medications or diabetes care across different health districts varied and participants in certain districts may have been disadvantaged in that regard compared to

others. Organization of the healthcare system and the layout of the current diabetes services provided suggested that healthcare provision is currently fragmented and spread over several places which are inconveniently geographically distanced from each other. Undoubtedly, this may limit the cooperation and communication between healthcare providers at different sites and also constitute access difficulties to patients.

One finding which needs particular attention was relating to the perceptions of lack of trust in the government healthcare system. This was unfortunate, and maybe interlinked and complicated by other findings of the study, such as paternalism and lack of healthcare providers' compassion towards patients.

2.6.2 Methodological limitations

2.6.2.1 Sampling and recruitment of patients

Participants were mostly recruited from clinics, polyclinics and hospitals. This might have introduced bias towards including those who access medical care which are likely to be more concerned about their health than those who do not and thus may face different barriers while adhering to their diabetes medications (or treatment regimens).

2.6.2.2 Patient information leaflets and consent forms

With regards to the use of patient information leaflets and consent forms, one difficulty was relating to the illiteracy of some participants who could not read what was written in leaflets or sign the consent forms. In such cases, the researcher read the leaflets to participants and explained to them the need to obtain their consent for ethical purposes in case they wished to participate. Illiterate participants were happy to provide a fingerprint instead of signatures as this was seen as more convenient.

One consideration which was common to all participants was relating to the completion of paperwork (e.g., patient information leaflets, consent forms, consent to recording forms) as participants found it intimidating and it made them anxious to take part in the study. Although all but one of all patients approached agreed to participate in the study, this should be taken into consideration for future research purposes. Careful attention must be given as extensive paperwork may cause patients to become anxious and reluctant to participate in research.

2.6.2.3 Recording of interviews

One limitation with regards to recoding of interviews is that some participants were a little anxious about being recorded. This was apparent with two participants, one of them asked for the recorder to be switched off at the end of the interviews before he went on to criticize the health care system and accused the Ministry of Health of corruption. The other participant was anxious about the digital recorder from the start for cultural reasons as she was not sure who would be listening to her voice. However, the researcher reassured her that she was the only one who would listen to the recording, and explained to her that data will be anonymous and confidential, and that it would be destroyed upon completion of the study. Once the patient realized this she was happy to for the interview to be recorded. It is worth noting that for future research purposes, careful attention must be paid for this issue as some patients may find it intimidating to be recorded and may not feel free to provide their honest views.

2.6.2.4 During interviews

One difficulty was relating to the novelty of the use of interviews as a research method in this particular population. Therefore, it was difficult for some participants to provide deep and extensive views despite extensive probing by the researcher. As a result, some interviews were very short in duration (two interviews were around 11 minutes in duration). It is unknown whether this was as a result of a failure of the interview guide to capture these participants' individual experiences or whether it was simply because they did not have much to talk about in this regard. Nevertheless, when participants talked about their experience, their feelings and beliefs became apparent and all interviews included rich and informative data which contributed to the findings of this study.

2.6.3 Summary

Based on this study, a number of barriers to medication and other self-care behaviours were found. Personal, health-care provider-related, and health-care system-related barriers appeared to come into play which influenced patients' adherence, and often were influenced by each other. However, the relevance of these barriers to the wider population of Kuwaiti patients with T2DM is still unknown at this point and further assessment is needed. Major themes identified in this study needed to be tested in a larger sample, using a quantitative survey. In addition, the extent of nonadherence to medications

and other diabetes self-care behaviours (e.g. diet, exercise, SBGM, foot care, and smoking cessation advice) among Kuwaitis with T2DM is still unknown. This will be the focus of the next chapter.

CHAPTER 3

THE QUANTITATIVE STUDY

3.1 INTRODUCTION

Systematic reviews concluded that nonadherence to medications in type 2 diabetes mellitus (T2DM) is high, reporting frequencies of 7-64% for oral hypoglycaemic medications, and 19-46% for insulin only or insulin concomitant therapy (Cramer, 2004; Lee et al., 2006). Studies from nearby Arabian Middle East countries estimated that about 1.4-27.1% of diabetic patients were nonadherent to their medications (Kamel et al., 1999; Khattab et al., 1999; Roaeid and Kablan, 2007; El-Shazly et al., 2000).

In Kuwait, nonadherence to diabetes medications among Kuwaiti patients with T2DM has never been estimated but current practice and data from the qualitative study suggests that it is a challenge. Furthermore, it is not known whether nonadherence to medications among this population is mainly intentional or unintentional. This information is critical to guide intervention or national programmes aimed at addressing the issue of nonadherence. In addition, possible predictors of medication adherence have never been tested in Kuwait. Based on data from the qualitative interviews, participants raised a number of issues that might have been relevant to their adherence/nonadherence to their diabetes medications. These include beliefs about medicines, perceptions of support received from healthcare providers, social support provided by family or friends, medication education by pharmacist, knowledge about diabetes through the media, health care system issues such as availability of medications and organization within the system. Qualitative data showed that these can be barriers to medication adherence among this population.

Barriers related to adherence to other diabetes self-care behaviours (diet, exercise, SBGM, foot care, smoking cessation advice) were also discussed in qualitative interviews. However, due to the limitations of qualitative research, findings could not be confirmed and results could not be generalised to the population of Kuwaitis with T2DM. The prevalence of nonadherence to other diabetes self-care behaviours was also never assessed. This chapter will address all of these issues.

3.2 AIMS AND OBJECTIVES

3.2.1 AIMS

1- To assess the prevalence of nonadherence to medications among Kuwaiti patients with T2DM and to identify factors related to it based on the literature and on data from the qualitative interviews.

2- To assess the prevalence of adherence to other parts of the diabetes treatment regimen (i.e., diet plans, exercise, self blood glucose monitoring, foot care and smoking cessation advice), and to describe reasons for nonadherence to these.

3.2.2 OBJECTIVES

1- To describe the number of adherers/nonadherers to diabetes medications among Kuwaiti patients with T2DM using different methods of adherence assessment: clinical outcome measure (HBA1c levels) and patients' self-report (directly and using the MARS scale), and to assess whether there are differences in categorization of patients adherence using these three different methods.

2- To describe the type of nonadherence among those who were nonadherent using the direct self-report method (intentional, unintentional).

3- To describe reasons for nonadherence as reported in the direct self-report method.

4- To assess whether there are differences in demographics (i.e., age, gender, education, having a professional qualification, employment status, health district, place of care), disease or treatment-related factors (duration of diabetes, duration since on diabetes medications, mode of treatment, number of diabetes tablets taken, name of medications, dosage regimen, comorbidity, presence of complications, number of other medications taken) between those who are adherent and those who are nonadherent to their diabetes medications.

5- To assess patients beliefs about their diabetes medications and their beliefs about medications in general using the beliefs about medicines questionnaire (BMQ-G and BMQ-S), and to assess whether there are differences in these beliefs between adherers and nonadherers.

6- To assess patients' perceptions of support provided by healthcare providers using the physician and health care team support subscale of the Chronic Illness

Resources Survey (CIRS) and to assess whether there are differences in these perceptions between adherers and nonadherers.

7- To describe other issues raised in the qualitative interviews (i.e., social support provided by family or friends, medication education by pharmacist, knowledge about diabetes through the media, health care system issues such as availability of medications and organization within the system) and assess whether they are relevant to participants in the quantitative survey.

8- To assess adherence to other parts of the diabetes treatment regimen (i.e., diet, exercise, self blood-glucose monitoring (SBGM), foot care, smoking cessation advice) using direct self-report, and to describe reasons for nonadherence to these aspects of the diabetes treatment regimen among Kuwaiti patients with T2DM.

9- To assess whether adherence to medications among Kuwaiti patients with T2DM is related to their adherence to other parts of the diabetes treatment regimen (i.e., diet, exercise, self blood-glucose monitoring (SBGM), foot care, smoking cessation advice).

10- To assess whether adherence to medications is associated with adherence to appointments.

3.3 METHODS

This section will describe the methods used and justify the choice of specific measures and procedures to meet the study objectives.

3.3.1 Study design

5.3.1.1 Rational for methods chosen

Quantitative methods are more suitable for gathering factual data, testing existing theories, and quantifying relationships between clearly defined variables (Smith, 2002). Since the aims of this part of the thesis are to "quantify" the prevalence of nonadherence to medications and other parts of the diabetes self-care behaviors among Kuwaiti patients with T2DM and to describe the prevalence of reasons for nonadherence to these aspects, quantitative methods were more appropriate. The study design was a cross-sectional questionnaire tool that was designed to facilitate straight-forward data collection. This

approach was appropriate to meet the study objectives, allowing the variables of interest to be gathered easily and objectively.

3.3.1.2 The questionnaire tool

A questionnaire was developed to meet the study objectives. The instrument was designed to collect demographic information and clinical variables to assess adherence to medications and other diabetes self-care behaviors (e.g., diet, exercise, SBGM, foot care, smoking cessation advice), to assess beliefs about medicines and perceptions of health care provider support, as well as additional information salient from the qualitative interviews (i.e., relating to social support provided by family or friends, medication education by pharmacists, knowledge about diabetes through the media, health care system issues such as availability of medications and organization within the system).

3.3.1.2.1 Patient demographics

Patient's age, gender, and variables which reflect socioeconomic status (area of residence, occupation, and level of education) were included in this section. Although healthcare in Kuwait is provided free of charge for all Kuwaitis, inequality in healthcare may still be present, with a possible impact on patients' adherence to medications. Based on the experience of the principal investigator (who has worked in a rural hospital in Kuwait and observed practice in other suburban hospitals), there is a general impression that patients with higher socioeconomic status tend to receive better healthcare from their doctors, and that medication supplies are available in more abundance to patients living in suburban areas of Kuwait. In contrast, rural areas of Kuwait often suffer shortage in medication supplies, and less variety of generic brands of medications. Qualitative interviews provided evidence that these issues may be relevant and needed to be tested. Therefore, it was decided that socioeconomic descriptors were important variables to add in the questionnaire to tap in the possible impact of inequality in healthcare and access to medications on patients' adherence to their medications.

3.3.1.2.2 Clinical variables

This section of the questionnaire assessed type of treatment (diabetes tablets, insulin, or both), number of diabetes tablets taken per day, number of other medication tablets taken per day, duration of diabetes, duration since being on diabetes medications,

name of diabetes medications, latest HbA1c levels recorded and, and dates of last 6 appointments attended.

3.3.1.2.3 Measurement of adherence to medications

The definition of adherence was defined using the definition of Sackett and Haynes (Haynes, 1976a; Haynes et al., 1979):

> *"The extent to which a person's behavior (in terms of taking medications) coincides with the medical or health advice"*

Direct self-report was chosen as the method of adherence assessment because of its simplicity, speed, an feasibility for most care settings and heterogeneous regimens (Gao and Nau, 2000). In addition, many studies of medication adherence comparing self-report with other methods of assessment have yielded significant correlations (Butler et al., 2004a; Schroeder, 2006; Fairley et al., 2005). A literature review evaluating the concordance of self-report measures of medication adherence (interviews, diaries, or questionnaires) with non self-report measures (administrative claims, pill counts or canister weights, plasma drug concentrations, electronic monitors, or clinical opinion) found that self-report measures were concordant with electronic measures in 17% of comparisons, and with other types of non-self report measures in 58% of comparisons. Within self-report measures, questionnaires and diaries were statistically more concordant than interviews ($p=0.01$) (Garber et al., 2004). Another study among patients specifically with T2DM found that patients self-report of their adherence to medications was strongly correlated with indirect measures of medication taking (Diehl et al., 1987). It was therefore decided to use self-report as the method of medication adherence assessment in this research. Although self report may overestimate adherence to medications (Waterhouse et al., 1993), and may be subject to memory and social desirability biases, several steps were taken to minimize possible bias and to ensure validity and reliability. These will be discussed later under the selected self-report method.

Direct determination of drug assays was not used because it is expensive, resource consuming, and inappropriate for large samples. In addition, many patients of the sample were expected to be on multiple medications, so it was neither convenient nor feasible to use drug assays.

Pill counts were also deemed inappropriate for assessing patients' adherence to medication in Kuwait. Many patients tend to buy their medications from other private pharmacies therefore the supply provided by the Ministry of Health does not reflect patients' actual medication supply.

Electronic monitoring using electronic monitoring devices was not used for many reasons: (1) the monitors are expensive, (2) they can only be used with single solid dosage and cannot assess the use of insulin, and (3) biased assessments may results as patients may remove tablets from the containers or transfer tablets between containers without actually taking them, thus the method is not fool-proof. Also, many patients of the sample were expected to be on multiple medications, so it was neither convenient nor feasible to use electronic monitoring devices.

Use of pharmacy records was also inappropriate in Kuwait, because in most hospitals and clinics, pharmacy records are incomplete and manual (paper-based). The possibility that patients in Kuwait may use different pharmacies for medication refills further limited the use of this method of adherence assessment.

Use of the therapeutic outcome measure HbA1c levels reflects diabetes control over the past 2-3 months (Hill-Briggs et al., 2005) and therefore can reflect the level of patients' adherence to medications. This method has many advantages. It is inexpensive, unobtrusive, nonresponsive to reactivity bias, and therefore it is practical for clinical practice. A disadvantage of this method however is that HbA1c levels can change for reasons other than adherence/nonadherence to medication (e.g., infections, stress, diet or exercise). Furthermore, some studies have failed to find a relationship between adherence and glycemic control (McCaul et al., 1987; Watkins et al., 1967). Therefore, the method (if used alone) has limited validity in assessing patients' adherence to medications. In this research, HbA1c level assessment was used to support the accuracy of self-reported adherence to medications. For example, for a given patient, if data obtained from self-report suggested that the patient was adherent to medications, and if HbA1c levels for this patient reached the recommended goal, then it was more likely that self-reported adherence assessment was valid. It is standard practice for diabetic patients in Kuwait to have their HbA1c levels measured and monitored. These measurements are readily available in patients' medical notes, which is convenient given the limitations of time and resources.

HbA1c levels suggesting good adherence to medications were based on the NICE criteria for management of diabetes (NICE clinical guideline 87, 2009), which suggest that HbA1c <7.5% mmol/L would indicate reasonable control of diabetes mellitus. Therefore:

- Patients with HbA1c levels <7.5% mmol/L were considered likely to be adherent to their medications.
- Patients with HbA1c levels ≥7.5% mmol/L were considered likely to be nonadherent to their medications.

Having chosen the self-report method for estimating nonadherence to medications in this research, the next step was to determine which self-reporting method to use. It was important to make sure that the method chosen was effective and efficient in gathering data and that the responses were a reliable and valid reflection of the issue being measured (Smith, 2002). Three methods are commonly used to retrieve information from patients: patient interviews, patient-kept diaries, and self-reported questionnaires.

I will discuss the feasibility of each method briefly, ending with the selected method and justifying why it was more suitable for this research.

Patient interviews might be the simplest method for assessing their adherence and involves having patients explain how they take their medications. Nevertheless, several studies have shown that patient interviews are unreliable for accurately assessing adherence (Park and Lipman, 1964; Straka et al., 1997; Inui et al., 1981; Gordis et al., 1969). It was not suitable to use in this research due to the following limitations:

- High potential for social desirability bias, with patients trying to impress the interviewer by providing favourable responses.
- Inconvenience for large numbers of patients, as it is time and resource consuming.

Patient-kept diaries require patients to record events, rather than asking them to recall events retrospectively (Smith, 2002). Patients are usually asked to record when and how exactly they take their medications. Smith (2002) highlighted that a drawback of using diaries for data collection is that patients may not record events in certain cases, such as the following:

- At busy times of the day.

- When events are so rare that regular use of the diary is not established.
- When events are so routine that actions go unnoticed.

This method was not suitable for this research due to the following imitations:

- Patients' acceptability issues, since it requires time and high degree of commitment on the patients' part to complete and return the diaries which may be cumbersome.
- Inconvenience for large numbers of patients (because of difficulty of follow-up and collecting the diaries, in addition to analysing of the data from diaries).

Self-report questionnaires may be the most efficient and cost-effective method for measuring adherence (Thompson et al., 2000). It has several advantages:

- Quick and easy to administer and assess.
- Cheap as it is time and resource-saving.
- Suitable for use in larger samples.

Therefore, it was decided to use a self-reported questionnaire in this research. However, adaptation of existing questionnaires may be advantageous as development of new questionnaires can take a considerable amount of time and require substantial amounts of money for field testing, compiling technical information and norms (Hambleton and Patsula, 1998). The decision whether to adapt a questionnaire or construct a new one depends on the purpose of the study, time resources, expertise available and the relevance of the construct measured by the test across different cultures (Hambleton and Patsula, 1998).

Several validated questionnaires are available in the literature to measure nonadherence to medications. Smith (2002) argued that using readily available validated questionnaires may save time and resources, and allow comparisons among populations. Nevertheless, instruments developed and tested by others may not be transferable to other populations and settings. Often modification of instruments is warranted, which allows the instrument to be sensitive to people's culture and background. Nevertheless, this might impact reliability of the instrument. Smith (2002) argues that reliability and validity of instruments cannot be assured once they have been modified, and therefore, care was taken to address these issues.

The Medication Adherence Report Scale (MARS) (Horne, personal communication, 2007) is a simple, valid and reliable tool for assessing adherence to medications. It has been used in several studies across a range of different illnesses (Horne and Weinman, 2002b; Barnes et al., 2004; Brown et al., 2005; Byrne et al., 2005; Grunfeld et al., 2005). The scale was validated and showed favourable psychometric properties. In the validation study, the scale showed good internal reliability (0.67 to 0.90) when used across a range of diseases (asthma 0.83, diabetes 0.90, hypertension 0.67, and chronic pain 0.81). Two-week test-retest reliability was high (Pearson's $r=0.97$, $p<0.001$). Concurrent validity was established by comparison of scores with another existing validated self-reported measure of adherence (Morisky et al., 1986) (Pearson's $r= 0.62$, $p<0.01$). Construct validity was established by comparison with a validated measure of beliefs about medicines (Horne et al., 1999), higher levels of self-reported adherence was associated with stronger beliefs in the necessity of taking prescribed medications($r=0.33$, $p<0.01$) and was negatively associated with stronger beliefs of concerns regarding taking prescribed medications and ($r=-0.30$, $p<0.01$). Criterion related validity was established by assessment of blood pressure control among the hypertensive group, adherent patients showed better blood pressure control than those who were nonadherent ($\chi^2=4.24$; $df=1$; $p<0.05$). The scale had a higher internal reliability than an existing validated self-reported measure, as measured by Cronbach's alpha (Morisky et al., 1986) (0.67 to 0.90 vs. 0.24, respectively). In addition to its favourable psychometric properties, the MARS had the advantage of allowing for assessment of adherence on a continuous scale, rather than a dichotomous division into adherent/nonadherent categories, although the latter is also possible. Therefore, it was decided to use the MARS scale for assessing participants' adherence to their diabetes medications in this research. Items on of the MARS scale are shown in Table 3.1.

Table 3.1: Items of the MARS scale

MARS
I forget to take this medicine
I alter the dose of this medicine
I stop taking this medicine for a while
I decide to miss out a dose
I take less than instructed

Using a 5-point Likert scale, participants were asked to rate the frequency with which they engaged in each of the medication-taking behaviours (1 = very often, 2 = often,

3 = sometimes, 4 = rarely and 5 = never). Scores were summed to give a total score ranging from 5-25, where higher scores indicated higher levels of adherence.

The scale was also dichotomised (as instructed by the its developers) using a cut-off point which was assessed after running the frequencies of all scores of participants, the score which corresponded to the point that divided the sample into 30% and 70% was selected (in this data set, it was 20), and participants with scores above this cut-off point were deemed high adherers, whereas those with scores below this point were deemed low adherers. The rationale behind this division is that the authors' assume that about 30% of patients are nonadherent to their medications. Therefore, participants which have the lowest 30% of scores are considered low adherers to medications.

In addition to the MARS, another simple self-reported measure was used in the questionnaire tool, which involved questioning of patients about their adherence. A systematic review of studies involving adherence measures revealed that asking patients about their adherence will detect more than 50% of those with low adherence, with a specificity of 87% (Stephenson et al., 1993). It has been described that patients reporting missing one or more doses of their medication in the past week indicate problems of low adherence (Haynes et al., 2002). Therefore, participants were asked the following question:

> *"People often miss taking doses of their medicines, for a whole range of reasons. Thinking first of the medicines that you take for diabetes (which are……..), when was the last time you missed taking a dose of this medicine(s)?"*

A participant was deemed as nonadherent if any doses were missed in the last 7 days. Moreover, if the participant reported missing a dose in the previous seven days, he/she was asked to report the reasons. These reasons were then categorised by two independent researchers (B.A. and F.A.) as intentional or unintentional nonadherence. Any discrepancies were resolved by discussion. Intentional nonadherence resulted if participants decided not take their medications for some reason. Unintentional nonadherence resulted if participants could not take their medication(s) for some reason such as forgetting or running out of medications. This method has been used before and proved to be successful (Clifford, 2004).

3.3.1.2.4 Measurement of beliefs about diabetes medicines and beliefs about medicines in general

The literature was reviewed to search for published scales which had good validity and reliability which could be used to assess participants' beliefs about medicines which had good validity and reliability. The Beliefs about Medicines Questionnaire (BMQ), which was validated for use across a range of different diseases including diabetes, asthma, renal, cardiac, psychiatric, and general medical illnesses was selected (Horne and Weinman, 1999). The scale comprises two main sections, the BMQ-Specific, which assess patients' beliefs about their specific medicines, and BMQ-General, which assesses patients' beliefs about medicines in general. The BMQ-Specific is comprised of two subscales; BMQ necessity which assesses patients' beliefs about the necessity of their medicines, and BMQ concerns which assesses patients' beliefs about the potential adverse consequences of taking their medicines. The BMQ-general is comprised of two subscales; BMQ overuse which assesses patients' beliefs as to whether medicines are being overused by doctors, and BMQ harm which assesses patients' beliefs about potential harm that can result of taking medicines in general. A third subscale, BMQ benefit, which assess patients' beliefs about benefits that would result from taking medicines was later added (Horne et al., 2004).

In the validation study of BMQ, except for the harm subscale, the authors reported high internal consistencies of the various BMQ subscales when used across different diseases. Reported Cronbach's alpha were; BMQ necessity =0.55-0.86, BMQ concerns =0.63-0.80, BMQ overuse =0.60-0.80, BMQ harm =0.47-0.83, depending on the specific diseases. Two week test-retest of the BMQ among the asthmatic group indicated reliability of its various subscales (BMQ necessity r=0.77, BMQ concerns r=0.76, BMQ overuse r=60, BMQ harm r=0.78; $p<0.001$). Criterion and discriminant validity of the subscales were also established, as expected correlations were obtained between BMQ subscale scores and other measures of illness and medication beliefs and between BMQ concerns scores and self reported adherence to medications. The BMQ subscales were able to distinguish different illness groups and treatment modalities, between particular adherence behaviours and between users of allopathic and complimentary therapies (Horne et al., 1999). Table 3.2 illustrates the specific original items within each subscale of the BMQ.

Table 3.2: Items of individual BMQ subscales

BMQ-Specific Necessity Subscale
My health at present depends on this medicine
My medication controls my diabetes
Without this medicine I would be very ill
My health in the future will depend on this medicine
My medications prevent my blood sugar from becoming too high
BMQ-Specific Concerns Subscale
Having to take these medicines worries me
I sometimes worry about the long-term effects of these medicines
Diabetes medications are a mystery to me
These medicines disrupt my life
I sometimes worry about becoming too dependent on these medicines
BMQ-General Overuse Subscale
Doctors use too many medicines
Natural remedies are safer than medicines (e.g. herbs, accupunture, etc.)
Doctors place too much trust in medicines
If doctors had more time with patients they would prescribe fewer medicines
BMQ-General Harm Subscale
People who take medicines should stop their treatment for a while every now and again
Most medicines are addictive
Most medicines are poisons
Medicines do more harm than good
BMQ-General Benefits Subscale
In most cases the benefits of medicines outweigh the risks
In the future medicines will be developed to cure most diseases
Medicines help many people to live better lives
Medicines help many people to live longer

Using a 5-point Likert scale, participants were asked to rate their agreement with the specific statements (1= strongly disagree, 2= disagree, 3= uncertain, 4= agree and 5= strongly agree). Subscale scores were computed from the sum of all items of each subscale and ranged from 5-25 for the BMQ necessity and BMQ concerns, and from 4-20 for the BMQ overuse, BMQ harm and BMQ benefits.

The necessity-concerns differential was also computed by subtracting the concerns subscale score from the necessity subscale score. Therefore, if the differential score was positive, it is an indication that participants perceived the benefits of their medicines

(necessity) to outweigh the risks (concerns). If the differential score was negative, it is an indication that participants perceived the cost of taking their medicines to outweigh their benefits. Scores on the differential ranged from –20 to 20.

In addition to the original items of the BMQ necessity, the following items were added based on results from a previous study which reported improved internal consistency with the use of additional items (Parham et al., 2008):

- "These medicines are less important than other parts of my treatment"
- "I understand why I need to control my blood glucose levels"
- "These medicines effectively control my blood glucose levels"
- "Controlling blood glucose levels is essential for my health"
- "Keeping my heart healthy in the future will depend on this medicine"

Scores for the extended BMQ necessity were calculated from the sum of responses to all original and additional items, except for the item "These medicines are less important than other parts of my treatment" for which the score is reversed first.

Similarly, the following items were added to the BMQ concerns:

- "These medicines give me unpleasant side-effects"
- "I am concerned that taking these medicines regularly will make them less effective in the future"
- "I worry about how many tablets I need to take to manage my blood glucose levels"
- "Having to take these tablets is a big hassle for me"

Scores for the extended BMQ necessity were calculated from the sum of responses to all original and additional items.

3.3.1.2.5 Measurement of health care provider support

The Chronic Illness Resources Survey (CIRS) was developed by Glasgow et al. (2000) to assess patients' perceptions of support and resources for chronic illness management provided at seven levels of psychosocial environmental support using seven subscales: family and friends, physician/health care team, personal actions, neighbourhood/ community, media and policy, workplace, and organizations. To meet the aims of this

study, only the physician/health care team support subscale of the CIRS was relevant and selected.

The subscale was chosen because it had good validity and reliability, with a reported Cronbach alpha of 0.91 and test-retest reliability of 0.77 and 0.60 at one week and one month, respectively (Glasgow et al., 2000). In addition, the subscale was applicable across multiple illnesses including diabetes, heart disease, arthritis, and COPD. Construct validity of the physician/health care team support subscale of the CIRS was established by comparison of scores with an existing validated self-reported measure of satisfaction about medical advice (Glasgow et al., 1996), where a significant correlation was found ($r= 0.75$, $p<0.01$). The subscale predicted illness management at 4-months, as measured by an established measure for illness self management behaviours (Sherbourne et al., 1992), therefore showing predictive validity (controlling for age, $r=0.30$, $p\leq0.01$). Furthermore, the scale has been successfully adapted for use in Spanish (Eakin et al., 2007) and Chinese languages (Yin et al., 2008), and demonstrated reasonable levels of reliability and validity similar to the previously validated English-language version. Table 3.3 shows the items of the CIRS scale.

Table 3.3: Items of the physician/health care team support subscale of the Chronic Illness Resources Survey (CIRS)

Physician/heath care team support subscale of the CIRS
Has your doctor or other health advisor (nurse, dietician) clearly explained what you needed to do to manage your illness? (If you have not had any doctor visits in the past 3 months, think back to the last visit you had.)
Has your doctor or other health advisor provided support between visits such as phone calls, reminder letters, or newsletters
Has your doctor involved you as an equal partner in making decisions about illness management strategies and goals?
Has your doctor or other health care advisor listened carefully to what you had to say about your illness?
Has your doctor or other health advisor (nurse, dietician) answered your questions and addressed your concerns during office visits?
Has your doctor or other health care provider thoroughly explained the results of tests you had done (e.g., cholesterol, blood pressure, or other laboratory tests)?
How important are health care team resources to you in managing your illness?

Participants were asked to rate their responses relating to the scale questions on a five-point Likert scale (1 = never, 2= to a little extent, 3= to a certain extent, 4= to a good extent, and 5= to a great extent). Responses to the items were summed to give a total score, which ranged from 7-35.

3.3.1.2.6 Measurement of adherence to other diabetes healthcare behaviors (in relation to adherence to medication)

The Summary of Diabetes Self-Care Activities (SDSCA) Measure was selected for use in this study. The measure was originally developed in 1994 (Toobert and Glasgow, 1994), but was later revised using data from 7 different studies, involving a total of 1,988 people with diabetes . It assesses diabetes self-management behaviours and consists of items assessing the following aspects of the diabetes regimen: general diet, specific diet, exercise, self blood glucose monitoring, foot care and smoking. The scale was selected for use in this study due to its favourable psychometric properties. With the exception of specific diet, inter-item correlations within scales were high (mean 0.49). Test-retest correlations over 3-4 months were moderate (mean 0.40). The scale correlated with other measures of diet and exercise which supported its criterion validity (mean 0.23) (Toobert et al., 2000). In addition, the scale has been successfully adapted for use in other languages, such as Chinese (Yin et al., 2008).

The developers of the scale provided a number of additional items that could be used with the original measure items if needed. In order to allow comparisons with medication adherence, the additional items related to medication were also used. Table 3.4 shows the items of the SDCA subscales.

For all subscales except for smoking, participants were asked to circle/tick the number of days they performed the relevant behaviour on a continuous scale of 1-7.

For the smoking subscale, participants were asked to tick a "Yes" or "No" for the first question, and space was provided for participants to write the number of cigarettes smoked for the second question.

Table 3.4: Items of the SDSCA subscales

Medications items
On how many of the last SEVEN DAYS, did you take your recommended diabetes medication?
OR On how many of the last SEVEN DAYS did you take your recommended insulin injections?
On how many of the last SEVEN DAYS did you take your recommended number of diabetes pills?
Diet items
How many of the last SEVEN DAYS have you followed a healthful eating plan?
On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?
On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?
On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?
Exercise items
On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (total minutes of continuous activity, including walking).
On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?
SBGM items
On how many of the last SEVEN DAYS did you test your blood sugar?
On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?
Foot care items
On how many of the last SEVEN DAYS did you check your feet?
On how many of the last SEVEN DAYS did you inspect the inside of your shoes?
Smoking items
Have you smoked a cigarette—even one puff—during the past SEVEN DAYS?
If yes, how many cigarettes did you smoke on an average day?

3.3.1.2.7 Measurement of other issues raised in qualitative interviews

Several issues were raised in the qualitative interviews with regards to provision of medications by the Ministry of Health, care provided by pharmacists, social support received from family and friends, medication-taking made difficult at specific situations, role of the media in patient education, difficulty of medication taking compared to diet or exercise, negative views about Western medication and learning from others' experiences with the disease. Statements were developed to represent these issues and to assess their relevance to the sample participants. Table 3.5 shows these statements.

Table 3.5: Statements developed based on qualitative data used in the questionnaire tool

Items developed based on qualitative findings
Availability of certain brands of medication affects the way I take my medications.
When I'm travelling or when I'm away from home I change the way I take my medications.
When I'm with a group of friends or family I avoid taking my medications.
The pharmacist plays no or little role in educating me about my medications
I depend on myself for educating myself about my illness or medication.
The media, such as radio and TV programmes constitute an important resource for educating the public about illness and medications.
Adhering to diet or exercise is more difficult and problematic than adherence to my diabetes medications.
I don't trust Western medications; I believe they are poisons promoted to us by the West.
Seeking experience and advice from other people who have diabetes affects the way I manage my diabetes.
The weather is a big barrier preventing me from exercising.
Lack of motivation prevents me from doing exercise.
Social compliments prevent me from sticking to a healthy diet plan for my diabetes.
I don't monitor my blood glucose level because I don't want to get used to it.
Lack of organization/coordination within the healthcare system diminishes the level of services provided for patients with diabetes.

Participants were asked to rate their responses to each statement on a 5-point Likert scale (1= strongly disagree, 2= disagree, 3= to a certain extent, 4=agree and 5= strongly agree).

3.3.1.2.8 Development, translation, adaptation, and piloting of the questionnaire tool

Once the first draft of the questionnaire tool was developed, it was distributed to the research team for feedback. Comments relating to the contents and structure of the questionnaire were incorporated into a second draft which was circulated on another round to the research team. After revision, the tool was ready for translation and adaptation for use in Arabic language.

As described in Section 3.3.1.2.3 to Section 3.3.1.2.6, the Medication Adherence Self-Report Scale MARS, the Beliefs about Medicines Questionnaire (BMQ), the Summary of Diabetes Self-Care Activities (SDSCA) measure, and the physician and health care team support subscale of the Chronic Illness Resources Survey (CIRS) were incorporated into the instrument. However, these scales were developed, validated and tested for use in English language and the empirical evidence supporting the validity and reliability of the

scale has been derived primarily from studies conducted among English-speaking patients. Although full validation of the questionnaire is beyond the scope of this research, careful attention was needed to ensure that data gathered using these scales produced valid estimates of variables they were supposed to measure. Therefore, a translation protocol was developed.

The literature was searched for available methods of translation. Three methods of for translation of questionnaires and other research instruments will be discussed in this section: direct translation, translation/back-translation, and the parallel blind technique method. In the end, I will highlight the method selected and justify why it was used.

Direct translation methods involve the use of one bilingual individual who translates the instrument from the source to the target language (Behling and Law, 2000). Despite the simplicity and practicality of this method, it does not provide objective information about the accuracy and/or quality of translation as it depends on a single translator's judgement and skills (Behling and Law, 2000).

Translation/back-translation is an iterative method which involves translating an instrument by a bilingual individual initially into the target language. Then, a second bilingual individual who knows nothing about the original wording of the source language version translates this draft back to the source language, after which the original and the back-translated source language versions are compared. The process is repeated until the two source language versions are identical or contain only minor differences (Behling and Law, 2000). This method is criticised because it is impractical, time consuming and suffers limitations inherent in the process of the translation itself. It is argued that back-translating a test correctly does not guarantee the validity of the target language version (Hambleton and Patsula, 1998). Behling and Law (2000) listed some of the limitations of translation/back-translation methods based on their review of the literature as the following:

- Both individuals doing the forward and back-translation may apply the same set of conventions for handling the material that is not in fact equivalent.

- Some back-translators may be able to make sense of the target language version, even if it depicts the original ideas poorly, and thus may come up with back-translated drafts that are close to the original source language wording.
- The draft target language version may contain elements of the source language grammatical structure that make it possible for a bilingual individual to guess the source wording.
- When translators know that their work is going to be back-translated, they may use wording that ensures that a second translation would faithfully reproduce the original version rather than translating using the optimal wording in the target language.

Parallel blind technique (Werner and Campbell, 1970) involves the use of two translators who independently translate an instrument to the target language. This method has the advantages of speed and practicality because the two translators work in parallel rather than in sequence (as in the translation/back-translation method). In addition, the parallel blind technique has the element of security, i.e., it allows checking on the work of the translators, as comparisons between drafts increases the confidence in the accuracy of translation (Behling and Law, 2000). This method was the translation method adopted for translation of all instruments used in this research.

To enhance the quality of translation, the random probe technique was also applied as recommended in the literature (Behling and Law, 2000). This involved circulating the draft target language instruments to a group of the target language speakers who were then asked to explain what they understood by translated items, and why they have responded in a given way. Similarly, the translated draft was submitted to an expert committee for appraisal, as is recommended by the literature. These steps will be clarified more detail in the next section.

It is now recognized that in order to use a measure in a different culture, in addition to linguistic translation, cross-cultural adaptation of the measure is pivotal to reach equivalence between the original and the target version of the measure. The term "cross-cultural adaptation" refers to the processes that encompass both translation and cultural adaptation issues to prepare a questionnaire suitable for use in another cultural setting (Beaton et al., 2000). Hambleton and Patsula (1998) argued that the term "adaptation" is

therefore the preferred term to use than "translation" because it is broader, and more reflective of the processes that should take place when preparing a test for use in another language/culture. Quite often, cultural differences are not accounted for in current translation methodologies and the relevance of the adapted versions of measures to the target populations is generally overlooked (Herdman et al., 1998; Hambleton and Patsula, 1998; Bowden and Fox-Rushby, 2003).

Many existing translation methodologies are based on simple forward (and sometimes backward) translations, lay panel testing and psychometric or statistical analyses of instruments to demonstrate equivalence, without initial investigation of whether the underlying concepts that constitute an instrument actually apply to people in a different cultural setting (i.e. conceptual equivalence). Such approach would arguably be imposing one cultures' norms or values onto another (Herdman et al., 1998).

Hambelton and Pastula (1998) identified three categories of error that can arise when adapting measures. These are: cultural/language differences, technical methods, and interpretation of results. Failure to address any error in each category can compromise the equivalence between the original and adapted versions of questionnaires. Table 3.6 lists examples of errors in each category and how these may be addressed, as recommended by Hambelton and Pastula (1998). Furthermore, Herdman et al. (1998) developed a model to assess equivalence between source and target language versions of a health-related quality of life measure which might be useful for researchers when adapting measures for use in other languages and/or cultures. The usefulness of Herdman's model was highlighted in a systematic review which operationalized the model to evaluate the processes used in translating and adapting nine generic health-related quality of life measures for use in Africa, Asia, Eastern Europe, the Middle East and South America (Bowden and Fox-Rushby, 2003). In the model, six different types of equivalence were defined, and strategies for their evaluation were suggested along with the order in which this evaluation should take place, as shown in Table 3.7.

It can be concluded that in order to use an instrument in another culture, simple translation techniques may not be sufficient, and often cultural adaptation of the instrument is warranted. For example, a graded item response may not be familiar to certain cultures and other response styles may have to be adapted, to avoid biasing the results. Concepts or

items within an instrument may not be easily translated into another language/culture, either because they do not exist or because alternative expressions are more relevant. Careful attention was needed to ensure that the adapted questionnaire conveyed the meaning as closely as possible to the target culture, without having to omit items or make substantial changes in the original questionnaire in which case it would have been necessary to revalidate the questionnaire and to re-test its psychometric properties.

Table 3.6: Categories of error arising when adapting measures for use in other languages

Error Category	Examples of sources of errors	Possible issues to consider
Cultural/language difference	- Construct equivalence - Test administration - Test format - Speed of response - Other response styles	Does the measure test the same constructs in each language? Will the test be administered in an identical fashion? Will the format of the test be equally appropriate in each language? Will speed of response be an issue? Will acquiescence, tendency to guess, or social desirability be an issue?
Technical methods	-The test itself -Selection and training of translators -Process of translation -Judgemental designs for adapting tests -Empirical analysis for achieving equivalence	Is the content/format of the test appropriate for the target population? Are translators familiar with the culture of the target group? How many translators will be involved? Are they competent? How dialects will be handled, if present? How words will be matched from one language to another? How will tests be translated (forward or backward translation)? What tests will be carried out to establish equivalence (e.g., factor analysis, item analysis, structural equation modelling)?
Interpretation of results	- External factors	Are there any external factors in the target culture that might interfere with test results (e.g., wealth, educational standards, living standards, motivation to take the test, etc.).

Adapted from Hambelton and Pastula (1998).

Table 3.7: Types of equivalence that need to be assessed when adapting measures for use in other languages

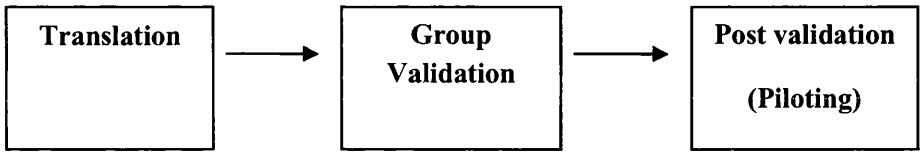
Equivalence	Definition	Possible issues to consider
Conceptual	Achieved when the questionnaire has the same relationship to the underlying concept in both cultures, primarily in terms of the domains included and the emphasis placed on different domains.	Will there be a review of local literature, or local questionnaires? Will there be a discussion among researchers, involvement of sociologists, and involvement of local people? What kind of people will be asked to judge the appropriateness of the questionnaire? Will any theoretical arguments be presented questioning or accepting conceptual equivalence? What are the outcomes? How will judgements be made and justified?
Item	Exists when items estimate the same parameters on the latent trait being measured and when they are equally relevant and acceptable in both cultures.	What evidence will be presented suggesting that lifestyle patterns were similar in the source and target countries? How will the relevance or acceptability of individual items to target population be addressed? What quantitative analysis of items equivalence will be undertaken? What are the outcomes? What judgements will be made about item equivalence?
Semantic	Concerned with the transfer of meaning across different languages, and achieving a similar effect on the respondents in different languages.	How will authors be sure about what was meant by the original questionnaire in the target language? Will original developers of the questionnaire be contacted? What is the nature of the contact? Will translation guidelines be referred to? How will the meaning of keywords/phrases be investigated in the target language? What kind of people will do the translations? Who will be involved in judging the quality of translations? Will a translation protocol be followed? Will problems in the translations be identified and how will they be dealt with? Will items be considered difficult/easy/impossible to translate?
Operational	The possibility of using a similar questionnaire format, instructions, mode of administration, and measurement methods.	Will the same instructions and format be used in the source and target versions of the instrument? What are the literacy rates in the source and target countries? How will respondents be addressed? How will the response modes be considered? Will the same time frames be used in the source and target questionnaires? Will the time frame be investigated? Will reviews of the literature be consulted about appropriate response modes?
Measurement	Achieved when psychometric properties of the adapted version are similar.	How will reliability/validity/ sensitivity/scoring norms/effect size of the instrument be addressed? Will socioeconomic and demographic relationships with the instrument be addressed?
Functional	The extent to which an instrument does what it is supposed to do equally in different cultures. It is judged by the degree to which the other five types of equivalence (above) have been achieved.	How the underlying trait is defined or conceptualized in the target culture? How well the instrument design reflects that underlying trait? * Functional equivalence is assessed by the degree to which other types of equivalence are achieved.

Adapted from Herdman et al. (1998) and Bowden and Fox-Rushby (2003).

3.3.1.2.8.1 Translation protocol

A three stage process of instrument translation and validation was developed and adopted based on review of the literature. The translation process involved sequential processes of translation, group validation and post validation testing. The source language was English, and the target language was Arabic. Figure 3.1 summarizes the translation protocol which was adopted:

Figure 3.1: Summary of translation protocol



For quality assurance of the content of instruments:

- Items of each of the instruments were assessed by all three stages of the translation protocol.
- Framing text and items eliciting demographic, clinical or data other than that of the original instruments involved translation and post validation stages only.

3.3.1.2.8.2 Translation process

The questionnaire was translated using the parallel blind technique. Two bilingual speakers simultaneously and independently translated the questionnaire items into Arabic. One translator was the principal researcher and the other was another native bilingual person with no medical or clinical background. This was consistent with what was recommended by the literature (Beaton et al., 2000), suggesting that one of the translators must be aware of the concepts being examined in the questionnaire, while the other translator being naive (neither aware nor informed) of these concepts. This was preferred to ensure providing a more reliable equivalence from a measurement perspective, yet reflecting the language used by the population in which the questionnaires to be used. The two translations were compared and discrepancies in the translation were noted. The translators resolved any discrepancies by discussion. An agreed upon translated draft was prepared, according to the following steps:

- Translations for individual items were compared with one another.
- If translations were identical or nearly identical in such a way that caused no disagreement between the two translators, the item was accepted immediately.
- In case of disagreement between translators regarding an item, they discussed their individual points of view of why an item should be translated in their suggested way. Preserving the meaning of the original English item (both semantically and conceptually) was the aim and the decisive factor in reaching an agreement about a particular item.
- If one translator accepted the point of view of the other, the translation of the latter was accepted and used.
- If not, translators suggested alternative translations of the item, and discussed their views in the same way described above until agreement was reached.

3.3.1.2.8.3 Group validation

Three experts in the field (one diabetologist, one behavioural medicine researcher, and one practicing pharmacist) were recruited to review and critique the translated questionnaires. With regards to the translation of the MARS, the content experts were provided with the definition of adherence as proposed by Sackett and Haynes (1976, 1979) quoted earlier:

> *"The extent to which a person's behaviour (in terms of taking medications) coincides with the medical or health advice"*

Further, they were provided with a copy of the MARS questionnaire, and written instructions to review the instrument. The following instructions were used, which were adopted based on a previous study which validated a tool for measuring patients' adherence to diabetes activities (Hernandez, 1997):

- Is the definition of adherence clear, concise, and consistent with the meaning of adherence in health care? Feel free to reword if appropriate.
- Is each item of the instrument consistent with the meaning of the definition of adherence?
- Is each item clear and concise? If not, feel free to reword, make additions, or delete.

- Have the major aspects of the 'domain' of medication adherence been tapped? If not, please identify important areas that are missing.

In addition, the MARS as well as all the other instruments used, i.e. the Beliefs about Medicines Questionnaire (BMQ), the Summary of Diabetes Self-Care Activities (SDSCA) measure, and the physician and health care team support subscale of the Chronic Illness Resources Survey (CIRS), were assessed by the expert panel who were asked to answer the following questions:

- Is each item clear and concise? If not, feel free to reword, make additions, or delete.
- Could you explain your understanding of each item?
- Compare this to the original English item? Is it the same?
- If not, please suggest an alternative translation?
- Is the translation (or substituted translation) culturally appropriate in Arabic language?
- Is the translation (or substituted translation) easily comprehended in Arabic language?

The expert group were asked to reach consensus with regards to the above questions. Once this was achieved the complete questionnaire tool was ready for the next stage, i.e. post validation.

3.3.1.2.8.4 Post validation

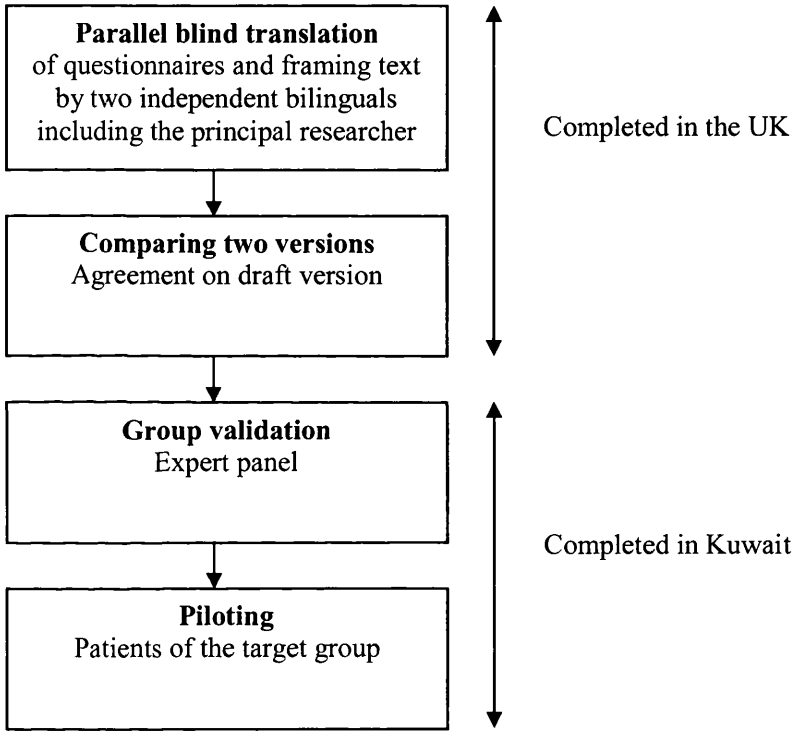
The amended questionnaire was piloted on five patients of the target population for comments on the comprehensibility and appropriateness of the language in the Kuwaiti cultural context. These patients were sampled as they attended their appointment at a diabetes clinic at one of the hospitals. After completing the questionnaire, they were asked probing questions such as:

- Could you explain your understanding of this item?
- What do you mean by this response?
- Would you suggest a better way we could have expressed this item?
- Would you say that the questions included are appropriate and non-intimidating?

- Do you have any other comments on how we could improve the content and format of this questionnaire?

Patients were also asked to comment on the framing texts and questionnaire contents which were not included in the group validation process. Comments were noted and further amendments were made if necessary. Figure 3.2 summarizes the complete processes of translation used in this research.

Figure 3.2: Summary of all steps involved in cultural adaptation of the questionnaires



After development, translation and piloting of the questionnaire using input from the research team, expert panel and patients, the following amendments were made to the questionnaire tool:

- The demographic and clinical variables sections were moved to the beginning of the questionnaire, to ease patients into the next more difficult questions (e.g. beliefs, perceptions of healthcare providers, etc.)
- In the clinical variables section, four additional variables were considered necessary therefore the following questions were incorporated into the relevant sections in the questionnaire (shown between brackets):

1- Dosage regimen (the word "Dosage" was added in the medications table next to each medication).
2- Comorbidity (Apart from your diabetes, do you have any other disease(s)? please specify).
3- Presence of diabetes complications (Do you suffer any of the diabetes complications, e.g. eye damage, kidney damage, heart disease, numbness of the extremities?)
4- Date of latest HbA1c measurement (Next to the latest HbA1c level, this question was added "When was it measured?")

- In the diabetes self-care activities section, it was decided to abandon the use of the Summary of Diabetes Self-Care Activities Measure (SDSCA) tool because it was too complicated and participants found it confusing. Instead, participants were asked directly about their adherence to each self-care activities using a closed "Yes" or "No" question (e.g. do you follow a healthy diet plan for your diabetes?). If participants responded with a "Yes", then they were asked to rate the extent of their adherence to each behavior (Never, rarely, sometimes, often, always). If participants responded with a "No", then they were asked to provide reasons which prevented them (If not, what the reasons or barriers which prevented you?).
- In the perceptions about doctors and healthcare team, the last item "How important are health care team resources to you in managing your illness?" was deleted because it did not make sense to use it on its own in this research. In the original study it was meant to compare how important patients feel about the role of the healthcare team support as compared to support received from other sources (e.g. community, personal, policy, etc.). Also, patients found it hard to interpret so deleting this item was appropriate.
- In the section your personal views and preferences, some items were reworded to ensure better understanding by participants, these are:
  1- The first item "Availability of certain brands of medication affects the way I take my medications" was reworded to "The ministry of health provides the appropriate types of medicines for diabetic patients". This was to make it more straight-forward and easier to interpret; it was also required by the ethics committee particularly not to use the word "brands".

2- Item 3 "When I'm with a group of friends or family, I avoid taking my medications" was reworded to "I avoid taking my medications in situations where my family or friends can see me". This change was suggested because the original item implied that patients would not take their medications altogether when they were with other people, however some patients might avoid taking their medications only when they are seen by people, but still manage to take them when they are not.

3- Another item was added "My friends or family help make sure I take my medications properly". This was done to represent patients who held the opposite view; those who thought that friends or family were an asset to their medication-taking instead of an obstacle.

4- Item 6 "I depend on myself for educating myself about my illness or medication" was reworded into "The pharmacist provides me with enough information about my medications", this change was required by the ethics committee.

5- Item 7 "The media, such as the radio and TV programs constitute an important resource for educating the public about illness and medications" was reworded into "The media, such as radio and TV programs constitute an important resource for educating me about my illness and medications". This change was suggested because the original item was too general. Making the item more specific, i.e., asking whether the media was a helpful educational tool for each respondent in terms of his/her own illness and medications was the primary interest.

6- Item 8 "adherence to diet or exercise is more difficult and problematic than adherence to my diabetes medications" was split into two items "Adhering to diet is more difficult and problematic than adherence to my diabetes medications" and "Adhering to exercise is more difficult and problematic than adhering to my diabetes medications". This was to separate those who found adherence to diet only or to adherence exercise only, more difficult and problematic than adherence to medications. The original item combined both diet and exercises in the same item and made it confusing for those who might hold different views about each aspect.

- In the same section, some items were removed because they were already addressed in the diabetes self-care activities section. This made the questionnaire tool shorter to increase the feasibility of administration, as participants found the questionnaire too long (it took around 30 minutes to administer each questionnaire on average).

The deleted items were:

1- Items 10 "The weather is a big barrier preventing me from exercising"
2- Item 11 "Lack of motivation prevents me from doing exercise"
3- Item 12 "Social compliments prevent me from sticking to a healthy diet plan for my diabetes"
4- Item 13 "I don't monitor my blood glucose level because I don't want to get used to it"
5- Item 5 "My doctor takes full responsibility for making decisions about my medications, and never involves me in my treatment plan" was also removed because it was already addressed in the section about doctors and other health care team.

- In the end of the questionnaire tool, a space was provided to add any extra issues which might be relevant to respondents but not addressed by the questionnaire tool.

The final version of the questionnaire is included in Appendix 9.

3.3.1.2.8.5 Validity and reliability of the questionnaire tool

In addition to the field testing detailed above, the internal reliability of the each scale used was calculated and reported in the relevant sections of the results in this chapter. Reliability of the completed tool was also assessed by testing it on 20 participants, two weeks apart. Results are also reported in the relevant results section.

3.3.1.2.9 Recruitment of patients

To maximise the generalizability of results (i.e. external validity), participants were selected from different health districts which covered different geographical areas of the state of Kuwait. There are six health districts in Kuwait, including one hospital in each, and a total of 44 primary care diabetes clinics which are geographically and administratively linked to these hospitals. Four of the hospitals had specialized diabetes clinics within them. Table 3.8 illustrates the sampling frame.

Table 3.8: Different heath districts, type of population, and diabetes clinics within each

Health District	Urban/Rural classification	Primary care centres with diabetes clinics linked to that hospital
Al-Sabah	Mixed	None.
Al-Amiri	Urban	Al-Ahqafi Specialized Clinic Hamad Al-sager Specialized Clinic Kaifan Family Center Al-Surra Family Center Al-Nuzha Clinic Al-Rawda Clinic Al-Khaldia Family Center Al-Yarmouk Family Center Al-Dasma Family Center **Al-Qadsia Family Canter*** Al-Shamia Family Center* Abdullah Al-Salem Family Clinic* ** Not specialized for diabetes, but T2DM Patients are followed-up there.*
Al-Jahra	Rural	Al-Qaser Clinic **Al-Oyoun Clinic** Al-Naeem Clinic **Al-Waha Clinic** South Al-Sulaibia Clinic
Al-Farwaniya	Rural	Al-Ferdous Clinic South Al-Jeleeb Clinic Al-Rabya Clinic South Khaitan Clinic Al-Rehab Family Center West Al-Farwaniya Clinic **South Al-Ardia Clinic** North Al-Ardia Clinic Al-reqee Family Center Al-Andalus Clinic
Mubarak Al-Kabeer	Urban	Naser Soud Al-Sabah Clinic South Hawalli Clinic Al-shaeb Family Center Mishref Family Center Al-Rumaithia Specialized Center **Salwa Clinic** Sabah Al-Salem Specialized Clinic
Al-Ahmadi	Mixed	**Al-Fahaheel Specialized Clinic** Al-Fahaheel Clinic for Foreigners Al-Mangaf Clinic West Al-Sabahi Clinc Al-Daher Clinic Al-Rugga Clinic Hadia Family Clinic Al-Ahmadi Clinic **Al-Qurain Specialized Center** Al-Qurain Family Center

For sampling, one diabetes clinic within each health district was randomly selected in the following way:

- The name of each primary care clinic within a health district was written on a piece of paper and placed in an envelope.
- The envelopes will be mixed and a colleague was asked to draw one envelope, the clinic named inside the envelope was selected.

For the districts that did not have a specialised diabetes clinic within its hospitals, two clinics (instead of one) were randomly selected in the same way for that district so that equal proportions of participants are drawn from each health district. This sampling procedure ensured inclusion of patients from both urban and rural areas.

In the end, seven primary health care clinics and three hospitals were chosen for recruitment of patients, which are highlighted in Table 3.8. In hospitals data collection commenced in the mornings, which is the time given for diabetes clinic appointments. In polyclinics, data collection commenced at different shifts (mornings and evenings). In both hospitals and polyclinics, participants were sampled at different days of the week (and at different times), to avoid selection bias and to ensure diversity the sample.

Before the researchers approached patients, the principal researcher informed doctors in each site of patient recruitment about the nature and aims of the research. Doctors were provided with a leaflet which briefly explained the study, and included contact details of the principal researcher for further information (Appendix 6).

Patients were approached by the researcher(s) as they attended their diabetes clinic appointments. Those who agreed to participate signed a written informed consent. This was obtained after the researcher had explained the study to the patient, and provided a patient information sheet to read which included the necessary information they needed to know and contact details of the researcher for further details. The Patient information sheet and the consent form are attached in Appendix 7. In some recruitment sites, it was not possible for the researcher to directly assess patients' medical records. In such cases, as suggested by the ethics committee, a data abstraction form was prepared (Appendix 8) and given to each research participant to present to their doctor during their outpatient appointments. In this form, all data needed by the researcher were listed and doctors were kindly asked to

extract this data from the participant's medical record, report it on the form and then hand it to the participant. Research participants returned these forms to the researcher(s) on their way as they left the clinic.

Data collection was conducted mainly by the main investigator (F.A.), however, help was received from four other researchers (F.S., M.M., S.A. and B.A.). To minimise the potential of bias, the main investigator (F.A.) trained and instructed all other investigators on how to administer the questionnaire, so that it would be administered in the exact same way to all participants. The importance of not influencing participants' responses in any way was emphasized.

3.3.1.2.10 Inclusion and exclusion criteria

The inclusion and exclusion criteria for the recruitment of patients are shown in Table 3.9 and Table 3.10.

Table 3.9: Inclusion criteria

Inclusion criteria
- Kuwaiti, 18 years of age and older. - Diagnosis with T2DM - Prescription of medications for management of diabetes (oral hypoglycaemic tablets, insulin or both)

Table 3.10: Exclusion criteria

Exclusion criteria
- Non Kuwaitis, and those aged under 18 - Patients with Type 1 diabetes mellitus or gestational diabetes - Patients with T2DM who are diet controlled - Patients with salient physical distress or cognitive dysfunction hindering ability to participate in the research

3.3.1.2.11 Plan for analysis

The statistical package SPSS for Windows, release version 17 (© SPSS, Inc., Chicago, IL) was used to analyse the quantitative data. Statistical advice was sought. Descriptive results were predominantly sought, as this was most appropriate to meet the study aims and objectives. When it was appropriate to explore relationships between variables (e.g., to assess differences between adherers and non-adherers in terms of age,

beliefs about medicines, perceptions of healthcare providers) the parametric independent samples t-tests were conducted. To explore relationships between adherers and nonadherers in terms of discrete variables which can only take whole numbers and if the range of values was small then non-parametric Mann-Whitney U tests were conducted. It is worth noting that parametric tests were mainly used in this study as they are more powerful than non-parametric tests and the data allowed for their use. However, after re-analysis of data using non-parametric tests (where appropriate) the researcher found that there was no difference in results and conclusions reached whether parametric or non-parametric tests were used.

Qualitative data (e.g., reasons for nonadherence to medications) were analyzed separately by two independent researchers (F.A.) and (B.A.) who coded the reasons into "intentional" or "unintentional". Any disagreement were resolved by discussion (number of disagreements resolved, N=3). As for qualitative data relating to reasons for nonadherence to other diabetes self-care behaviours (e.g., diet, exercise, SBGM, foot care), it was analyzed in the same way by (F.A.) and (B.A.), who coded the reasons into different categories as they emerged. Any disagreement was resolved by discussion (number of disagreements resolved, N=2).

3.3.1.2.12 Ethical approval

The study was approved by Research Ethics Committee of the Ministry of Health (MOH), State of Kuwait. A copy of the ethics approval is attached in Appendix 2.

3.4 RESULTS

Data collection took place between November 2008 and January 2009. A total of 250 out of 299 Kuwaiti patients with T2DM approached were recruited and completed the questionnaire. Participants were drawn from different clinics, polyclinics and hospitals of Kuwait, of all six health districts.

3.4.1 Response rate

The response rate was approximately 84 % (250/299). Approximately (61%) of non-responders were females. Reasons for non-response were similar for both males and females, and included: lack of time (49%), lack of interest (20%) and tiredness (12%). Approximately 18% returned incomplete questionnaires. Since over 10% of data was missing, all incomplete questionnaires were excluded from the analysis and were not

counted as part of the 250 responders. Table 3.11 illustrates participants' response rate from different health districts in Kuwait.

Most participants (72%) preferred the investigator(s) to read the questionnaire and complete it for them based on their oral responses. Some participants (11%) completed parts of the questionnaire on their own and the researcher(s) helped them complete the other parts. Only 17% of participants completed the questionnaire completely on their own. F.A and M.M. were the main investigators involved in data collection, collecting about 78% of the questionnaires, although help was received from other investigators (S.A., F.S. and B.A.) who collected a further 4%. Approximately 86% of questionnaires were collected during the morning shift (when most diabetes clinic appointments are usually given) while 5% were collected during an evening shift. With the remaining 9% it was not possible to determine when they were collected as they constituted the test-retest reliability study where participants were allowed to take questionnaires to their homes to complete and return later.

Table 3.11: Response rate from different health districts in Kuwait

Health district	Total approached	Total responded	Male responders	Female responders	Response rate
Hawalli	63	44	21	23	69.8%
Al-Asma	49	43	20	23	87.8%
Al-Ahmadi	49	41	21	20	83.7%
Al-Farwania	52	42	20	22	80.8%
Al-Jahra	46	40	20	20	87.0%
Al-Sabah	20	20	10	10	100.0%
Total	279*	230*	112*	118*	82.4%*

*An additional 20 patients were recruited to assess test-retest reliability of the questionnaire, which were later added to the main sample of the study. These account for the difference between the numbers reported in this table and those described previously in Section 3.4.1.

3.4.2 Demographic variables of the sample

The demographic details of the sample are shown in Table 3.12. Just over half of the sample participants were female (51.6%) with a mean age of 54.5 (SD=10.3) years. Participants were randomly selected from different hospitals, specialized clinics, and general clinics from all over the country. Nearly two thirds of participants (63.2%) were recruited from specialised polyclinics, which are the most common place for diabetes care in Kuwait. Most participants (75%) were either retired (43%) or looking after children

(32%). The vast majority of participants (75%) completed their education beyond the minimum school leaving age, which is 4 years at primary school, although only a about third (30%) held a professional degree or equivalent qualification.

Table 3.12: Demographics of the research participants

Factor	Mean (SD)	Range
Age	54.5 (10.3)	23-88
	N	**%**
Gender		
Male	121	48.4
Female	129	51.6
Health district		
Hawalli	54	21.6
Al-Asma	45	18.0
Al-Ahmadi	43	17.2
Al-Farwania	42	16.8
Al-Jahra	40	16.0
Al-Sabah	20	8.0
Place of care		
General polyclinic	27	10.8
Specialized polyclinic	158	63.2
Hospital	62	24.8
Employment status		
Employed (self/part-time)	57	22.8
Unemployed	2	0.8
Doing voluntary work	1	0.4
Looking after children	81	32.4
Retired	107	42.8
At school/in full time education	1	0.4
Education		
Continued education after minimum school leaving age	187	74.8
Hold a degree or equivalent qualification	75	30.0

3.4.3 Clinical variables of the sample

Over half of participants (54%) were solely using tablets (i.e., oral medications) compared to approximately 46% who were solely on insulin or insulin plus tablets. About half of participants (50%) were taking a once or twice daily regimen, compared to 48% who were taking a three or more times daily regimen. The majority of the sample (79%) had comorbidities in addition to diabetes, with cardiovascular comorbidity being the most common (71%). More than half the sample (63%) had already developed diabetes complications, with retinopathy being the most common (28%). For the sample participants, the mean total number of diabetes tablets taken per day was 2.8 tablets (SD= 2.1, range= 0-11 tablets), the mean total number of other tablets taken per day for other comorbidities was 3.3 tablets (SD= 3.5, range 0-29 tablets). The mean duration of diabetes was 11 years (SD= 7.9, range= 0.25-34 years), and the mean duration since taking diabetes medications was 10.5 years (SD= 7.9 years, range= 0.17-34 years). The vast majority of participants were taking oral hypoglycaemic tablets (82%), with metformin being the most commonly used (64%). Table 3.13 and Table 3.14 illustrate types of diabetes medications the participants were taking and the clinical variables of the research participants, respectively.

Table 3.13: Types of diabetes medications research participants were taking

Type of diabetes medication	n	%
Oral hypoglycaemics	207	82.8
Glucophage® (metformin)	159	63.6
Diamicron® (gliclazide)	66	26.4
Daonil® (glibenclamide)	27	10.8
Amaryl®(glimepiride)	14	5.6
Minidiab® (glipizide)	8	3.2
Avandia® (rosiglitazone)	7	2.8
Novonorm® (repaglinide)	4	1.6
Glustin® (Pioglitazone)	2	0.8
Glucobay® (acarbose)	1	0.4
Januvia® (sitagliptin)	1	0.4
Insulin	114	45.6

*All medications are considered generically in this table.

Table 3.14: Clinical variables of the research participants

Factor	n	%
Type of treatment		
Tablets	136	54.4
Insulin	43	17.2
Both	71	28.4
Diabetes dosage regimen		
Once daily	29	11.6
Twice daily	95	38.0
Three times daily	87	34.8
Four or more times daily	32	12.8
Presence of comorbidity	197	78.8
Cardiovascular	177	70.8
Skeletal	34	13.6
Metabolic diseases	27	10.8
Gastrointestinal	20	8.0
Respiratory	18	7.2
Neurological	8	3.2
Hematological	6	2.4
Autoimmune disease	2	0.8
Cancer	2	0.8
Presence of diabetes complications	158	63.2
Retinopathy	69	27.6
Nephropathy	45	18.0
Neuropathy	105	42.0
Cardiovascular	43	17.2
No. of diabetes complications Present		
1	77	30.8
2	57	22.8
3	21	8.4
4	2	0.8
	Mean (SD)	**Range**
Total number of diabetes tablets taken per day	2.8 (2.1)	0-11
Number of other tablets taken per day (for other comorbidities)	3.3 (3.5)	0-29
Duration of diabetes	132.5 (94.6) months 11.0 (7.9) years	3-408 months 0.25-34 years
Duration since taking diabetes medications	126.4 (94.7) months 10.5 (7.9) years	2-408 months 0.17-34 years

3.4.4 Number of adherers/nonadherers to diabetes medications among Kuwaiti patients with T2DM

3.4.4.1 Using clinical outcomes measure (HbA1C)

Sixty (24%) of the participants (N=250) reported that their HbA1c levels were measured within the past three months as recommended by the clinical guidelines; of these however, measurements were recorded in medical records for only 49/250 of the sample (20%). HbA1c levels were not recorded for 31/250 of the sample (12%), and outdated measurements were recorded for 107/250 of the sample (43%). As for the remaining 52/250 of the sample (21%), it was not possible to assess HbA1c measurements as their medical records were not accessible at the time of data collection.

Independent samples T-tests, Fisher's Exact Test, or the Mann-Whitney U Test (where appropriate) were used to assess whether there was any difference between those who had and those who did not have HbA1c levels in terms of demographic variables (age, gender, health district, place of diabetes care, employment status, education), clinical variables (type of treatment, dosage regimen, presence of comorbidity, number of comorbidities present, presence of complications, number of diabetes complications present, number of diabetes tablets taken per day, number of other tablets taken per day, duration since having diabetes, duration since taking diabetes medications), and psychological measures (beliefs about medicines as measured by BMQ necessity scores, BMQ concerns scores, BMQ differential scores, BMQ harm scores, BMQ benefits scores, BMQ overuse scores, and perceptions of doctor support as measured by the total scores of the physician and health care team support subscale of the Chronic Illness Resources Survey, CIRS).

In terms of demographic and clinical variables, results of statistical analyses showed that there was a statistically significant difference between those who had and those who did not have HbA1c levels available in terms of place of diabetes care, employment, education, having a professional degree, and dosage regimens, Table 3.15. Those who had HbA1c levels available tended to be treated at hospitals or specialized polyclinics, educated, without a professional degree, retired, and taking more complex dosage regimens compared to their counterparts. However, results showed that those who had and those who did not have HbA1c levels available did not differ in terms of age, gender, health district,

type of treatment, presence of comorbidities, presence of diabetes complications, number of diabetes complications present, number of comorbidities present, total number of diabetes tablets taken per day, number of other tablets taken per day (for other comorbidities), duration of diabetes, and duration since taking diabetes medications, as shown in Table 3.15.

In terms of psychological measures, results showed there was no difference between those who had and those who did not have HbA1c level in perceptions of support provided by doctors. As for beliefs about medicines, there was a statistically significant difference between those who had and those who did not have HbA1c levels in beliefs about necessity of their diabetes medicines (as measured by BMQ- necessity), and beliefs about benefits of medicines in general (as measured by BMQ-benefit). However, there was no statistically significant difference between those who had and those who did not have HbA1c levels in terms of beliefs about concerns regarding taking diabetes medicines (BMQ-concerns), beliefs about harm which may result of taking medicines in general (BMQ-harm), and beliefs that medicines were overused by doctors (BMQ-overuse). Results are illustrated in Table 3.16.

In sum, Table 3.15 and Table 3.16 illustrate that there was a statistically significant difference between those who had and those who did not have HbA1c levels available in terms of place of diabetes care, employment, education, having a professional degree, dosage regimen, participants' beliefs about necessity of diabetes medicines (as measured by BMQ- necessity), and beliefs about benefits of medicines in general (as measured by BMQ-benefit).

This suggests that the subset of participants who had HbA1c levels recorded is not typical of the whole sample of study participants as there are differences between those who had and those who did not have HbA1c levels available in terms of some demographic, clinical and psychological measures. These differences may contribute to variability for which we do not have a clear explanation. Therefore, in section 3.4.4.5 (Selection of method of adherence assessment), when assessing sensitivity of the MARS and direct-self report in detecting nonadherence as compared to HbA1c levels, the conclusions must be interpreted with caution as these differences limit the generalizability

of the findings. There is still considerable uncertainty in measuring adherence and further research is needed in this area.

Table 3.15: Statistical analyses for differences between those who had and those who did not have HbA1c levels in terms of demographic and clinical variables

Clinical/demographic variables	Test	Result	Significant difference?
Age	Independent samples t-test	Mean 1= 53.1 vs. mean 2= 54.8; mean difference= -1.7; 95% confidence interval of the difference= -4.95 to 1.55; t=1.03; df= 241; p= 0.305 (two-tailed).	No
Gender (male/female)	Fisher's Exact Test with Bonferroni correction	Fisher's Exact p value= 0.336	No
Health District (Hawalli/Al-Asma/Al-Ahmadi/Al-Farwania/Al-Jahra/Al-Sabah)	Fisher's Exact Test with Bonferroni correction	Fisher's Exact p value= 0.138	No
Place of care (General polyclinic/Specialized polyclinic/Hospital)	Fisher's Exact Test with Bonferroni correction	Fisher's Exact p value= 0.006	Yes
Employment (Employed/Unemployed/Doing voluntary work/Looking after children/Retired/At school or in full time education)	Fisher's Exact Test with Bonferroni correction	Fisher's Exact p value=0.006	Yes
Continued education after minimum school leaving age (yes/no)	Fisher's Exact Test with Bonferroni correction	Fisher's Exact p value=0.036	Yes
Holding a degree/ professional qualification (yes/no)	Fisher's Exact Test with Bonferroni correction	Fisher's Exact p value=0.030	Yes
Type of treatment (tablet/insulin/both)	Fisher's Exact Test with Bonferroni correction	Fisher's Exact p value= 2.04	No
Diabetes dosage regimen (Once/twice/three times daily/ four or more times daily)	Fisher's Exact Test with Bonferroni correction	Fisher's Exact p value= 0.012	Yes
Presence of comorbidity (yes/no)	Fisher's Exact Test with Bonferroni correction	Fisher's Exact p value= 4.134	No
Presence of diabetes complications (yes/no)	Fisher's Exact Test with Bonferroni correction	Fisher's Exact p value= 4.392	No
Number of diabetes complications present	Mann-Whitney U Test with Bonferroni correction	Mann-Whitney U Test p value= 0.54	No
Number of comorbidities present	Mann-Whitney U Test with Bonferroni correction	Mann-Whitney U Test p value= 3.9	No
Total number of diabetes tablets taken per day	Mann-Whitney U Test with Bonferroni correction	Mann-Whitney U Test p value= 0.48	No
Number of other tablets taken per day (for other comorbidities)	Mann-Whitney U Test with Bonferroni correction	Mann-Whitney U Test p value= 3.84	No
Duration of diabetes	Mann-Whitney U Test with Bonferroni correction	Mann-Whitney U Test p value= 4.32	No
Duration since taking diabetes medications	Mann-Whitney U Test with Bonferroni correction	Mann-Whitney U Test p value= 4.68	No

Table 3.16: Statistical analyses for differences between those who had and those who did not have HbA1c levels in terms of psychological measures

Clinical and demographic variables	Test	Result	Significant difference ?
Beliefs about necessity of diabetes medications (BMQ necessity scores)	Independent samples t-test	Mean 1= 20.24 vs. mean 2=19.31 ; mean difference=0.937; 95% confidence interval of the difference=0.177 to1.696; t=2.429; df=245; p=0.016 (two-tailed)	Yes
Beliefs about concerns of diabetes medications (BMQ concerns scores)	Independent samples t-test	Mean 1=14.09 vs. mean 2=14.30; mean difference=-0.211; 95% confidence interval of the difference=-1.411to 0.990; t=-0.346; df=240; p=0.730 (two-tailed)	No
Beliefs about necessity- concerns of diabetes medications (BMQ necessity-concerns scores)	Independent samples t-test	Mean 1=6.16 vs. mean 2=5.03; mean difference=1.130; 95% confidence interval of the difference=-0.542 to2.802 ; t= 1.352; df=58.68; p=0.182 (two-tailed)	No
Beliefs about overuse of medications (BMQ overuse scores)	Independent samples t-test	Mean 1= 12.90 vs. mean 2= 12.54; mean difference=0.358; 95% confidence interval of the difference= -0.439 to1.155; t=0.885; df=247; p=0.377 (two-tailed)	No
Beliefs about harm of medications (BMQ harm scores)	Independent samples t-test	Mean 1=11.73 vs. mean 2=11.06; mean difference=0.679; 95% confidence interval of the difference=-0.091 to1.449 ; t=1.737; df=244; p=0.084 (two-tailed)	No
Beliefs about benefits of medications (BMQ benefits scores)	Independent samples t-test	Mean 1=15.51vs. mean 2=14.65; mean difference=; 95% confidence interval of the difference = 0.274 to1.452 ; t=2.887; df=239; p=0.004 (two-tailed)	Yes
Perceptions of doctor support (the physician and health care team support subscale of the CIRS scores)	Independent samples t-test	Mean 1=19.89 vs. mean 2=18.75; mean difference=1.139; 95% confidence interval of the difference=-0.589 to 2.867; t= 1.298; df= 242; p=0.196 (two-tailed)	No

Based on the 49 of the sample for whom recent HbA1c levels were captured, adherence level was assessed using the NICE guidelines cut-off point of 7.5%, whereby those with HbA1c level <7.5% were classified as having controlled diabetes and therefore adherent to their medications, and those with HbA1c level ≥7.5 were classified as having uncontrolled diabetes and therefore nonadherent to their medications. Table 3.17 and Table 3.18 illustrate data relating to HbA1c levels of participants with valid HbA1c levels available (i.e., measured within the past three months).

Table 3.17: Mean (and range) of HbA1c levels of participants with valid HbA1C levels

HbA1c levels (n=49)	Mean (SD)	Range
	8.5 (2.0)	4.6-15.0

Table 3.18: Number (and %) of adherers and nonadherers based on HbA1c assessment for the 49 participants with valid HbA1c levels

Adherence based on HbA1c level (n=49)	Adherers n (%)	Nonadherers n (%)
	16 (32.7%)	33 (67.3%)

3.4.4.2 Using direct method of self-report

Data was available for 241/250 of the sample (96%). Only 9/250 of the sample (4%) had missing responses for this method of self-reported adherence assessment.

Participants who reported not missing a dose of their diabetes medications over the past week were deemed adherent to their medications, whereas those who reported missing a dose or more of their diabetes medications over the past week were deemed nonadherent to their medications.

Table 3.19 illustrates participants' adherence data based on direct self-report, and Table 3.20 lists the types and frequencies of participants' reasons for their nonadherence to medications.

Table 3.19: Number (and %) of adheres and nonadherers based on direct self-report

Direct Self-Report (n=241)	Adherers n (%)	Nonadherers n (%)
	138 (57.3%)	103 (42.7%)

Table 3.20: Types, frequencies and % of reported reasons of nonadherence to medication

Reasons for medication nonadherence (n=250)	n	%	Valid%
Forgetting	44	17.6	41.5
Taking less/altering doses to avoid/decrease adverse effects	35	14.0	32.1
Travelling/being away from home	32	12.8	29.6
Skipping doses as a result of missing meals	16	6.4	14.8
Running out of medications	14	5.6	13.0
Delaying doses	12	4.8	11.1
Taking medication holidays	11	4.4	10.2
Distractions	9	3.6	8.3
Skipping doses due to fear of hypoglycaemias	7	2.8	6.5
Carelessness	5	2.0	4.6
Stopping medication(s) for good on one's own	4	1.6	3.7
Switching to tablets instead of insulin	3	1.2	2.8

As for reasons for nonadherence to medications, the sample participants reported forgetting as the most frequent reason for their nonadherence to medications.

According to the reported reasons, nonadherence of the sample was classified into "intentional", "unintentional" or "combined intentional and unintentional" by two independent researchers (F.A. and B.A.). About 37/250 of the sample as a whole (15%) had intentional nonadherence, while 57/250 of the sample as a whole (23%) had unintentional nonadherence. Only 12/250 of the sample as a whole (5%) had combined intentional and unintentional nonadherence. By looking at only those who were nonadherent, unintentional nonadherence was far more common than intentional nonadherence. Table 3.21 summarises these findings.

Table 3.21: Number (and %) of intentional, unintentional and combined nonadherers by direct self-report

Type of nonadherence (n=103)	Intentional n (%)	Unintentional n (%)	Both n (%)
	34 (33.0%)	54 (52.4%)	12 (11.7%)

For 3/103 participants who were nonadherent, it was not possible to assign a category for their nonadherence as they have failed to provide reason(s) for it, accounting for the remaining 2.9%.

3.4.4.3 Using MARS scale

The Medication Adherence Report Scale (MARS) was also used to assess adherence to diabetes medications. Data was available for 248/250 of the sample (99%). In this data set, the scale had moderate internal reliability, with a Cronbach's Alpha coefficient of 0.63. Test-retest reliability of MARS was also established by assessing 20 participants' responses to the scale two weeks apart, results showed good test-retest reliability of MARS (Kappa=0.77). Table 3.22 illustrates the mean and range of MARS scores of research participants, and Figure 3.3 illustrates participants' responses to the individual items from the MARS.

Table 3.22: Mean (SD) and range of scores using the MARS (potential range from 5-25)

MARS Total Score (n=248)	Mean (SD)	Range
	21.7 (3.4)	9-25

Figure 3.3: Participants' responses to the individual items from the MARS

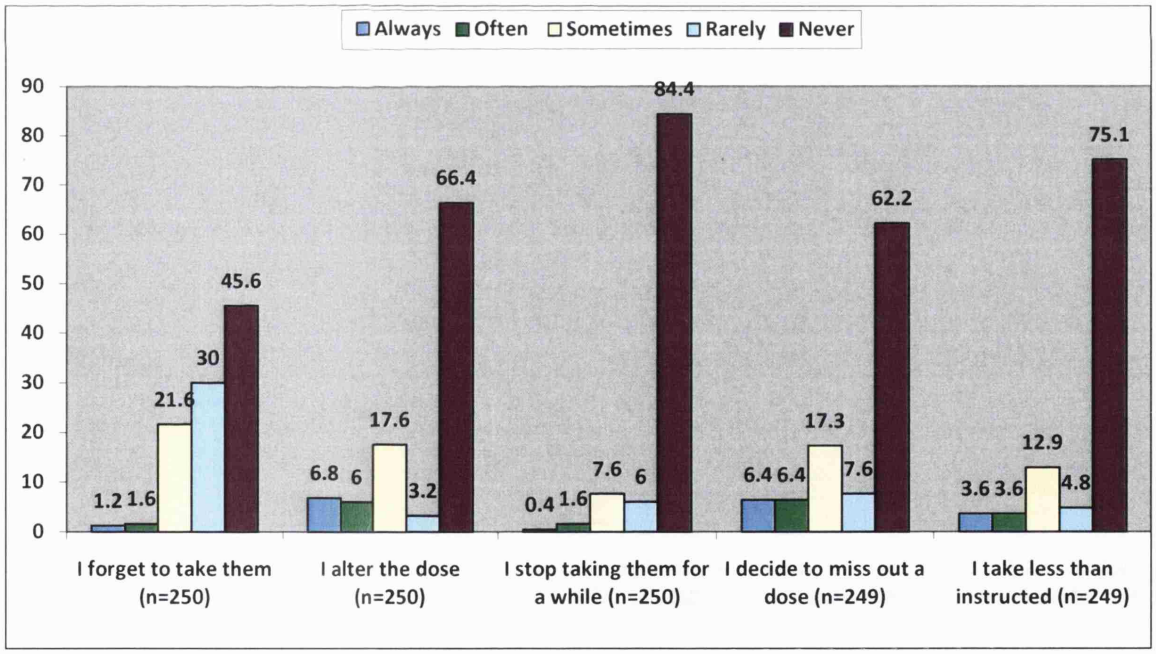


Figure 3.3 illustrates that results are highly skewed towards responses that denote high adherence. On each item, the majority of patients responded that they "never", "rarely" or "sometimes" perform that behaviour. A few patients responded that they "always", "often" did. Patients' scores from each item were summed to give an overall adherence score.

Figure 3.4: Histogram of the overall adherence scores using MARS

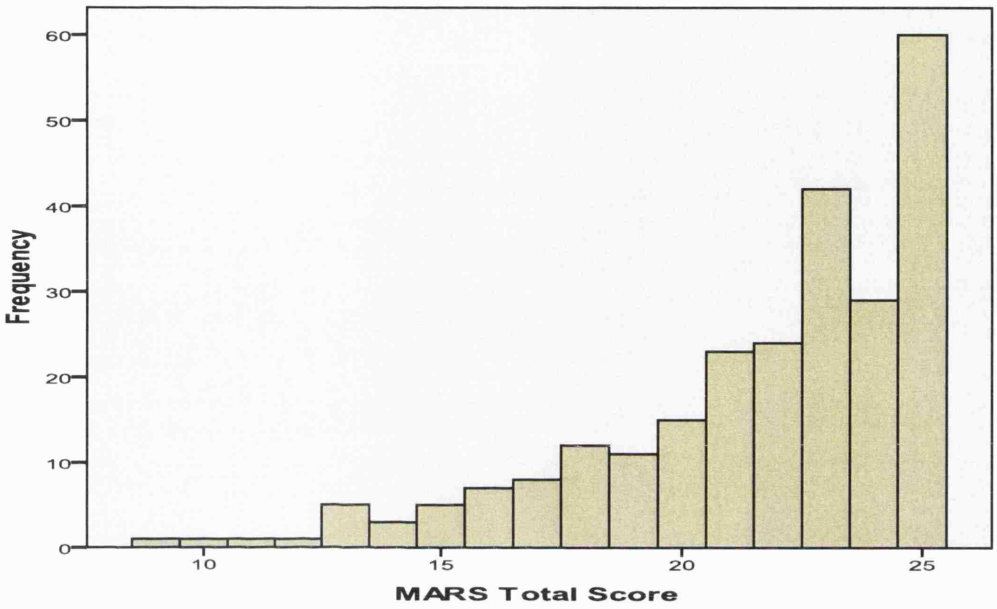


Figure 3.4 illustrates that data are negatively skewed. As recommended by the authors of the MARS (Horne and Hankins, personal communication), the MARS scale can be dichotomised at the point that divides the responses in two proportions (30%:70%); thus creating two categories of "high adherers" and "low adherers". Within this data set, the cut-off point was 20 so scores >21 were categorised as high adherers, and scores of ≤ 20 were categorised as low adherers. Table 3.23 shows the number (and %) in each category.

Table 3.23: Number of "high adherers" and "low adherers" using MARS data.

MARS (n=248)	High adherers n (%)	Low adherers n (%)
	178 (71.2%)	70 (28.0%)

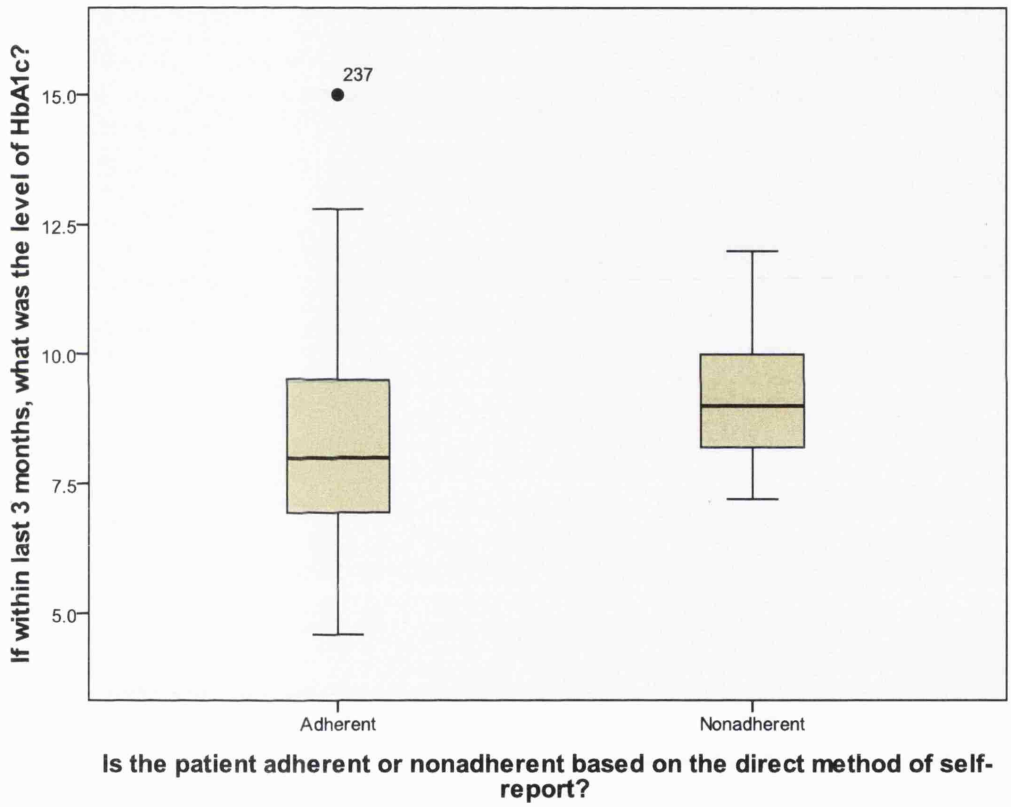
3.4.4.4 Comparisons between different measures of adherence assessment

3.4.4.4.1 HbA1c and direct self-report

A box plot was used to visually assess the relationship between adherence as indicated by direct self-report and HbA1c levels. Figure 3.5 illustrates that those who were nonadherent to their medications as indicated by direct-self report tended to have higher HbA1c levels than those who were adherent to their medications, as expected. The lines in the middle of the boxplots represent the median of HbA1c levels for adherent and nonadherent patients.

Using dichotomous categorisation of participants HbA1c levels into adherent or nonadherent (based on the cut-off of 7.5), agreement between adherence based on direct-self-report and HbA1c levels was measured by Cohen's Kappa, which ranges from 0-1 where 1 denotes perfect agreement, and 0 denotes that agreement is no better than what you would get by chance. Cohen's Kappa = 0.28, denoting fair agreement according to Altman's classification of Kappas (Chapman and Hall, 1991).

Figure 3.5: Box plot for adherence by direct self-report vs. HbA1c levels



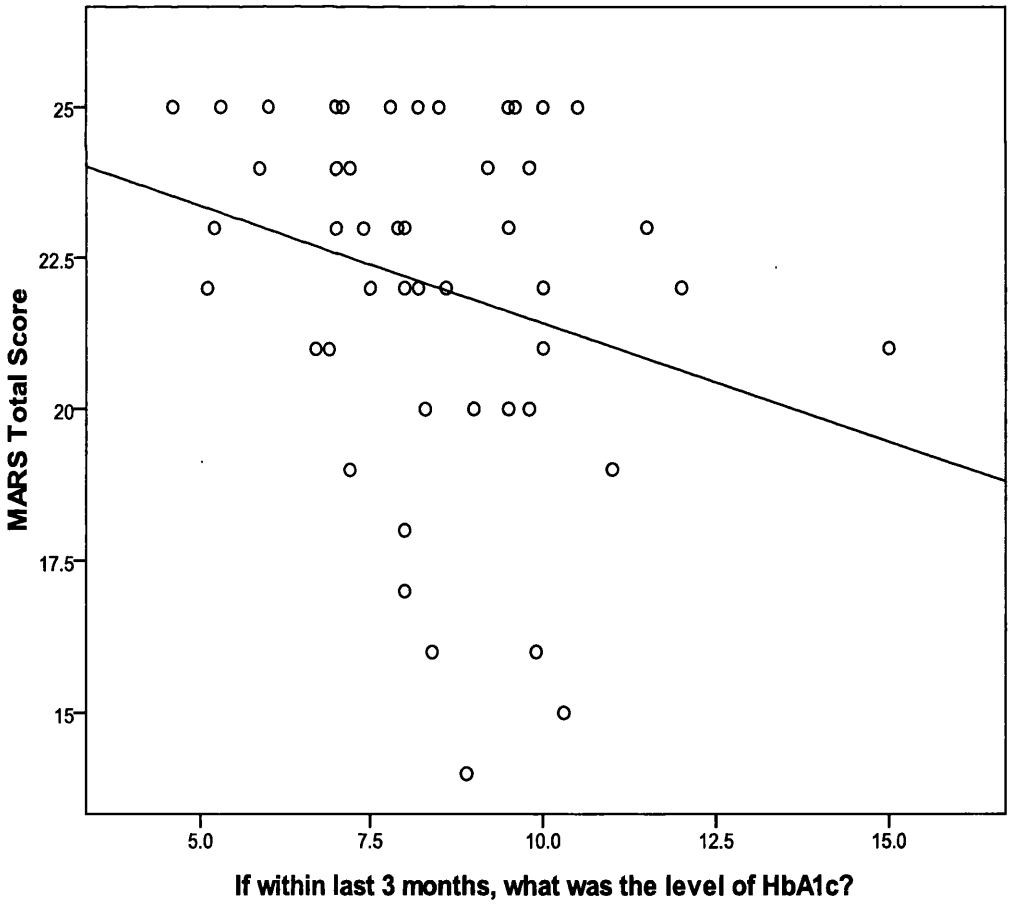
3.4.4.4.2 HbA1c and self-report using MARS scale

A scatter plot was used to visually assess the relationship between adherence scores as measured by MARS and HbA1c levels. Figure 3.6 illustrates that there is a negative relationship between MARS scores and HbA1c levels, those who score highly on MARS (i.e. the more adherent) tend to have lower HbA1c levels, as expected. However the relationship is weak as points are scattered far away from the straight line.

Spearman's Correlation (rho) was used to statistically test association between total MARS scores and HbA1c levels. There was a small negative correlation between total MARS scores and HbA1c levels (r= -0.284, p=0.05, two-tailed). Those who scored highly on MARS (i.e. the more adherent) tended to have lower HbA1c levels.

Using the dichotomous categorisation of participants into adherent or nonadherent according to their HbA1c levels (cut-off point=7.5), and the dichotomous categorisation of participants as low or high adherers according to their MARS scores (cut-off point=20), agreement between dichotomous variables was measured by Cohen's Kappa; kappa = 0.24 denoting fair agreement between the two measures of adherence.

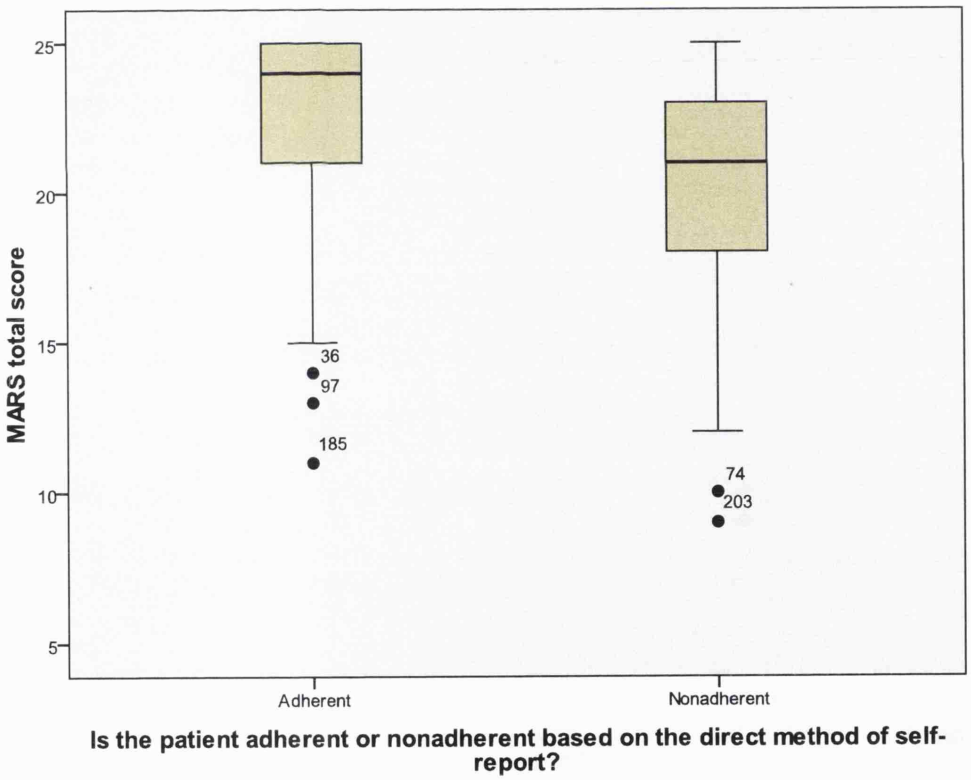
Figure 3.6: Scatter plot illustrating a regression line of the relationship between adherence by MARS scores vs. HbA1c levels



3.4.4.4.3 Direct self-report and self-report using MARS scale

A box plot was used to visually assess the relationship between adherence as indicated by direct self-report and by MARS total scores. Figure 3.7 illustrates that those who were nonadherent to their medications as indicated by direct-self report tended to have lower MARS total scores than those who were adherent to their medications, as expected. The lines in the middle of the boxplots represent the median MARS scores for adherent and nonadherent patients. Using the dichotomous categorisation of participants as low or high adherers according to their MARS scores (cut-off point=20), agreement between adherence based on direct-self report and MARS was measured by Cohen's Kappa (kappa= 0.20) denoting poor agreement.

Figure 3.7: Box plot for adherence by direct self-report vs. MARS scores



The MARS was further tested against the direct measure of adherence in two ways:

- To compare the proportion of adherers and non-adherers using each measure.
- To test how well each measure could identify nonadherence as assessed by HbA1c levels.
- To test how well the MARS could identify intentional and unintentional non-adherence as assessed by direct self-report.

Table 3.24: Comparison of adherers and non-adherers from MARS and direct self-report

		Adherence level based on MARS		Total
		Low adherence	High adherence	
Based on the direct method of self-report	**Adherent**	28	109	137
	Nonadherent	40	62	102
Total		68	171	239

Table 3.24 shows that direct self-report identified 102/239 (43%) nonadherers compared to MARS which identified 68/239 (29%) nonadherers among participants who had valid data for both direct self-report and MARS.

The MARS was able to identify only 40/102 (39%) of nonadherers and 109/137 (80%) of adherers detected by direct self-report (i.e. compared to direct self report, MARS had a sensitivity of 39.2% for detecting nonadherence and a specificity of 79.6%). Thus, the MARS fared worse than direct self-report at identifying nonadherence among the study participants.

Table 3.25: Comparison of adherers and non-adherers from MARS and HbA1c levels

		Adherence level based on MARS		Total
		Low adherence	High adherence	
Based on HbA1c levels in the last three months?	**Adherent**	1	15	16
	Nonadherent	11	21	32
Total		12	36	48

Table 3.25 shows that HBA1c method identified 32/48 (67%) nonadherers compared to MARS which identified 12/48 (25%) of nonadherers among participants who had valid data for both HbA1c and MARS.

MARS could identify only 11/32 (34%) of nonadherers and 15/16 (94%) of adherers as indicated by their HbA1c levels (i.e., compared to HbA1c levels, MARS had a sensitivity of 34.4% for detecting nonadherence, and a specificity of 93.8%).

Table 3.26: Comparison of adherers and non-adherers from direct self-report and HbA1c levels

		Adherence based on the direct method of self-report?		Total
		Nonadherent	Adherent	
Based on HbA1c levels in the last three months?	Adherent	1	14	15
	Nonadherent	16	17	33
Total		17	31	48

Table 3.26 shows that direct self report identified 17/48 (35%) of nonadherers compared to HBA1c levels which identified 33/48 (69%) of nonadherers among participants who had valid data for both HbA1c and direct self-report.

Direct self-report could identify 16/33 (48%) of nonadherers and of 14/15 (93%) of adherers as indicated by their HbA1c levels (i.e. compared to HbA1c levels, direct self report had a sensitivity of 48.5% for detecting nonadherence and a specificity of 93.3%).

Table 3.27: How intentional and unintentional non-adherers as assessed by direct self-report were classified by the MARS

		Adherence level based on MARS		Total
		Low adherence	High adherence	
Type of nonadherence based on direct-self report	Intentional	29	19	48
	Unintentional	13	44	57
Total		42	63	105

Table 3.27 shows that MARS was able to identify 29/48 (60%) of intentional nonadherers, and 13/57 (23%) of unintentional nonadherers as assed by direct self-report. Therefore, MARS fared worse at identifying unintentional nonadherence among the study participants.

3.4.4.5 Selection of the method for adherence assessment

HbA1c levels detected the largest number of nonadherers across the three different methods of adherence assessment used in this sample. However, as detailed in Section 3.3.1.2.3 using HbA1c as the sole method of medication adherence assessment is not recommended because it is impossible to separate the impact of diet, exercise, stress, or infection on HbA1c levels. Thus, data from HbA1c was meant to be used for comparisons with self-report only. However, valid HbA1c levels were not available for many participants so it was not always possible to do this.

In deciding whether to use the MARS or direct self-report results as the primary method of adherence assessment in this study, it was acknowledged that agreement between the two may not be reached as these methods require participants to recall their medication-taking behaviors over a different time period. With direct self-report, participants were asked to report whether they had missed taking a dose (or more) of their diabetes medications *over the past week*. With MARS, participants were asked to rate whether they had *ever* engaged in one of five statements denoting nonadherence to medications, in general, and without specifying a time period.

As reported in the literature, if a patient reports nonadherence, it is more likely that he/she is telling the truth, and therefore should be considered as nonadherent. The opposite cannot be ascertained due to social desirability bias which is well documented in the literature (Horne et al., 2005). For this reason, it was decided that the method which identified more nonadherers would be selected for use in this research, and be used in all analyses carried out throughout this chapter.

Direct self-report detected a larger percentage of nonadherers among the sample compared to MARS (43% vs. 29%, respectively). Nonadherers by direct self-report correlated better with nonadherence based on HbA1c levels than nonadherence based on MARS (kappa = 0.28 vs. kappa 0.24). When compared to HbA1c levels, direct self report had a sensitivity of 48.5% for detecting nonadherence and a specificity of 93.3%, while MARS had a sensitivity of 34.4%, and a specificity of 93.8%. Nevertheless, these data must be interpreted with caution, as the subset of participants who had HbA1c levels recorded were not typical of the whole sample in terms of some demographic, clinical and psychological measures, as illustrated in Section 3.4.4.1.

In terms of the type of nonadherence, direct self-report gave better insight regarding types of nonadherence (intentional/unintentional) which occurred compared to MARS, as participants had freedom to report any reason for their nonadherence, which was then classified by researchers into intentional or unintentional. Identifying the type of nonadherence is important when designing interventions aimed at improving adherence. Unintentional nonadherence may benefit from special reminder packaging systems, whereas intentional nonadherence may be less likely to benefit from such intervention and may require interventions aimed at increasing their motivation and awareness to adhere to their medications.

With MARS, participants were forced to rate five statements denoting nonadherence to medications and with the exception of the first item "I forget to take them" which clearly denotes unintentional nonadherence, and the third item "I decide to miss a dose" which clearly denotes intentional nonadherence, none of the other items can be clearly said as describing intentional or unintentional nonadherence. For example:

- The item "I alter the dose" seems to denote intentional nonadherence but may also denote unintentional nonadherence if participants had to alter the dose for reasons outside their control, e.g., if they misunderstood dosage instructions provided.

- The item "I stop taking them for a while" seems to denote intentional nonadherence but may also denote unintentional nonadherence if participants stopped taking them for a while because of running out of supply for example.

- The item "I take less than instructed" seems to denote intentional nonadherence but may also denote unintentional nonadherence if participants took less than instructed because of lack of manual dexterity for example, preventing them from opening the medication bottle, or because of forgetting, etc.

As direct self-report detected a larger number of nonadherers in this particular sample, and as it was easier to determine the type of nonadherence that existed with direct self-report compared to MARS, it was decided to use direct self-report as the main method of adherence assessment in this research. All analyses carried out from this point onward will be based on adherence using direct self-report only.

3.4.5 Relationship between demographic variables and adherence

Demographic variables (age, gender, health district, place of diabetes care, employment status and education) were assessed in relation to adherence to diabetes medications as assessed by the direct self-report method.

An independent samples t-test was used to compare age in years for adherers and nonadherers. There was a significant difference in age between adherers and nonadherers [mean 1= 56.12 vs. mean 2= 52.07; mean difference=-4.0526; 95% confidence interval of the difference=-6.6775 to -1.4276; t=-3.042; df= 232; p= 0.003 (two-tailed)]. Older patients were more adherent to their diabetes medications than younger patients.

A Fisher's Exact Test was used to assess if there was any association between gender, health district, place of diabetes care, employment status, education and adherence to diabetes medications. There was no difference in adherence in relation to any of these demographic variables except for the place where the participants received their care, where a significant difference in adherence was found between patients treated at different places of care.

As illustrated in Table 3.28., those who were treated at a hospital were more adherent than those treated at a specialised polyclinic, and those treated at a specialised polyclinic were more adherent than those treated at a general polyclinic (Fisher's Exact Test p=0.039).

Table 3.28: Results of Fisher's Exact Test for associations between demographic variables and adherence

Demographic variable		Adherent n (%)	Nonadherent n (%)	Total n (%)	Fisher's Exact p value
Gender	Male	71 (60.7%)	46 (39.3%)	117 (100.0%)	0.301
	Female	67 (54.0%)	57 (46.0%)	124 (100.0%)	
	Total	138 (57.3%)	103 (42.7%)	241 (100.0%)	
Health district	Hawalli	28 (53.8%)	24 (46.2%)	52 (100.0%)	0.420
	Al-Asma	27 (64.3%)	15 (35.7%)	42 (100.0%)	
	Al-Ahmadi	23 (56.1%)	18 (43.9%)	41 (100.0%)	
	Al-Farwania	18 (43.9%)	23 (56.1%)	41 (100.0%)	
	Al-Jahra	26 (65.0%)	14 (35.0%)	40 (100.0%)	
	Al-Sabah	11 (57.9%)	8 (42.1%)	19 (100.0%)	
	Total	133 (56.6%)	102 (43.4%)	235 (100.0%)	
Place of care	General polyclinic	13 (50.0%)	13 (50.0%)	26 (100.0%)	0.039
	Specialized polyclinic	81 (52.9%)	72 (47.1%)	153 (100.0%)	
	Hospital	42 (71.2%)	17 (28.8%)	59 (100.0%)	
	Total	136 (57.1%)	102 (42.9%)	238 (100.0%)	
Employment	Employed	30 (54.5%)	25 (45.5%)	55 (100.0%)	0.236
	Unemployed	0 (0.0%)	2 (100.0%)	2 (100.0%)	
	Doing voluntary work	1 (100%)	0 (0.0%)	1 (100.0%)	
	Looking after children	43 (54.4%)	36 (45.6%)	79 (100.0%)	
	Retired	64 (62.7%)	38 (37.3%)	102 (100.0%)	
	At school/in full time education	0 (0.0%)	1 (100.0%)	1 (100.0%)	
	Total	138 (57.5%)	102 (42.5%)	240 (100.0%)	
Education: Continued education after minimum school leaving age	Yes	100 (55.9%)	79 (44.1%)	179 (100.0%)	0.552
	No	38 (61.3%)	24 (38.7%)	62 (100.0%)	
	Total	138 (57.3%)	103 (42.7%)	241 (100.0%)	
Education: Hold a degree or equivalent qualification	Yes	43 (59.7%)	29 (40.3%)	72 (100.0%)	0.671
	No	95 (56.2%)	74 (43.8%)	169 (100.0%)	
	Total	138 (57.3%)	103 (42.7%)	241 (100.0%)	

3.4.6 Relationship between clinical variables and adherence

Clinical variables (type of treatment, dosage regimen, presence of comorbidity, number of comorbidities present, presence of complications, number of diabetes complications present, number of diabetes tablets taken per day, number of other tablets taken per day, duration since having diabetes, duration since taking diabetes medications) were assessed in relation to adherence to diabetes medications as assessed by the direct self-report method.

A Fisher's Exact test was used for assessing associations between adherence and categorical variables (type of treatment, diabetes dosage regimen, presence of comorbidity, presence of diabetes complications). The Mann-Whitney U Test was used to test associations between adherence and continuous variables (number of diabetes complications present, number of comorbidities present, total number of diabetes tablets taken per day, number of other tablets taken per day, duration of diabetes, duration since taking diabetes medications).

Except for the presence of diabetes complications, none of the clinical variables was associated with adherence to medications. A higher proportion of nonadherers had complications compared to adherers (Fisher's Exact Test p =0.045). There was a trend to significance for presence of comorbidity (Fisher's Exact Test p =0.079), number of diabetes complications present (Mann-Whitney U Test p=0.097), duration of diabetes (Mann-Whitney U Test p=0.074), duration since taking diabetes medications (Mann-Whitney U Test p=0.085).

Those who had comorbidities other than diabetes, those who had fewer diabetes complications present, those who had diabetes for a longer period of time, and those who had been taking diabetes medications for a longer period of time were more adherent to their diabetes medications than their counterparts. Results are summarized in Table 3.29 and Table 3.30.

Table 3.29: Results of Fisher's Exact Test for associations between categorical clinical variables and adherence

Clinical variable		Adherent n (%)	Nonadherent n (%)	Total n (%)	Fisher's Exact p value
Type of treatment	Tablets	78 (58.6%)	55 (41.4%)	133 (100.0%)	0.291
	Insulin	26 (65.0%)	14 (35.0%)	40 (100.0%)	
	Both	34 (50.0%)	34 (50.0%)	68 (100.0%)	
	Total	138 (57.3%)	103 (42.7%)	241 (100.0%)	
Diabetes dosage regimen	Once daily	21 (75.0%)	7 (25.0%)	28 (100.0%)	0.146
	Twice daily	53 (58.2%)	38 (41.8%)	91 (100.0%)	
	Three times daily	46 (54.1%)	39 (45.9%)	85 (100.0%)	
	Four or more times daily	14 (46.7%)	16 (53.3%)	30 (100.0%)	
Presence of comorbidity	Yes	113 (60.1%)	75 (39.9%)	188 (100.0%)	0.079
	No	23 (46.0%)	27 (54.0%)	50 (100.0%)	
	Total	136 (57.1%)	102 (42.9%)	238 (100.0%)	
Presence of diabetes complications	Yes	81 (53.3%)	71 (46.7%)	152 (100.0%)	0.045
	No	51 (68.0%)	24 (32.0%)	75 (100.0%)	
	Total	132 (58.1%)	95 (41.9%)	227 (100.0%)	

Table 3.30: Results of Mann-Whitney U Test for associations between interval clinical variables and adherence

Clinical Variable	Adherent N (Median) / Mean Rank	Nonadherent N (Median) / Mean Rank	Total N (Median)	Mann-Whitney U Test p value
Number of diabetes complications present	131 (1) / 107.18	94 (1) / 121.12	225 (1)	0.097
Number of comorbidities present	138 (1) / 118.79	103 (1) / 120.45	241 (1)	0.843
Total number of diabetes tablets taken per day	138 (2) / 114.84	102 (3) / 128.15	240 (3)	0.137
Number of other tablets taken per day (for other comorbidities)	133 (3) / 122.23	103 (2) / 113.69	236 (2)	0.335
Duration of diabetes	137 (120) / 126.89	102 (96) / 110.74	239 (108)	0.074
Duration since taking diabetes medications	137 (120) / 126.09	101 (96) / 110.56	238 (96)	0.085

3.4.7 Beliefs about diabetes medications and beliefs about medications in general

Participants' beliefs about their diabetes medicines and beliefs about medicines in general were assessed using the Beliefs about Medicines Questionnaire (BMQ) as detailed in the Section 3.3.1.2.4.

3.4.7.1 Descriptive results

BMQ data was available for 96-100% of the sample, depending on the specific subscale. The BMQ necessity and BMQ concerns subscales had moderate and good internal reliability. The BMQ overuse, BMQ harm and BMQ benefit subscales had low internal reliabilities. Test-retest reliability of BMQ subscales was established by assessing 20 participants' responses to the subscales two weeks apart. Results showed that the BMQ necessity and BMQ overuse subscales had very good reliabilities, while the BMQ harm and BMQ benefit subscales had moderate reliabilities, and the BMQ concerns had low test-retest reliability. Tables 3.31-3.33 summarise participants' responses to the BMQ scales, and reliability analyses.

Table 3.31: Mean scores (and ranges) of individual BMQ subscales (potential range of scores is from 5-25 for BMQ necessity and BMQ concerns, from 4-20 for the BMQ overuse, BMQ harm and BMQ benefit, and from -20-20 for the BMQ differential necessity-concerns)

BMQ subscale	n	Mean score (SD)	Minimum	Maximum
Total necessity	247	19.49 (2.441)	12	25
Total concerns	242	14.26 (3.682)	5	25
Total differential (necessity-concerns)	240	5.24 (4.504)	-7	20
Total overuse	249	12.61 (2.536)	7	19
Total harm	246	11.19 (2.458)	4	18
Total benefit	241	14.81 (1.836)	9	20

Table 3.32: Cronbach's Alpha coefficient of individual BMQ subscales

BMQ subscale	n	Cronbach's Alpha coefficient
Total necessity *	247	0.64
Total concerns **	242	0.75
Total overuse	249	0.50
Total harm	246	0.57
Total benefit	241	0.43

*Reassessing the internal consistency of the BMQ necessity scale (including the five additional items) increased the Cronbach's alpha to 0.73.
**Reassessing the internal consistency of the BMQ concerns (including the four additional items) increased the Cronbach's alpha to 0.84. However, since Cronbach's alpha was already acceptable for these two subscales, it was decided to use the original items only for the analysis of BMQ necessity and BMQ concerns.

Table 3.33: Two week test-retest reliability of individual BMQ subscales

BMQ subscale	n	Kappa
Total necessity	20	0.78
Total concerns	20	0.51
Total overuse	20	0.84
Total harm	20	0.64
Total benefit	20	0.64

Participants' responses to individual items on the BMQ subscales are illustrated in the Figures 3.8-3.12.

Figure 3.8: Participants' responses to individual items on the BMQ necessity subscale

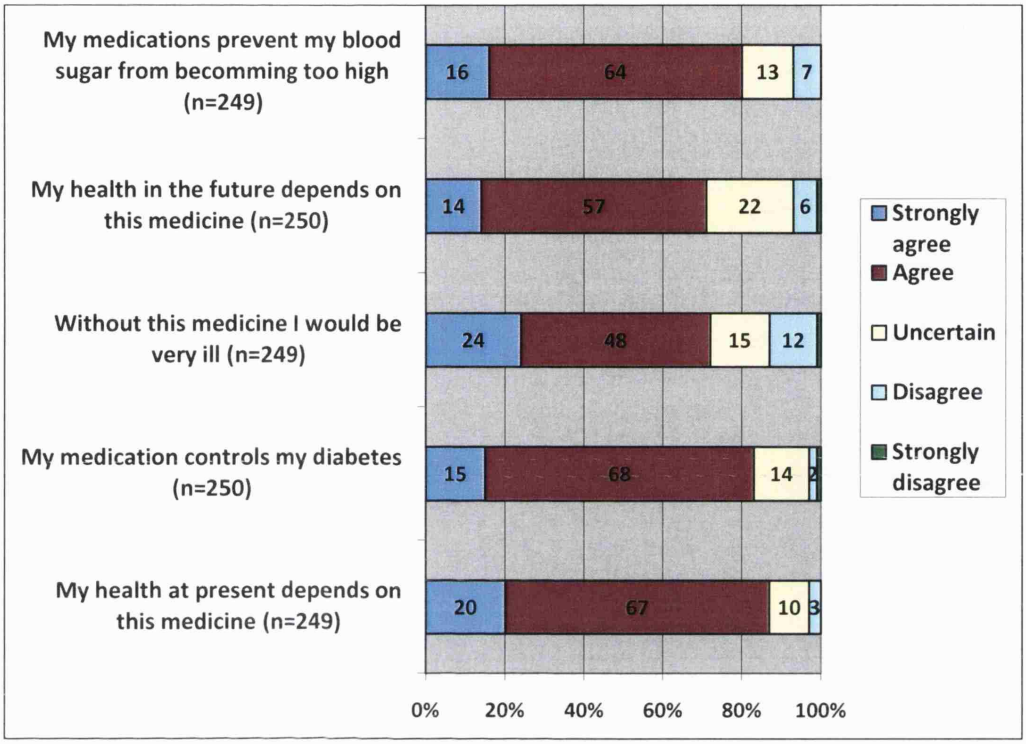


Figure 3.9: Participants' responses to individual items on the BMQ concerns subscale

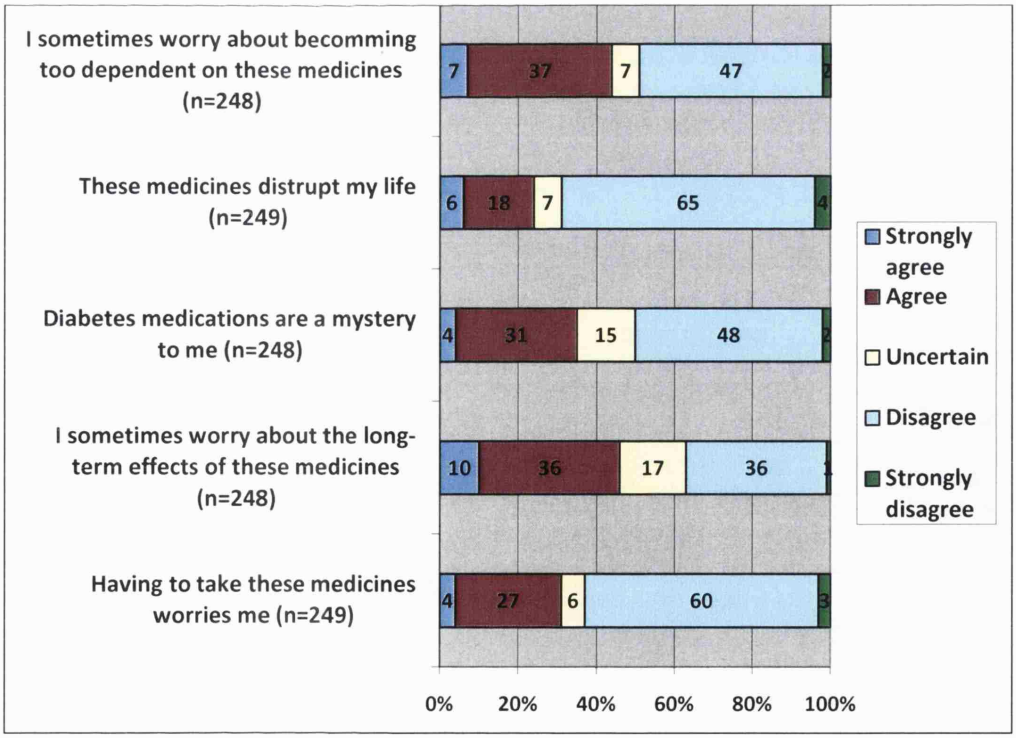


Figure 3.10: Participants' responses to individual items on the BMQ overuse subscale

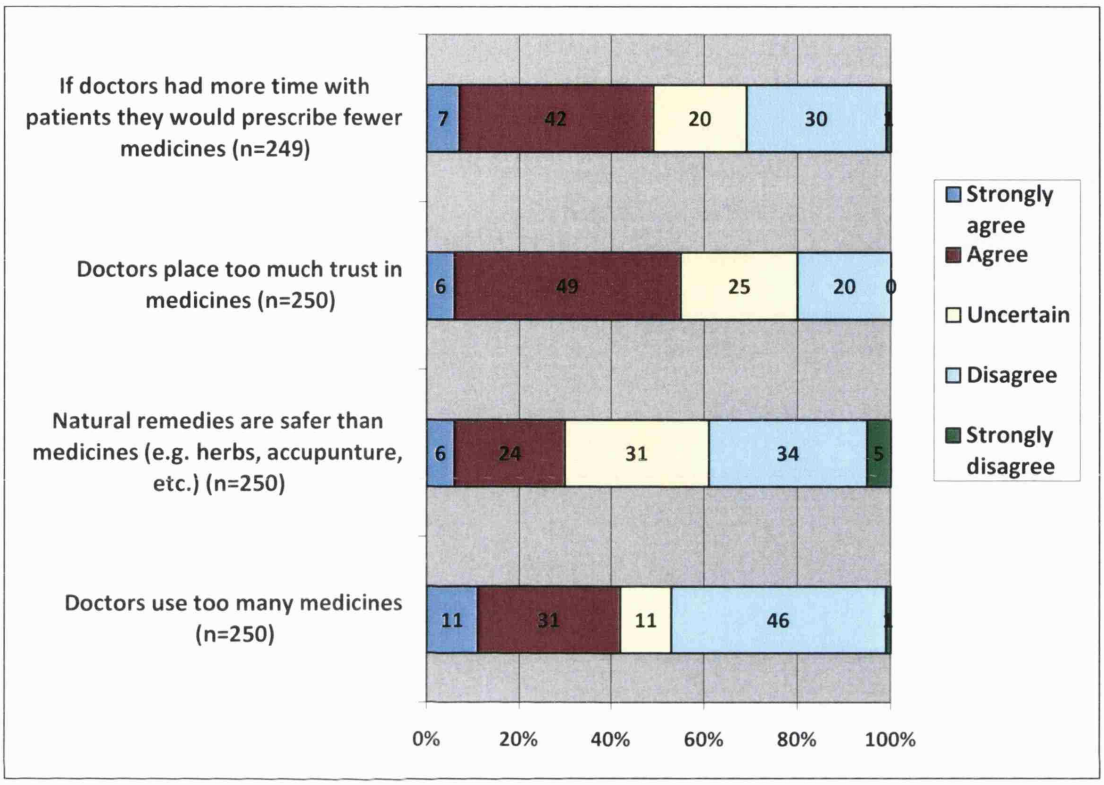


Figure 3.11: Participants' responses to individual items on the BMQ harm subscale

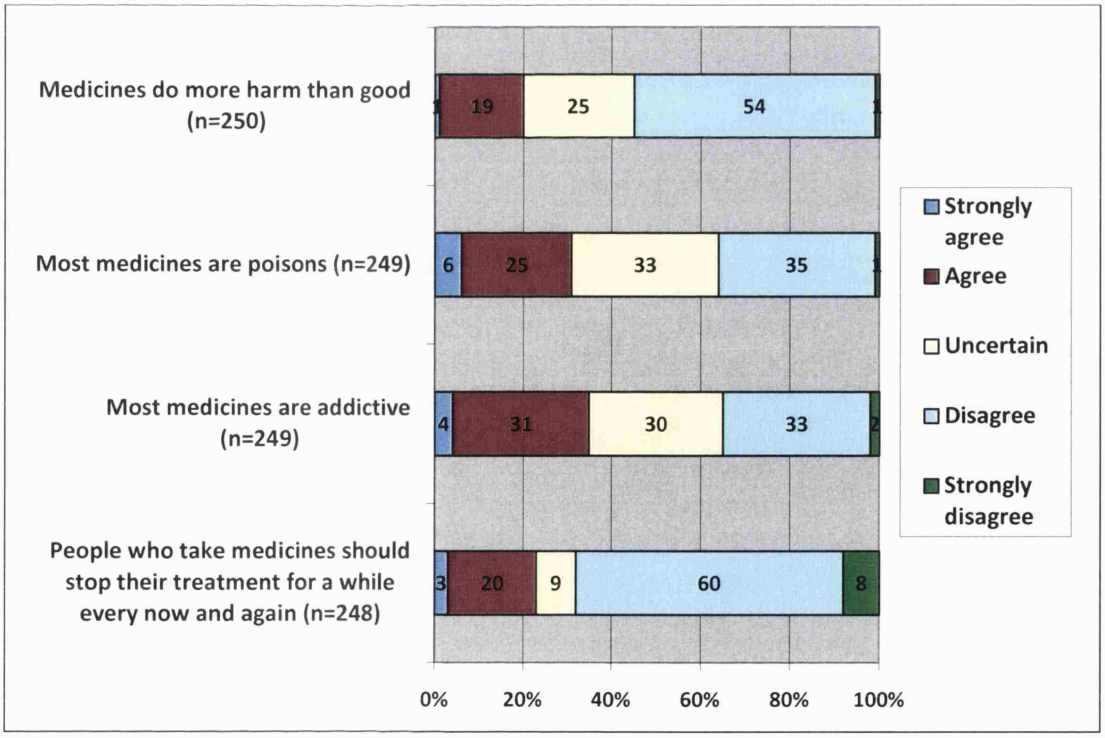
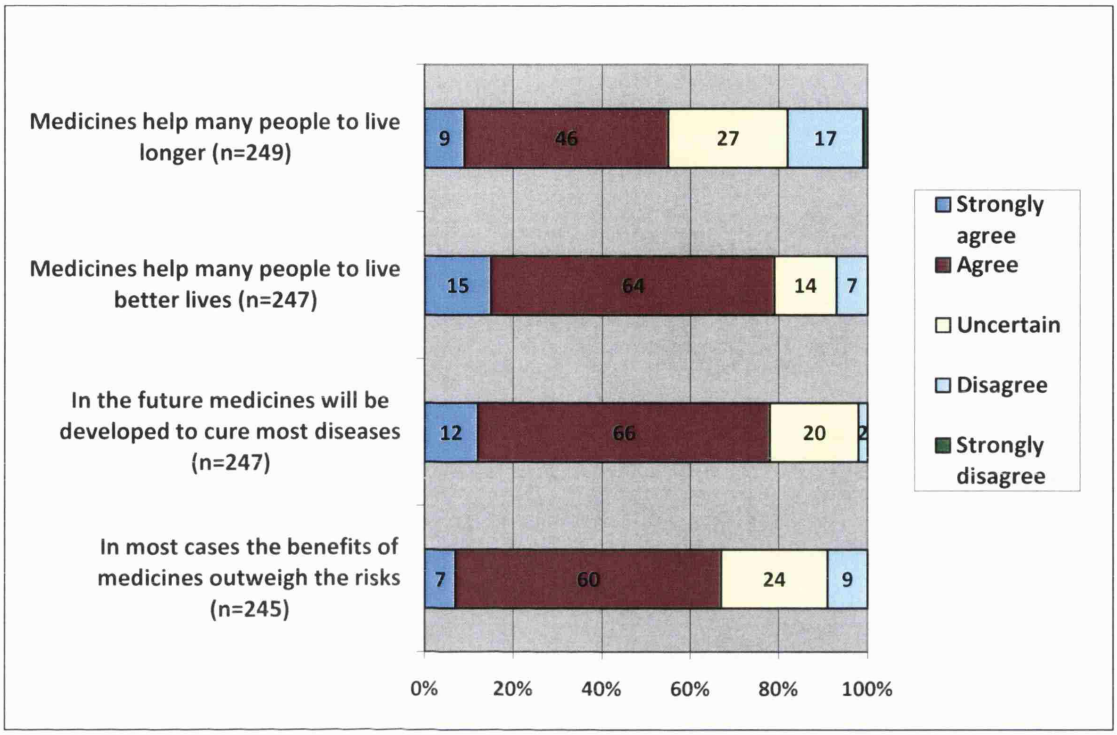


Figure 3.12: Participants' responses to individual items on the BMQ benefit subscale



3.4.7.1.1 BMQ-specific

3.4.7.1.1.1 Necessity

Figure 3.8 shows that although the majority of participants responded that they either agreed (48%-67%) or strongly agreed (14-24%) about the necessity of taking their diabetes medicines, depending on the specific statements still a substantial proportion of participants (10-22%) were uncertain about the necessity of these medicines.

Only a small proportion of participants either disagreed (2-12%) or strongly disagreed (0-1%) that their diabetes medicines were necessary.

The highest level of agreement was for three items:

- "My health at present depends on this medicine"; 86% of participants agreed or strongly agreed with this item.
- "My medication controls my diabetes"; 83% of participants agreed or strongly agreed with this item.

- "My medication prevents my blood glucose levels from becoming too high"; 80% of participants agreed or strongly agreed with this item.

The highest level of disagreement was for the item:

- "Without this medicine I would be very ill"; 13% of participants disagreed or strongly disagreed with this item. This indicates that a significant proportion of participants believed that it might be okay to be without medicines.

The highest level of uncertainty was for the item:

- "My health in the future depends on this medicine"; 22% of participants were uncertain about this item.

It is worth noting that about 10% of participants were uncertain that their health at present depended on their mediations. However, when speaking of the future, about twice as many participants (22%) were uncertain that their health in the future depended on their medications.

3.4.7.1.1.2 Concerns

Figure 3.9 shows that a larger proportion of participants either disagreed (36-65%) or strongly disagreed (1-4%) that they were concerned about their diabetes medicines compared to those who either agreed (18-37%) or strongly agreed (4-10%) that they had concerns about their medicines. However, there were two concern items that a considerable proportion of patients agreed with.

The highest level of agreement was for the two items:

- "I sometimes worry about becoming too dependent on these medicines"; 44% of participants agreed or strongly agreed with this item (i.e., over a third of participants held this concern).
- "I sometimes worry about the long-term effects of these medicines"; 46% of participants agreed or strongly agreed with this item (i.e., nearly half the participants held this concern).

The highest level of disagreement was for the two items:

- "These medicines disrupt my life"; 69% of participants disagreed or strongly disagreed with this item.

- "Having to take these medicines worries me"; 63% of participants disagreed or strongly disagreed with this item.

Therefore, about two thirds of participants were not concerned about these two items.

About 6-17% of participants were uncertain regarding the concerns about taking their diabetes medicines, with the highest level of uncertainty reported for the item:

- "I sometimes worry about the long-term effects of these medicines"; 17% of participants were uncertain about this item.

3.4.7.1.2 BMQ-general

3.4.7.1.2.1 Overuse

Figure 3.10 shows that depending on the specific statements, a substantial proportion of participants (11-25%) were "uncertain" about whether medicines were being overused by doctors.

Slightly more participants agreed (24-49%) or strongly agreed (6-11%) that medicines were being overused by doctors compared to those who disagreed (20-46%) or strongly disagreed (0-5%), depending on the specific items.

The highest level of agreement was for the items:

- "Doctors place too much trust in medicines"; 55% of participants agreed or strongly agreed with this item (i.e., over half of participants believed that doctors trusted too much in medicines).
- "If doctors had more time with patients they would prescribe fewer medicines"; 49% of participants agreed or strongly agreed with this item (i.e., nearly half of all participants believed that doctors would have prescribed fewer medicines had they spent more time with patients).

The highest level of disagreement was for the item:

- "Doctors use too many medicines"; 47% of participants disagreed or strongly disagreed with this item (i.e., nearly half of participants did not believe that doctors prescribed too many medicines).

With regards to the item relating to natural remedies, it is worth noting that there were equally significant proportions of participants who agreed and disagreed that natural remedies were safer than medicines (30% agreed or strongly agreed vs. 39% disagreed or strongly disagreed). About a third of participants (31%) were uncertain whether natural remedies were safer than medicines.

3.4.7.1.2.2 Harm

Figure 3.11 shows that a substantial proportion of participants (9-33%) were "uncertain" as to whether medicines in general can cause harm, depending on the specific statements. For example, a third of participants (33%) were uncertain whether most medicines were poisons. A similar proportion of participants (30%) were uncertain whether most medicines were addictive. A quarter of all participants (25%) were uncertain whether medicines do more harm than good. The least level of uncertainty was for the item "people who take medicines should stop their treatment for a while every now and again", which 9% of participants were uncertain.

More participants either disagreed (33-60%) or strongly disagreed (1-8%) that medicines can cause harm compared to those who agreed (19-31%) or strongly agreed (1-6%) about this, depending on the specific items.

The highest level of disagreement was for the items:

- "People who take medicines should stop their treatment for a while every now and again"; over two thirds of participants (68%) disagreed or strongly disagreed with this item.
- "Medicines do more harm than good"; over half of all participants (55%) disagreed or strongly disagreed with this item.

The highest level of agreement was for the items:

- "Most medicines are addictive"; over a third of participants (35%) agreed or strongly agreed with this item.
- "Most medicines are poisons"; nearly a third of participants (31%) agreed or strongly agreed with this item.

3.4.7.1.2.3 Benefit

Figure 3.12 shows that a substantial proportion of participants (14-27%), depending on the specific statements, were "uncertain" as to whether medicines in general are beneficial. It is worth noting that, about 14% of participants were uncertain whether medicines helped many people to live better lives. However, twice as many participants (27%) were uncertain whether medicines helped many people to live longer.

However, most participants agreed (46-66%) or strongly agreed (7-15%) that medicines were beneficial compared to those who disagreed (2-17%) or strongly disagreed (0-1%), depending on the specific items.

The highest level of agreement was for the items:

- "Medicines help many people to live better lives"; over two thirds of participants (79%) agreed or strongly agreed with this item.
- "In the future medicines will be developed to cure most diseases"; over a third of participants (78%) agreed or strongly agreed with this item.
- "In most cases the benefits of medicines outweigh the risks"; about two thirds of participants (67%) agreed or strongly agreed with this item.

The highest level of disagreement was for the item:

- "Medicines help many people to live longer"; 18% of participants disagreed or strongly disagreed with this item.

3.4.8 Relationship between beliefs about diabetes medicines, beliefs about medicines in general and adherence

Box plots (Figures 3.13-3.18) were used initially to visually explore the relationship between adherence as indicated by direct self-report and participants' scores on the different BMQ subscales.

Figure 3.13: Box plot for adherence by direct self-report vs. total necessity scores of participants

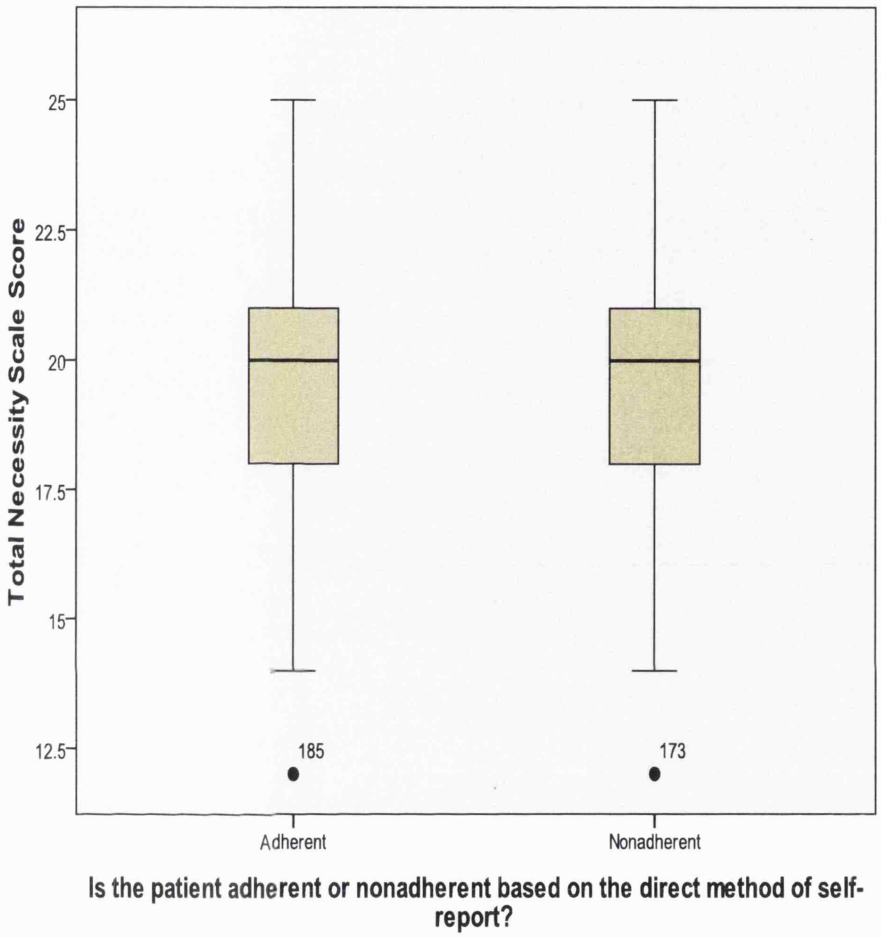


Figure 3.13 illustrates that both adherers and nonadherers had a similar distribution of scores on the BMQ necessity subscale. The median score is the same for both (20) and the range of scores for both adherers and nonadherers lied between 12 and 25.

Figure 3.14: Box plot for adherence by direct self-report vs. total concerns scores of participants

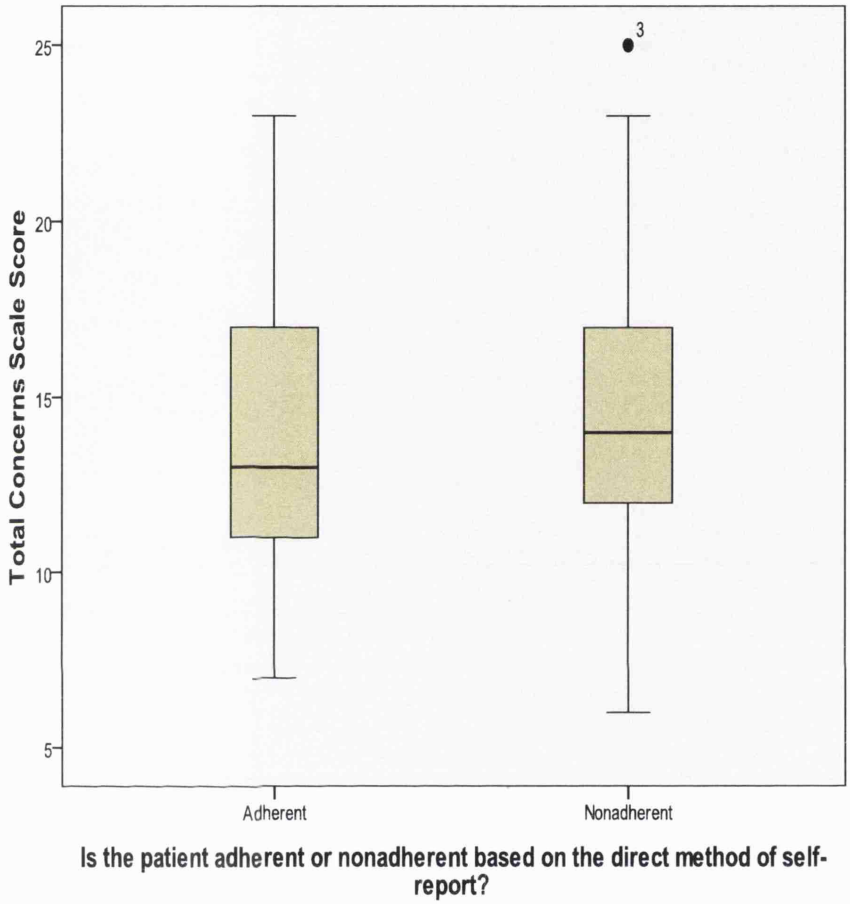


Figure 3.14 illustrates that both adherers and nonadherers had a similar distribution of scores on the BMQ concerns subscale. Although the median score was slightly higher for the nonadherent (14 vs. 13, respectively), the range of scores for both adherers and nonadherers was similar (7 to 23 vs. 6 to 25, respectively).

Figure 3.15: Box plot for adherence by direct self-report vs. total necessity–concerns (differential) scores of participants

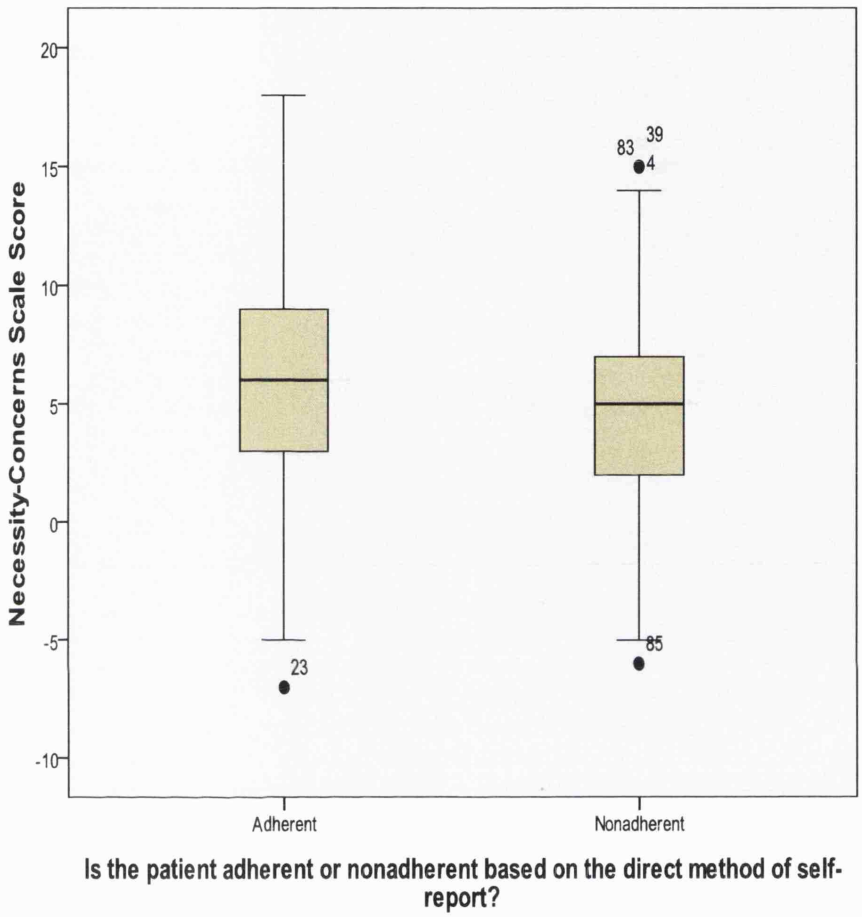


Figure 3.15 illustrates that both adherers and nonadherers also had a similar distribution of scores on the BMQ necessity-concerns subscale. Although the median score was slightly higher for the adherent participants (6 vs. 5, respectively), the range of scores for both adherers and nonadherers was similar (-7 to 18 vs. -6 to 15, respectively).

Figure 3.16: Box plot for adherence by direct self-report vs. total overuse scores of participants

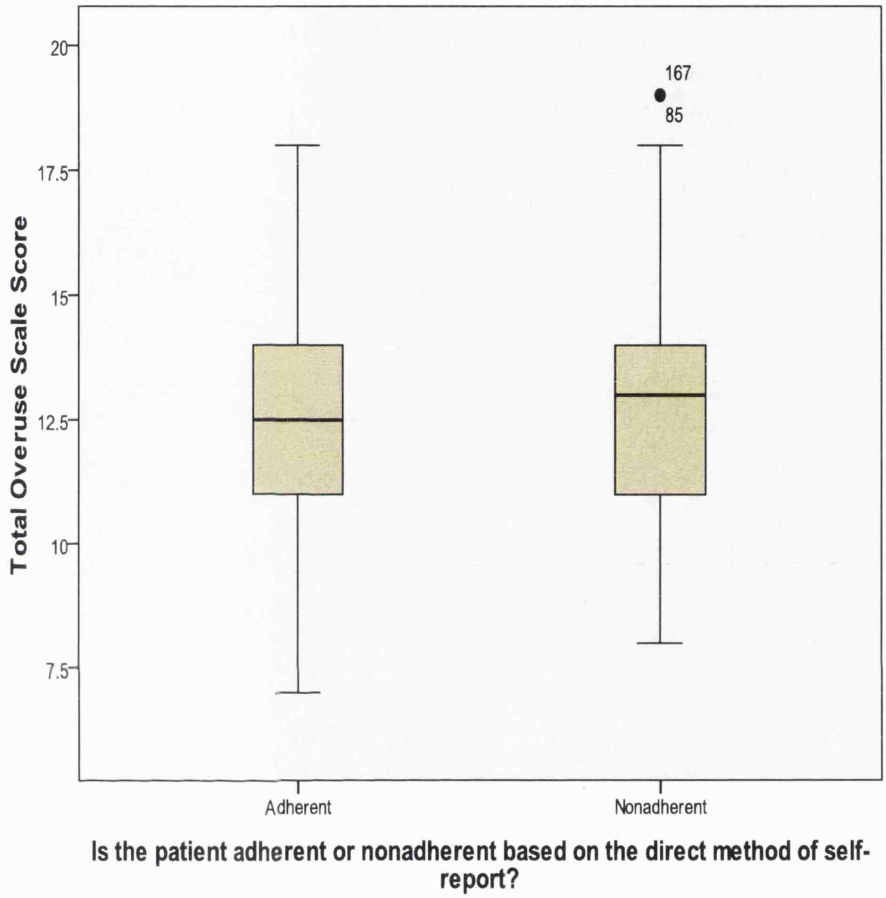


Figure 3.16 illustrates that both adherers and nonadherers also had a similar distribution of scores on the BMQ overuse subscale. The median scores were similar for both the adherent and nonadherent (12.5 vs. 13, respectively), and the range of scores for both adherers and nonadherers was also similar (7 to 18 vs. 8 to 19, respectively).

Figure 3.17: Box plot for adherence by direct self-report vs. total harm scores of participants

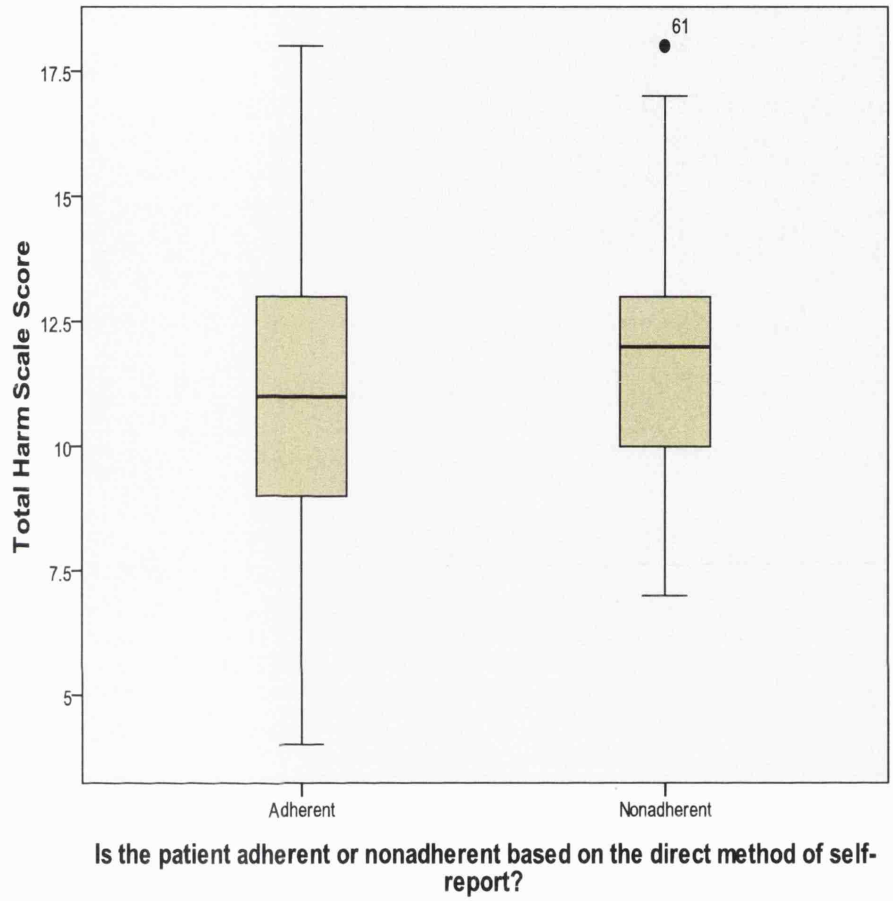


Figure 3.17 illustrates that both adherers and nonadherers had a similar distribution of scores on the BMQ harm subscale. The median scores were similar for both the adherent and nonadherent (11 vs. 12, respectively), and the range of scores for both adherers and nonadherers was also similar (4 to 18 vs. 7 to 18, respectively).

Figure 3.18: Box plot for adherence by direct self-report vs. total benefit scores of participants

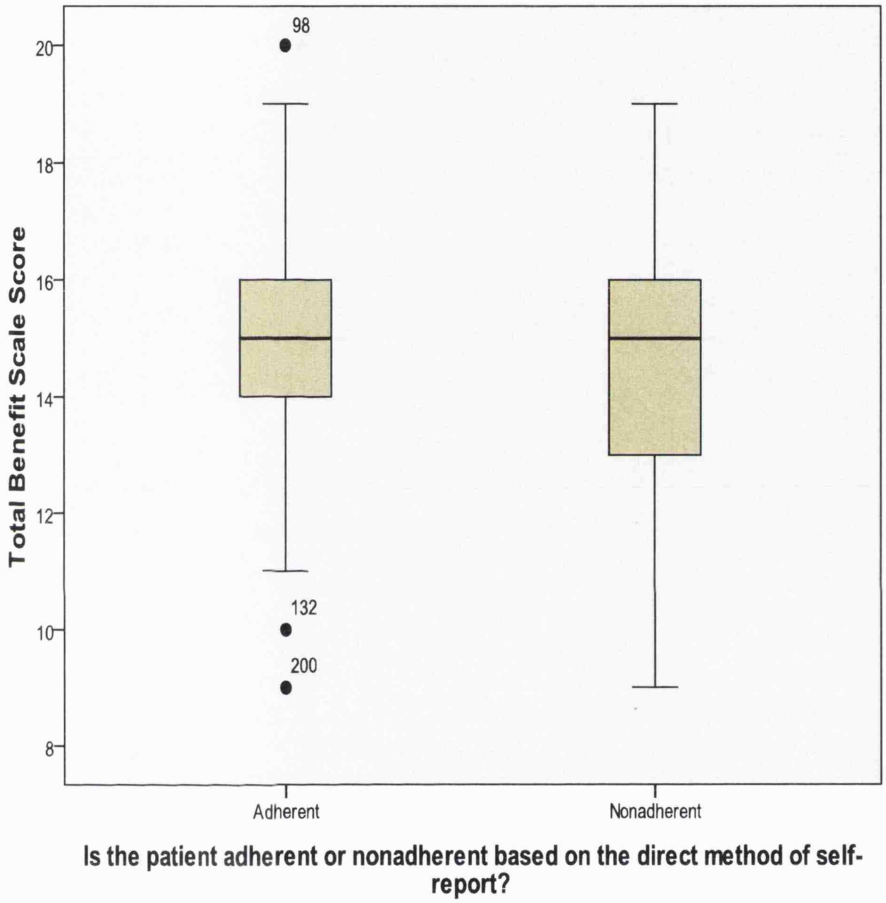


Figure 3.18 illustrates that both adherers and nonadherers had a similar distribution of scores on the BMQ benefit subscale. The median score was the same for both the adherent and nonadherent (15), and the range of scores for both adherers and nonadherers was similar (9 to 20 vs. 9 to 19, respectively).

Independent samples t-tests revealed that those who were adherent to their diabetes medicines had significantly higher beliefs in the benefits of medicines in general than those who were nonadherent [mean1= 14.99 vs. mean 2= 14.52; mean difference=-0.472; 95% confidence interval of the difference=-0.948 to 0.003; t= -1.958; df= 230; p=0.05 (two-tailed)]. There was a trend to significance for the harm scale; those who were adherent to

their diabetes medicines had fewer beliefs of harm that could result from taking medicines in general than those who were nonadherent [mean 1=10.99 vs. mean 2=11.56; mean difference=0.570; 95% confidence interval of the difference=-.063 to 1.203; t=1.773; df=235; p=0.08 (two-tailed)]. However any difference between the adherent and nonadherent was small. Table 3.34 and Table 3.35 illustrate data related to these findings.

Table 3.34: Table: Mean scores (SD) for adherers and non-adherers on the BMQ subscales and differential

BMQ Specific	**Adherent**		**Nonadherent**	
	n	**Mean (SD)**	**n**	**Mean (SD)**
BMQ necessity	136	19.61 (2.516)	102	19.35 (2.315)
BMQ concerns	131	13.99 (3.611)	102	14.73 (3.667)
BMQ differential	130	5.58 (4.446)	101	4.68 (4.352)
BMQ General	**Adherent**		**Nonadherent**	
	n	**Mean (SD)**	**n**	**Mean (SD)**
BMQ overuse	138	12.51 (2.515)	102	12.78 (2.631)
BMQ harm	138	10.99 (2.56)	99	11.56 (2.264)
BMQ benefit	132	14.99 (1.904)	100	14.52 (1.703)

*Potential range of scores is from 5-25 for BMQ necessity and BMQ concerns, from 4-20 for the BMQ overuse, BMQ harm and BMQ benefit, and from -20-20 for the BMQ differential necessity-concerns.

Table 3.35: Results of the t-tests for equality of mean scores for adherers and non-adherers on the BMQ subscales and differential

BMQ subscale scores	**t-test for Equality of Means**						
	t	**df**	**Sig. (2-tailed)**	**Mean Difference**	**Std. Error Difference**	**95% Confidence Interval of the Difference**	
						Lower	**Upper**
Total necessity *	-0.808	236	0.42	-0.257	0.319	-0.885	0.37
Total concerns**	1.527	231	0.128	0.733	0.48	-0.213	1.679
Total differential (necessity-concerns)	-1.543	229	0.124	-0.901	0.584	-2.053	0.25
Total overuse	0.806	238	0.421	0.27	0.335	-0.39	0.93
Total harm	1.773	235	0.078	0.57	0.322	-0.063	1.203
Total benefit	-1.958	230	0.051	-0.472	0.241	-0.948	0.003

* Using the extended necessity scale, there was still not difference between adherers and nonadherers in mean necessity scores [mean 1= 39.30 vs. mean 2= 38.71; t= 1.098; df= 230; p=0.273 (two-tailed)].
**Using the extended concerns scale, there was still not difference between adherers and nonadherers in mean concerns scores [mean 1= 24.88 vs. mean 2= 25.62; t= -0.921; df= 225; p=0. 358 (two-tailed)].

Independent samples t-tests for assessing differences between adhere and nonadherers in their responses to individual items of the BMQ subscales showed no difference in responses except for two items, neither of which was significant after applying the Bonferroni correction for multiple comparisons.

3.4.9 Intentional and unintentional nonadherence and beliefs about medicines

This section explores the relationship between beliefs about medicines (as indicated by participants' scores on the different BMQ subscales) and adherence, intentional or unintentional nonadherence (as assessed by direct-self report).

A one-way between groups analysis of variance was conducted to explore whether there was any difference between adherers, unintentional nonadherers and intentional adherers in their beliefs about medicines as measured by different BMQ subscales. There was no statistically significant difference between different groups in their beliefs about medicines as measured by any of the BMQ subscales. Table 3.36 illustrates data related to these findings.

Table 3.36: Results of the one-way ANOVA test for difference between adherers, unintentional nonadherers and intentional adherers in beliefs about medicines as assessed by BMQ subscales, and differential

BMQ subscale	Adherent		Unintentional Nonadherers		Intentional nonadherers		p value
	Mean(SD)	95% CI	Mean(SD)	95% CI	Mean(SD)	95% CI	
Necessity (n=247)	19.6 (2.5)	19.2-20.0	19.4 (2.3)	18.8-20.0	19.3 (2.6)	18.6-20.0	0.749
Concerns (n=242)	13.9 (3.6)	13.4-14.6	14.6 (3.9)	13.6-15.7	14.7 (3.6)	13.6-15.8	0.364
differential (necessity-concerns) (n=240)	5.6 (4.4)	4.9-6.3	4.9 (4.5)	3.7-6.1	4.6 (4.8)	3.2-5.9	0.351
Overuse (n=249)	12.5 (2.5)	12.1-12.9	12.7 (2.6)	12.0-13.4	12.8 (2.6)	12.0-13.5	0.802
Harm (n=246)	10.9 (2.6)	10.6-11.4	11.2 (2.1)	10.7-11.8	11.8 (2.4)	11.1-12.5	0.166
Benefit (n=241)	14.9 (1.9)	14.6-15.3	14.7 (1.8)	14.2-15.2	14.5 (1.7)	14.0-15.0	0.343

3.4.10 Perceptions of support provided by healthcare providers

The physician and health care team support subscale of the Chronic Illness Resources Survey (CIRS) was used to assess participants' perceptions of support provided by healthcare providers as detailed in Section 3.3.1.2.5.

3.4.10.1 Descriptive results

Data was available for 244/250 of the sample (97.6 %). The scale had good internal reliability, with a Cronbach's Alpha coefficient of 0.77, test-retest reliability of the scale was also acceptable (kappa was 0.68). This was based on assessment of 20 participants' responses to the scale two weeks apart.

Table 3.37 illustrate the mean and range of participants' scores on the physician and health care team support subscale of the CIRS. Figure 3.19 and Figure 3.20 illustrate a histogram of participants overall scores and participants' responses to individual items, respectively.

Table 3.37: Mean (SD) and range of the physician and health care team support total scores (potential range of scores for the scale is 6-30)

	Mean (SD)	Range
The physician and health care team support total score (n= 244)	18.9 (5.4)	6-30

Figure 3.19: Histogram of participants overall scores using the physician and health care team support subscale of the Chronic Illness Resources Survey (CIRS)

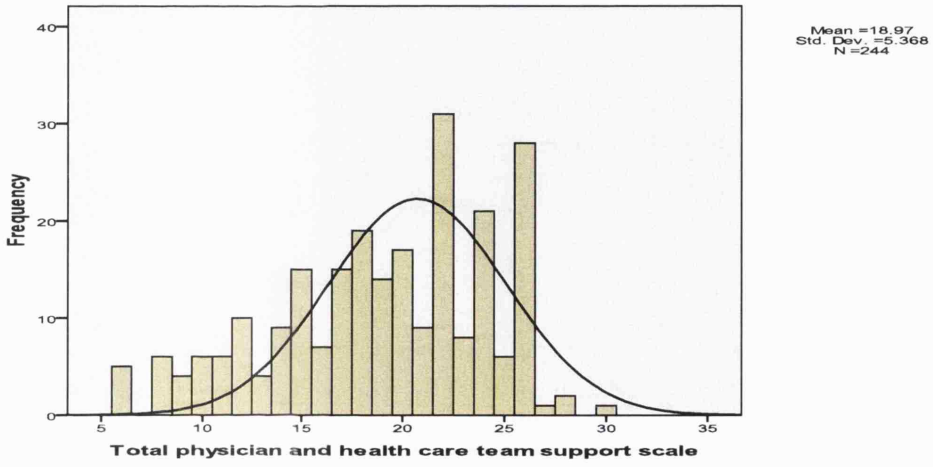
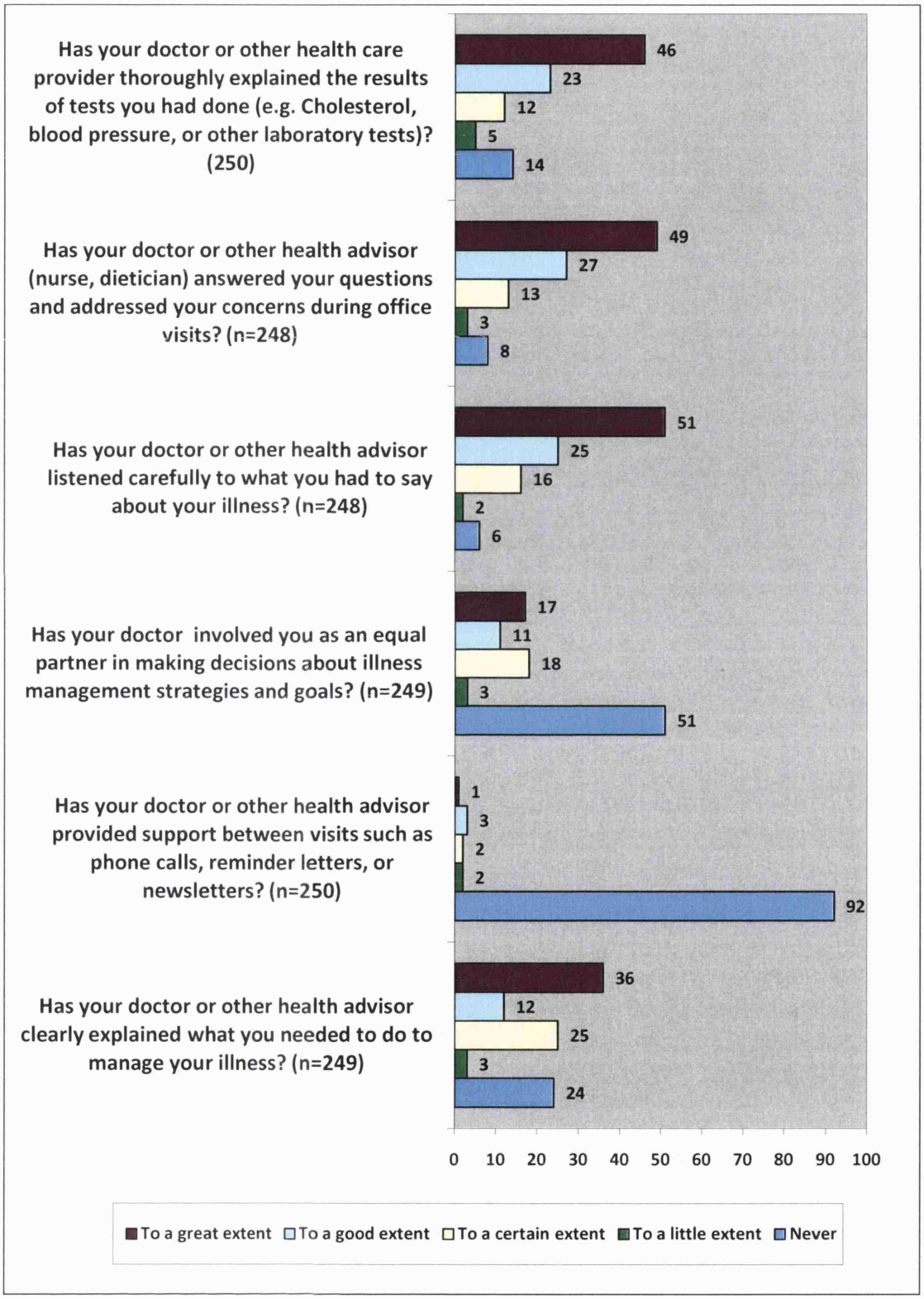


Figure 3.20: Percentages of participants' responses to individual items on the physician and health care team support subscale of the Chronic Illness Resources Survey (CIRS)



Responses illustrate that almost half of all participants perceived a great extent of doctor or other healthcare providers' support with regards to listening carefully to what they had to say about their illness (51%), answering their questions and addressing their concerns during office visits (49%), and explaining the results of tests they had done (46%). However, there is still room for improvement as a significant proportion of participants responded that their doctors provided support in these aspects "to a certain extent" (12-16%), "to a little extent" (2-5%) or "never" (6-14%), depending on the specific items.

Over a third of participants (36%) perceived a great extent of doctors or other healthcare providers' support with regards to clearly explaining what participants needed to do to manage their illness. However, between 3-25% of participants received support regarding this aspect only to certain or little extent, and 24% never received any support in this regard.

Most participants (92%) did not perceive any form of support from their doctor or other healthcare providers after leaving the clinic, i.e. between visits, such as phone calls, reminder letters, or newsletters. There is great room for improvement with regards to this aspect.

Moreover, over half participants (51%) reported that their doctor or other healthcare providers never involved them as equal partners in making decisions about their illness management strategies and goals. However 3-17% of participants reported that they received some support regarding this aspect, although the level of support provided varied from great to little.

3.4.11 Relationship between perceptions of support provided by health care providers and adherence

Independent samples t-tests revealed that there is no statistically significant difference between adherers and nonadherers in their perceptions of support provided by their health care providers, as measured by the physician and health care team support subscale of the CIRS [mean 1= 19.19 vs. mean 2= 19.14; mean difference=-0.055; 95% confidence interval of the difference= -1.422 to1.311; t= -0.08, df=233; p=0.94 (two-tailed)]. Table 3.38 and Table 3.39 illustrate data related to these findings.

Table 3.38: Mean scores (SD) for adherers and non-adherers on the physician and health care team support subscale of the Chronic Illness Resources Survey (CIRS)

	Adherent		Nonadherent	
	n	Mean (SD)	n	Mean (SD)
Total physician and health care team support scale score	134	19.19 (5.113)	101	19.14 (5.455)

Table 3.39: Results of the t-tests for equality of mean scores for adherers and non-adherers on the physician and health care team support subscale of the Chronic Illness Resources Survey (CIRS)

	t-test for Equality of Means						
	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
Total physician and health care team support scale score	-0.08	233	0.936	-0.055	0.693	-1.422	1.311

Independent samples t-tests for assessing differences between adherers and nonadherers in their responses to individual items of the physician and health care team support subscale showed no difference in responses between the two groups on their responses to any item.

3.4.12 Adherence to other parts of the diabetes self-care regimen

Adherence to other parts of the diabetes self-care behaviors (diet, exercise, SBGM, foot care, and smoking cessation advice) was assessed by direct-self report.

3.4.12.1 Descriptive results

Data was available for all 250 participants (100 %). According to participants self-report, the highest adherence rate of participants was for smoking cessation advice (84.8%) and foot care (81.6%), respectively. Medication adherence came third, with over half participants reporting it (57.3%). The least adherence rate was for exercise (32%) and diet (33.6%). About a third of participants managed to engage in exercise or diet for their diabetes. Just above half of participants (51.2%) were monitoring their blood glucose levels

on their own at home. These data are illustrated in Table 3.40, and Figure 3.21. Although some participants were engaged in diabetes self-care behaviors, their persistence was not perfect; this is illustrated in Figure 3.22.

Table 3.40: Number (and %) of adherers and nonadherers to individual aspects of the diabetes self-care behaviors

	Diet (n=250)	Exercise (n=250)	SBGM (n=250)	Foot care (n=250)	Smoking cessation (n=250)
Adherers n (%)	84 (33.6%)	80 (32.0%)	128 (51.2%)	204 (81.6%)	212 (84.8%)
Nonadherers n (%)	166 (66.4%)	170 (68.0%)	122 (48.8%)	46 (18.4%)	38 (15.2%)

Figure 3.21: Percentages of participants who were adherent to their medications compared to those adherent to other diabetes self-care behaviors

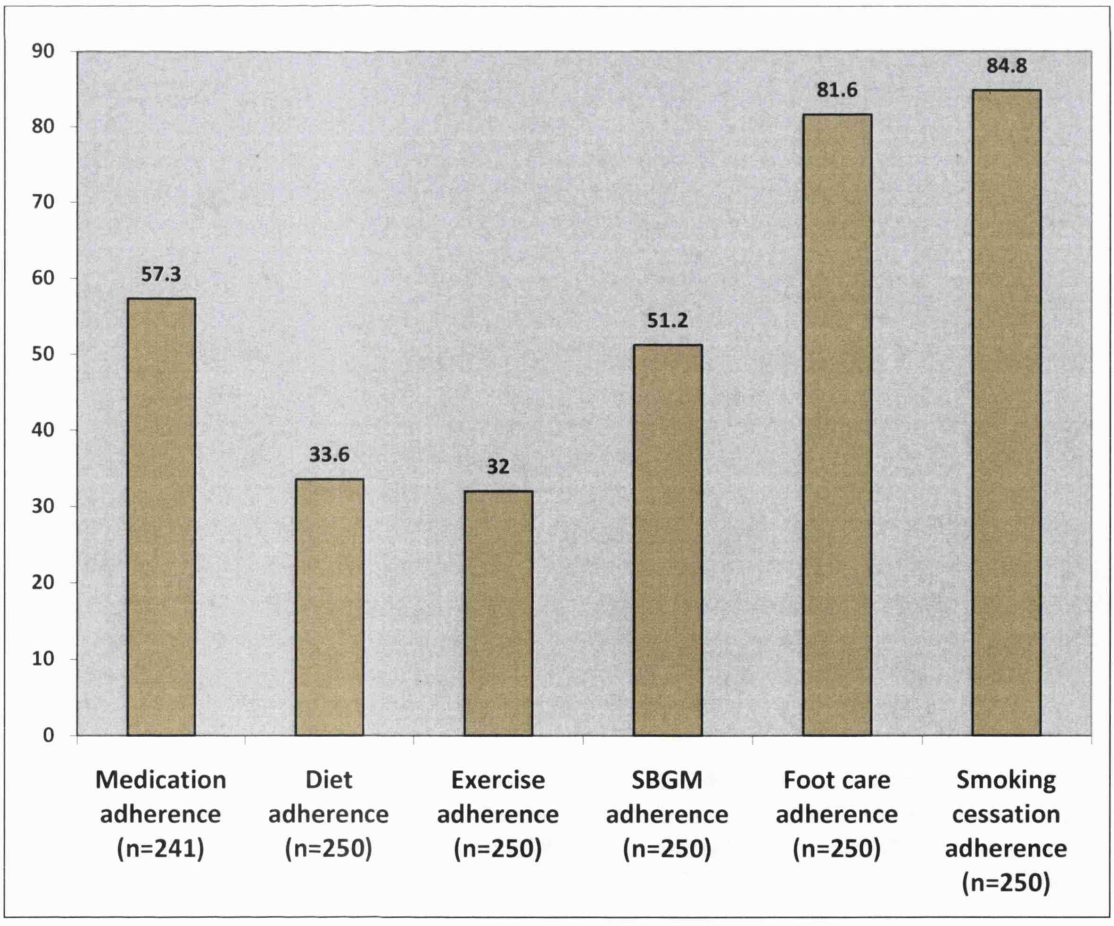


Figure 3.22: Percentage of participants' persistence to other parts of the diabetes self-care regimen over the last three months

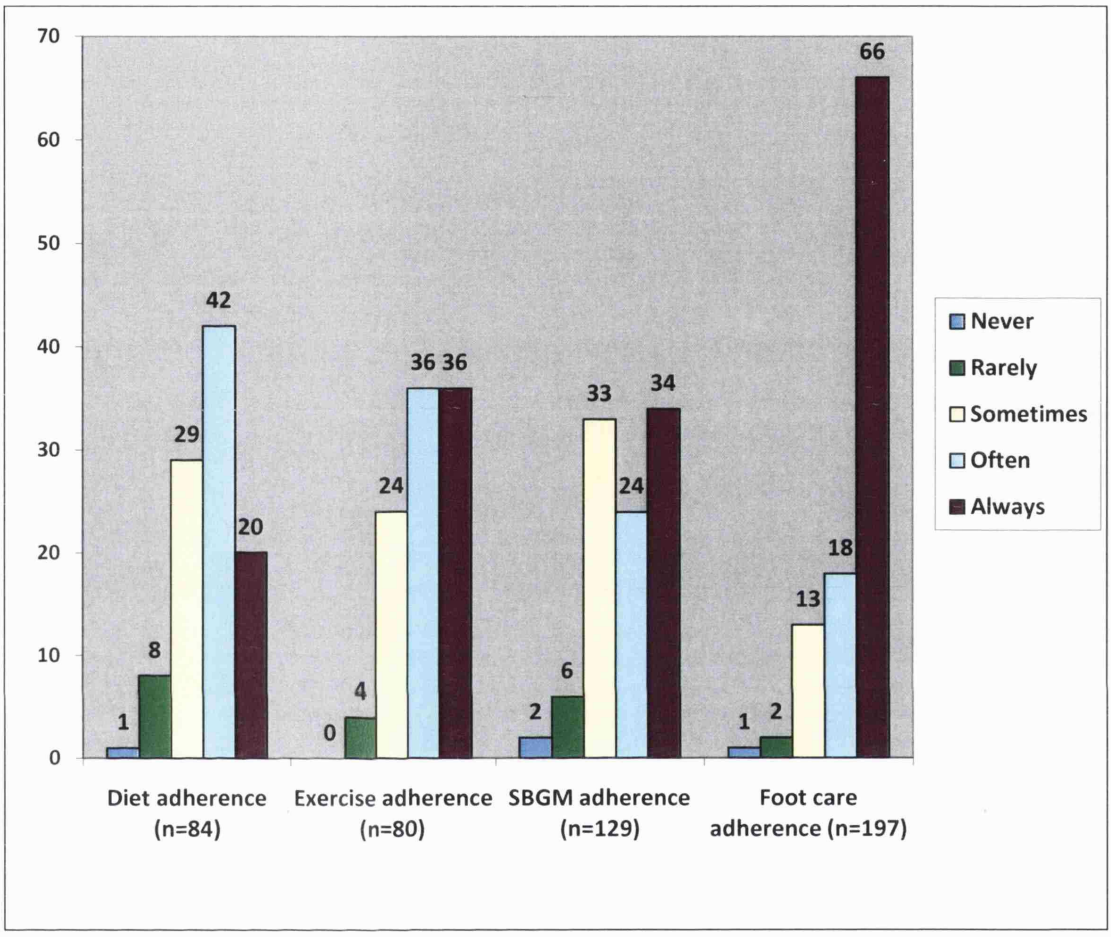


Figure 3.22 illustrates that:

- About two thirds of participants who checked their feet responded that they "always" did so over the last three months (66%).
- Over a third of those who exercised (36%) or monitored their blood glucose levels (34%) responded that they "always" did so over the last three months.
- Only one in five participants (20%) who followed dietary advice responded that they "always" did so over the last three months.
- Of those who performed the diabetes self-care behaviors, between 18-42% responded that they "often" checked their feet, self-monitored their blood glucose levels, exercised, or followed dietary advice over the last three months, depending

on the specific behavior. In contrast, between 13-33% of participants responded that they "sometimes" did.

- Very few of those who performed diabetes self-care behaviors (0-8%) reported that they "rarely" or "never" performed these behaviors over the last three months.

Therefore, participants' persistence to diabetes self -care behaviours was suboptimal and needs improvement. As for the reasons for nonadherence with diabetes self-care activities, Tables 3.41-3.44 list the reported range of barriers which prevented participants from performing each specific diabetes self-care behavior.

Table 3.41: Participants reported reasons for diet nonadherence (and %)

Reasons for diet nonadherence (n=166)	%
Loving to eat/ food cravings	44.4
Lack of motivation	41.2
Not confident in ability to do it	37.9
Difficulty finding healthy food choices	37.9
Lack of awareness	23.5
Social gatherings	13.7
Lack of family support	13.7
Fear of hypoglycaemias	2.0
Lack of time to think about it/do it	2.0

Table 3.42: Participants reported reasons for exercise nonadherence (and %)

Reasons for exercise nonadherence (n=170)	%
Not confident in ability to do it	48.2
Comorbidity	45.0
Lack of time	27.8
Laziness	14.2
House work is enough as exercise	12.9
Unsuitable weather	10.1
Lack of motivation	1.8
Lack of awareness	1.2
No suitable place to exercise	0.6

Table 3.43: Participants reported reasons for SBGM nonadherence (and %)

Reasons for SBGM nonadherence (n=122)	%
Don't have a monitor	43.1
Lack of awareness	29.5
Prefer clinic testing	20.2
Lack of motivation	19.8
Don't know how to do it	19.4
Only do it when needed	14.0
Causes me stress	10.9
Lack of time	5.4
Concerns about accuracy	4.7
Afraid of needles	2.3
Only prior to appointments	2.3
Fear of dependence	0.8

Table 3.44: Participants reported reasons for foot care nonadherence (and %)

Reasons for foot care nonadherence (n=46)	%
Lack of awareness	75.0
Carelessness	18.8
Lack of time	6.3
Stress	3.1

3.4.13 Adherence to other parts of the diabetes self-care regimen and medication adherence

A Fisher's Exact test was used for assessing associations between medication adherence and adherence to other parts of the diabetes self-care regimen. Adherence to diet, exercise, SBGM, and foot care were not associated with medication adherence. Adherence to smoking cessation advice was associated with adherence to medications. Those who adhered to smoking cessation advice were more adherent to their diabetes medications than those do not adhere (Fisher's Exact p value= 0.001). Data related to these findings are illustrated in Table 3.45.

Table 3.45: Results of Fisher's Exact Test for associations between adherence to different aspects of the diabetes self-care regimen and medication adherence

Adherers to diabetes self-care regimen	Total n	n (%) adherent to medications	n (%) nonadherent to medications	Fisher's Exact p value
Diet adherers	82	50 (61%)	32 (39%)	0.414
Exercise adherers	79	45 (57%)	34 (43%)	1.000
SBGM adherers	123	73 (59%)	50 (41%)	0.518
Foot care adherers	197	113 (57%)	84 (43%)	1.000
Smoking cessation adherers	204	126 (62%)	78 (38%)	0.001

3.4.14 Adherence to appointments

Participants' adherence to their appointments was assessed by direct self-report. For those who had their appointment booklet available with them, their self-reported adherence was validated against dates of attendance to their last 6 appointments as recorded in the booklet. Table 3.46 illustrates adherers and nonadherers to appointments among study participants.

Table 3.46: Numbers (and %) of adherers and nonadherers to appointments using direct self-report

Adherence to appointments (n=240)	Adherers n (%)	Nonadherers n (%)
	186 (77.5%)	54 (22.5%)

3.4.15 Adherence to appointments and medication adherence

A Fisher's Exact test was used for assessing associations between diabetes medication adherence and adherence to clinic appointments. There was no statistically significant association between adherence to appointments and adherence to diabetes medications, although there was a trend to significance. Those who adhered to their appointments tended to be more adherent to their diabetes medications than those did not adhere to their appointments (Fisher's Exact p value= 0.053). Table 3.47 shows data related to this finding.

Table 3.47: Results of Fisher's Exact Test for associations between adherence to appointments and medication adherence

	n (%) adherent to medications	n (%) nonadherent to medications	Fisher's Exact p value
Adherers to appointments (n=181)	109 (60.2%)	72 (39.8%)	0.053

3.4.16 Predictors of adherence to diabetes medication

Multivariate analysis (logistic regression) was used. A hierarchal method of entry was used whereby statistically significant demographic variables (age, place of care) were entered first, clinical variables (presence of comorbidity, presence of complications, duration since taking diabetes medications) were entered next and belief scores (BMQ total harm scores, BMG total benefit scores) were entered last. Using those variables where univariately p<=0.1, adherence was found to be significantly and independently associated with age (p=0.025) and presence of complications (p=0.011). Older participants, and those who had not developed the diabetes complications were more likely to be adherent to their medications. Conversely, younger age and presence of diabetes complications were predictive of nonadherence to medication:

- The odds of being nonadherent are increased by 1.038 for every one year decrease in age (CI=1.005 to 1.073).
- The odds of being nonadherent are increased by 2.48 if diabetes complications were present (CI=1.229 to 5.008).

Differences in place of care, presence of comorbidity, duration since taking diabetes medications, beliefs of harm or benefits of medications were not predictive of adherence to diabetes medications. Data related to these findings are illustrated in Table 3.48.

Table 3.48: Results of logistic regression for assessing predictors of medication adherence

Variables entered		B	S.E.	Wald	df	Sig.	Exp (B)	95.0% C.I. for EXP(B)	
								Lower	Upper
Demographic variables	Age	.038	.017	5.015	1	.025	1.038	1.005	1.073
	Place of care *Reference category: Hospital			1.970	2	.373			
	General polyclinic*	-.785	.579	1.839	1	.175	.456	.147	1.419
	Specialised polyclinic*	-.347	.370	.881	1	.348	.707	.343	1.459
Clinical Variables	Presence of comorbidity	-.020	.395	.003	1	.960	.980	.452	2.126
	Presence of complications	.909	.358	6.428	1	.011	2.481	1.229	5.008
	Duration since taking diabetes medications	.002	.002	1.254	1	.263	1.002	.998	1.006
Beliefs about medicines (BMQ scores)	BMQ total harm scores	-.073	.064	1.302	1	.254	.930	.821	1.053
	BMG total benefit scores	.144	.087	2.737	1	.098	1.154	.974	1.368
	Constant	-4.191	2.112	3.937	1	.047	.015		

3.4.17 Issues raised in qualitative interviews

The frequency of responses to issues raised in the qualitative interviews was assessed to check whether they were relevant to the sample participants. Data was available for 242/250 to 249/250 of participants (97-100%), depending on responses to specific statements. Figure 3.23 illustrates percentages of participants' responses to issues raised in qualitative interviews.

Figure 3.23: Percentages of participants' responses to issues raised in qualitative interviews

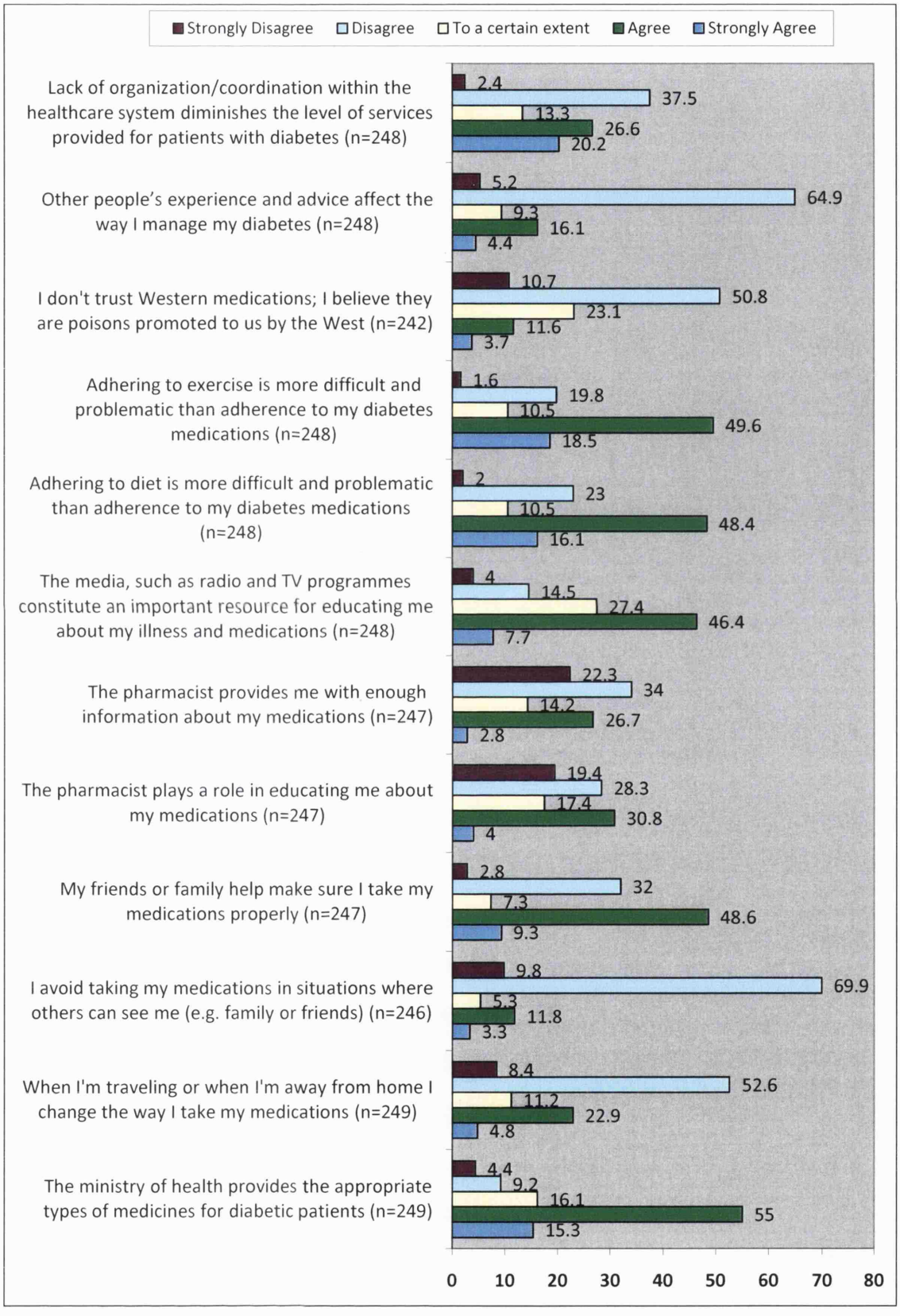


Figure 3.23 illustrates the following findings:

- Over two thirds of participants (70.3%) either agreed (55%) or strongly agreed (15.3%) that the Ministry of Health provided them with appropriate types of medications. However, about 13.6% of participants either disagreed (9.2%) or strongly disagreed (4.4%) with this statement, and thus were not happy with the types of medications provided. About 16.1% of participants did not feel strongly about this statement, and rated it "to a certain extent". In other words, nearly one in three participants (29.7%) were not happy about the types of medications provided by the Ministry of Health, at least to a certain extent.
- The lack of trust in Western brands of medications was tested with the item "I don't trust Western medications; I believe they are poisons promoted to us by the west". Interestingly, the majority of participants either disagreed (50.8%) or strongly disagreed (10.7%) with this statement. However, there was a significant proportion of participants (38.4%) who agreed (11.6%) or strongly agreed (3.7%) with it, or responded with "to a certain extent" (23.1%).
- Although over half of all participants did not agree that they would change their medication-taking behaviour in travel or when they were away from home (52.6% disagreed and 8.4% strongly disagreed), this was an issue for a significant proportion of participants (38.9%) who admitted that travelling or being away from home made them change the way they take their medications, at least to a certain extent.
- About 79.5% of all participants either disagreed (69.9%), or strongly disagreed (9.8%) with the statement "I avoid taking my medications in situations where others can see me (e.g. family, friends)". However, being witnessed by others while taking medications was an issue for 20.4% of participants, who responded with "strongly agree", "agree", or "to a certain extent".
- About two thirds of participants (65.2%) responded with "strongly agree", "agree" or "to a certain extent" that their family or friends helped them take their medication properly.
- As for the role of pharmacists in patient education, about a third of participants either agreed (30.8%) or strongly agreed (4%) that pharmacists played a role in

educating them about their medications. However, nearly half of participants (47.7%) either disagreed (28.3%) or strongly disagreed (19.4%) that pharmacists played a role in their education.

- As for the amount of information provided by pharmacists, about a third of participants either agreed (26.7%) or strongly agreed (2.8%) that medication information provided by pharmacists was sufficient. However, over half participants (56.3%) either disagreed (34%) or strongly disagreed (22.3%) that information provided to them by pharmacists was sufficient.
- As for sources of information about diabetes and medications, more than half of all participants either agreed (46.4%) or strongly agreed (7.7%) that the media constitutes an important resource for educating them about their illness or medications. However, about 18.5% did not appreciate the role of the media, responding with either disagree (14.5%) or strongly disagree (4%). About 27.4% responded that the media helped them "to a certain extent" in this regard.
- Learning from other peoples' experience with the disease and whether this affects the way participants manage their diabetes was assessed with the statement "Other people's experience and advice affect the way I manage my diabetes". Interestingly, most participants disagreed (64.9%) or strongly disagreed (5.2%) with this statement. However, a significant proportion (29.8%) strongly agreed (4.4%), agreed (16.1%), or agreed "to a certain extent" (9.3%) with it.
- As for adherence to medications compared to adherence to diet or exercise, about two thirds of participants (64.5%) either agreed (48.4%) or strongly agreed (16.1%) that adherence to diet is more difficult and problematic than adherence to medications.
- More than two thirds of participants (68.1%) wither agreed (49.6%) or strongly agreed (18.5%) that adherence to exercise is more difficult and problematic than adherence to medications.
- With regards to the statement "Lack of organization/coordination within the healthcare system diminishes the level of services provided for patients with diabetes" nearly two thirds of participants (60.1%) strongly agreed (20.2%), agreed (26.6%), or agreed to a certain extent (13.3%) with this statement.

3.5 DISCUSSION

This chapter assessed adherence to medications among Kuwaiti patients with T2DM and tested whether demographic, clinical variables or issues emerging from the qualitative interviews were associated or predictive of adherence to medications among this population. In qualitative interviews, participants' beliefs about medicines, and perceptions of support received from healthcare providers (especially doctors) were common and appeared to play a role in participants' adherence to their diabetes medications, although this could not be confirmed due to the limitations of qualitative research. In this chapter, these beliefs and perceptions were assessed and their association to medication adherence was tested. This chapter also looked at adherence to appointments and adherence to other parts of the diabetes self-care regimen including exercise, diet, SBGM, foot care and smoking cessation advice among the sample. It was possible to assess these and to test their association with adherence to medications. Moreover, reasons for nonadherence to medications and to other diabetes self-care activities were assessed and described in this chapter. Further, a number of issues and interesting themes which emerged from the qualitative interviews were tested for relevance to the sample population in this chapter. This section will discuss separately: (1) Key findings, (2) Methodological limitations, (3) Summary of findings.

3.5.1 Key findings

This study is the first to estimate the prevalence of nonadherence to diabetes medications among Kuwaitis with T2DM. In this study and based on simple direct self-report, approximately 43% of patients with T2DM were nonadherent to their diabetes medications. This is an alarming figure, given the definite benefits of diabetes medications as shown in major clinical trials and the negative personal and societal outcomes that could result from not taking these medications appropriately (Stratton et al., 2000; UK Prospective Diabetes Study (UKPDS) Group, 1998a).

Among nonadherers, unintentional nonadherence was more common than intentional nonadherence (52% vs. 33%), although many participants had combined intentional and unintentional nonadherence to their diabetes medications (12%). Unintentional nonadherence usually resulted from forgetting, although running out of medications and being away from home were frequently reported reasons for unintentional

nonadherence. Intentional nonadherence resulted mainly from a lack of awareness (e.g. skipping or taking less medication to avoid adverse effects, taking drug holidays to relieve body and avoid dependence, switching from insulin to tablets for convenience while travelling or being away from home). When the figures for those who had intentional nonadherence and those who had both types of nonadherence are collapsed into one category, it can be seen that about 45% of nonadherers in this study are intentional nonadherers. This is an alarming figure, as the consequences of intentional nonadherence have the potential to be more serious because intentional nonadherers may stop or alter their use of medications continuously, which can adversely impact patients' health and result in more waste of medicines. Using simple direct self-report, it was possible to identify a list of possible barriers for medication adherence among the sample of this study. These barriers must be addressed by healthcare providers to achieve better adherence to medications.

Preliminary analyses (using independent t-tests, Fisher's Exact test, Mann-Whitney U test, where appropriate) of the role of demographics, clinical variables, perceptions of healthcare provider support, beliefs about diabetes medicines and beliefs about medicines in general revealed that some significant associations were present. Of the demographic variables, older age was associated with greater adherence to diabetes medications. However, the mean difference in age between adherers and nonadherers was small (56.12 vs. 52.07, respectively) and may not be clinically significant. The literature of the role of demographic variables in predicting adherence is mixed and inconsistent, however, association of nonadherence with younger age has been reported (Bame et al., 1993; Yang et al., 2009; Nguyen et al., 2009). Place of care was also associated with adherence to medications, the more specialised the place of care was, the greater the adherence. Of the clinical variables, only presence of diabetes complications was associated with adherence/nonadherence to mediations. A higher proportion of nonadherers had diabetes complications compared to those who were adherent, suggesting that nonadherence was associated with poor diabetes outcomes in Kuwaiti T2DM patients.

Preliminary analysis showed that a greater belief in the benefits of medicines in general was associated with better adherence to diabetes medications among the study population. However, multivariate analysis provided evidence for the role of age, and

presence of diabetes complications in prediction of nonadherence to diabetes medications. Other demographic and clinical variables were not predictive of nonadherence. Moreover, participants' beliefs about diabetes medicines in particular or about medicines in general were not important in prediction of their nonadherence to diabetes medication, nor were their perceptions of support received from doctors or other healthcare providers. This is in contrast to other studies measuring medication perceptions where beliefs about medicines were found to be the strongest predictors of medication adherence (Horne et al., 2007; Horne and Weinman, 2002b; Butler et al., 2004b; Hunot et al., 2007). Similarly, perceptions of support and trust in healthcare providers has been associated with improved patients' adherence to medications and predicted adherence in other studies (Wroth and Pathman, 2006; Nguyen et al., 2009; Schneider et al., 2004). A possible explanation for the lack of association in this study might be related to the possibility that the influence of healthcare provider support on patients' adherence is mediated through other variables, such as knowledge or self-efficacy. These variables were not measured in the current study and therefore it would be interesting for future research to assess and confirm this. In one study assessing factors influencing diabetes self-management in Chinese patients with T2DM, it was found that patient-provider communication affected self management indirectly via beliefs and self-efficacy (Xu et al., 2008).

In addition, the lack of association between adherence to medications and beliefs about medicines as measured by the BMQ, or perceptions of support received from healthcare providers as measured by the physician and health care team support subscale of the Chronic Illness Resources Survey (CIRS) suggests that these scales may have been unsuitable measures of perceptions and in explaining adherence in the current study. Rennie (2007) faced a similar problem when adapting a scale that measured illness perceptions for use among a sample of Turkish, Urdu or Bengali speaking TB patients in North East London and concluded that the scale was an unsuitable measure for assessment of perceptions in explaining adherence as measured in his study (Rennie, 2007). He suggested three possible solutions for the purposes of future research, which may be used and employed in this study. Firstly, it may be necessary to further refine the scales and validate them fully in a culturally similar population before their use in a culturally different context. Secondly, new scales could be developed from grounded qualitative research within a Kuwaiti diabetes sample exploring issues most relevant to a Kuwaiti

diabetes population. This method would be advantageous in that it would eliminate the need for future translation. Alternatively, different measures may be used and tested for performance on this particular sample, for example social support received from family/friends or knowledge about disease. However, results from the qualitative study implied that beliefs about medications were more important predictors of nonadherence than social support or knowledge about diabetes.

Despite the lack of association between beliefs about medicines and adherence mediations in this study, participants held a number of beliefs that were important and needed to be addressed by healthcare providers to ensure that patients fully understand their medications to ensure appropriate medication use.

In this study, it was found that there was no difference between adherers, unintentional nonadherers and intentional nonadherers in their beliefs about medicines as measured by any of the BMQ subscales. This is in contrast to what was found by Clifford et al. (2008) who reported that intentional nonadherers held beliefs different than those of adherers and unintentional adherers. In their study, they found that intentional nonadherers, compared to adherers, had significantly lower beliefs in necessity of their medications and significantly higher beliefs in concerns about their medications as measured by the BMQ necessity and BM concerns subscales, respectively. In addition, they found that intentional nonadherers were significantly more likely to rate their concerns as high relative to their need for treatment (as indicated by lower necessity concerns differential scores) compared to both adherers and unintentional nonadherers. Finally, they found that there was no difference between adherers and unintentional nonadherers in terms of their beliefs about the necessity of their medications, concerns about taking them, and the balance of these beliefs as indicated by their BMQ necessity, BMQ concerns, and necessity-concerns differential scores, respectively (Clifford et al., 2008). The difference between these finding and the lack of association between types of beliefs and adherence in this study may be due to the fact that beliefs about medicines were not important predictors of adherence to medications among this particular sample. This may explain why the types of beliefs were also not important in distinguishing between adherers and nonadherers. This links back to the question as to whether the BMQ was appropriate for use in this particular sample.

Although perceptions of support received from healthcare providers were not predictive of adherence/nonadherence to medications in this study, the study provided evidence that support received from healthcare providers was suboptimal. While the majority of participants perceived a great or good level of support from their doctors with regards to careful listening, answering questions/addressing any concerns, explaining results of tests, and explaining to them what to do to manage diabetes, many others were less satisfied and thus required more support with regards to these areas. Dissatisfaction with aspects of the patient-provider relationship should be a cause of concern as it has been linked to primary nonadherence. In one study involving 3926 patients in rural areas of the United States, it was found that those who were not confident in their doctor's ability to help them with their medical problems, those who were not satisfied with the concern shown by the their doctors, and those who were not satisfied with how welcome and comfortable they were made to feel by the office staff were more likely to report not filling their prescriptions (OR=1.4, 95% CI 1.04-1.79; OR=1.8, 95% CI 1.03-3.03; OR=1.6, 95% CI 1.00-2.38, respectively) (Wroth and Pathman, 2006).

In this study the majority of participants reported that support between visits (e.g., phone calls, reminders or newsletters) was never provided which suggests a gap in care once the patient has left the clinic or hospital. Most notably, over half of participants reported that their doctors never involved them as equal partners in making decisions about their illness management strategies or goals. This suggests that, concordance models of patient-provider communication which are widely celebrated in Western countries may not be applied in Kuwait. This is a cause of concern as it has been shown that physician-patient concordance was associated with greater adherence to medications (Kerse et al., 2004).

Adherence to other diabetes self-care activities was suboptimal; nearly two thirds of participants did not adhere to diet or exercise. Food cravings and lack of motivation to go on a diet, especially within social gatherings where plenty of food is offered as part of the Kuwaiti culture were the two most commonly reported reasons for diet nonadherence. Lack of confidence in ability to exercise, comorbidity, and extreme weather conditions of Kuwait, being too hot in the summer and too cold in winter to allow any outdoor exercise, were among the most commonly reported reasons for exercise nonadherence. Nearly half of the participants did not self-monitor their blood glucose levels, with the main reason

being not having a monitor at home. Although most participants adhered to foot care and smoking cessation advice, about one in five participants were nonadherent, with the main reason being lack of awareness. This suggests that participants may not have received education about the importance of such self-care behaviours in the management of diabetes by their healthcare providers. It might also have been that participants found it more difficult to adhere to these more demanding behavioural changes. The literature highlighted that adherence is much lower for lifestyle prescriptions and other more behaviourally demanding regimens (Haynes et al., 2002).

It is worth noting that adherence to diabetes self-care activities was not associated with adherence to medications among this sample, with the exception of adherence to smoking cessation advice. Those who did not smoke were also more adherent to their diabetes medications. Adherence with diabetes appointments was also not optimal among the sample, with about one in five participants being nonadherent to their appointments. Like other diabetes self-care behaviours, adherence with appointments was not associated with adherence to medications. This may suggest that the different types of adherence measured are unrelated, which is consistent with other studies in the literature reporting lack of association between different types of adherence (Ogedegbe et al., 2007).

Probably the most interesting findings in this study were relating to the statements which were formulated based on data from the qualitative study. Participants rated the level of their agreement or disagreement with these statements and therefore it was possible to draw conclusions on whether these themes were relevant or could be generalized to patients with T2DM in Kuwait.

Most notably, although over two thirds of participants agreed that types of medications provided to them by the Ministry were appropriate, about one in three participants were not happy about the types of medications provided, at least to a certain extent. This is consistent with data from the qualitative interviews, where many participants described a greater belief and appreciation for Western brands of medications perceiving they were of better efficacy and less degree of adverse effects.

Interestingly, however, the questionnaire study showed that over a third of participants, at least to a certain extent, did not trust Western brands of medications and

believed they were poisons promoted to them by the West. This finding is novel and has never been reported in the literature.

Nearly two thirds of participants, at least to a certain extent, were not happy about the organization and coordination between different parts of the healthcare system which limited the level of services provided to diabetic patients in Kuwait. The healthcare system was largely criticized by participants in the qualitative interviews and findings from the questionnaire confirmed this finding.

In terms of assistance in medication taking, about two thirds of participants agreed, at least to a certain extent, that family and friends helped to make sure they took their medications properly. This was also described by participants in the qualitative study where participants often cited and acknowledged the role of family members in helping them with their medications.

One in five participants agreed that they avoided taking their medications, at least to a certain extent, in situations where they could be overseen by others. This highlighted and confirmed the perceptions of social stigma associated with diabetes described by participants in the qualitative study.

As for the issue of travelling or being away from home, over a third of participants agreed, at least to a certain extent, that they changed the way they took their medications in travel or when being away from home. Interestingly, in the questionnaire study travelling or being away from home was one of the most frequently reported reasons for nonadherence and was reported by nearly one in three participants (29.6%) which almost corresponds to the proportion of participants who agreed with the statement relating to changing medication intake in travel. This finding is also consistent with data from the qualitative interviews where some participants reported difficulties with sticking to their medications in travel or when they were away from home. This led some to forget their medication in travel, while others deliberately decided to stop their medications in such situations and resumed their intake once they got back home where their normal routine was resumed.

Regarding sources of information about diabetes, the majority of participants (81.5%) appreciated the role of the media in their education, at least to a certain extent.

However, nearly one in five participants disagreed that the media played a role in terms of providing the diabetes education and awareness. In this regard, data from qualitative interviews suggested that some participants turned to family members or friends with diabetes as they constituted an important source for advice and information about diabetes and its medications. The questionnaire study provided further evidence to this, with nearly one in three participants admitting to being affected by other friends or family members with diabetes in the way they managed their illness.

One of the most disappointing findings was related to pharmacist education and counseling. Over half of all participants disagreed that pharmacists provided sufficient information about their medications. A similar proportion disagreed that pharmacists played a role in educating them about their medications. This supports and confirms data from qualitative interviews whereby patients mentioned little or no pharmacist involvement in their care. A pharmacist was mainly perceived as a medication dispenser and many participants did not even recognize the role of pharmacists in providing medication counselling, assuming that it was the responsibility of doctors to do so. Pharmacists were often criticized for providing information about dosage regimen only and neglecting to mention other important information such as possible adverse effects, drug interactions, what to do if missed a dose, etc.

As for adherence to diet or exercise, about two thirds of participants agreed that adherence to diet or exercise is more difficult than adherence to medications, a finding which is also in line with data from qualitative interviews and also data from the questionnaire study. In the questionnaire study, it was found that nonadherence to diet and exercise was more prevalent than nonadherence to medications. Just above two thirds of the sample were nonadherent to diet and exercise, which corresponds to the same proportion of participants admitting difficulty in performing these more demanding diabetes self-care behaviors.

3.5.2 Methodological issues

3.5.2.1 Recruitment

Patients were recruited opportunistically as they attended their diabetes outpatient appointments. The sample of individuals who accessed clinics, polyclinics and hospitals

and agreed to participate in this study may not be representative of all patients with T2DM in Kuwait. Those who access medical care may be more concerned about their health than those who do not, and thus are likely to be more adherent to their medications. If this is the case, then the 43% prevalence of nonadherence to diabetes medications found in this study is likely an underestimate, which is a cause for greater concern. An alternative recruitment method may have been to identify those who had stopped or skipped their diabetes appointments frequently from hospital/clinic records and make efforts to include them in the sample. Time and resource limitations of the study prohibited the adoption of this method of recruitment. Moreover, results of this study cannot be generalized to other chronic diseases as the study was conducted mainly among Kuwaiti patients with T2DM.

3.5.2.2 Translation of measures used

Although efforts were made to make sure that instruments used in this study produced valid and reliable results, it was not possible to validate the translation or the translation process fully. This may explain the reason why these tools were not helpful in explaining/predicating adherence to medications as measured in this study. Nevertheless, moderate to high internal consistency and test-retest reliability of the translated scales allowed for their use. In addition, efforts made to ensure cultural adaptation of the tools provided confidence for their use in this research.

3.5.2.3 Administration of the questionnaire tool

Most participants preferred to be administered the questionnaire by the researcher (due to illiteracy, poor eyesight, or simply for convenience). Since more than one researcher was involved in data collection, there was a risk of inter-researcher variation in the administration of questionnaire. However, attention was given to this issue and all researchers received training about how to administer the questionnaire to participants in the exact same way. The importance of a non-judgmental tone of the researchers was emphasised, as was the importance of not influencing participants' responses in any way. In addition to training of researchers, data gathered by different researchers were examined for trends of variability of responses with different researchers. The assessment showed there was no variability in responses and all researchers gathered similar data.

3.5.2.4 Assessment of adherence/nonadherence

Adherence to medications was mainly assessed using self-report, a method which runs the risk of recall bias and obtaining socially desirable responses. However, careful attention was given to avoid this problem as the questions were phrased in a non judgmental manner. The nonadherence prevalence of 43% found in this study indicated that patients may not have found it difficult admitting to nonadherence to their diabetes medications.

Where possible, HbA1c levels were obtained and assessed for concordance with data from direct self-report. It was not possible to obtain HbA1c levels for 201 (80.4%) of the sample either because HbA1c measurements were missing in medical records, outdated, or medical records were inaccessible at the time of data collection. Nevertheless, where available, HbA1c data were examined carefully as they can be problematic because it is impossible to separate the impact of changes in diet, exercise, stress, or other illness on participants' HbA1c levels.

Adherence to other self-care behaviours were also assessed by direct-self report, therefore, a risk of socially desirable responses could not be excluded. Nevertheless, the questions were phrased in a non-judgemental manner to minimise biased responses, and the large number of participants who admitted nonadherence to these behaviours may indicate that socially-desirable responding was minimal or nonexistent.

3.5.2.5 Missing/unconfirmed data

Unfortunately, medical records were not accessible for all participants of this study at the time of data collection, due to ethical or site-specific limitations. Therefore, most data gathered depended mainly on participants self-report, and could not be confirmed. For example, where records were inaccessible, the diagnosis of T2DM could not be confirmed. In this case, a judgement by the researcher had to be made based on prescribed medications, age of diagnosis, and apparent body weight of participants. Using these variables, the researcher was able to decide whether the participant had type 2 or type 1 diabetes mellitus. Similarly, nationality of participants was sometimes a product of the researcher's judgment based on participants appearance, accent and medications prescribed (in Kuwait, some medications are only prescribed for Kuwaiti nationals, while other nationalities had alternative generic medications).

3.5.2.6 Design of the study

The cross-sectional design of this study means that it is only possible to conclude that nonadherence to medications were 43% at this particular point of time, and it was not possible to conclude whether adherence would change over time. Similarly, beliefs about medicines and perceptions of healthcare provider support were only assessed at this point of time and it would be interesting to find out whether these would change over time and whether this would be associated with a change in participants' adherence to medications. A longitudinal study design, with repeated assessments would allow assessment of the consistency of adherence/nonadherence, beliefs about medicines, and perceptions about healthcare providers over time. In this study, nonadherence was associated with presence of diabetes complications. The direction of causality could not be confirmed from the current study, and can only be ascertained with a longitudinal study design.

3.5.3 Summary

Nonadherence to medications and other diabetes self-care behaviours is a significant problem with a striking magnitude among Kuwaiti patients with T2DM. Furthermore, nonadherence to medications was associated with poor health outcomes, as reflected by a higher proportion of nonadherent patients with diabetes complications compared to those who were adherent. Although patients' beliefs about medicines and perceptions of healthcare provider support were not predictive of medication adherence in this particular population, findings revealed that these were problematic and need to be addressed by healthcare providers to improve diabetes care and outcomes of Kuwaiti patients with T2DM. In addition, findings from this study provided further support for themes raised in qualitative interviews, particularly in relation to beliefs about medicines, lack of education and counseling by pharmacists, perceptions of social stigma, intentionally altering medication use in travel, the influence of lay sources of information on medication adherence/nonadherence, and the role of social support in facilitating adherence to medications.

CHAPTER 4

GENERAL DISCUSSION AND IMPLICATIONS

Research presented in thesis is the first to explore nonadherence to medications and other diabetes self-care behaviours among Kuwaiti patients with T2DM. Only three other studies have addressed the problem of nonadherence to medications in Kuwait (Al-Saffar et al., 2005; Al-Saffar et al., 2003; Fido and Husseini, 1998), however all focused on psychiatric patients. Up to date, there have been no studies which included the patients' perspective. It is argued that diabetes improvement initiatives which neglect the patient perspective may be destined for limited success (Padgett et al., 1988; Ball, 1991; Lorenz et al., 1996). Furthermore, the methods employed in this research allowed access to participants' views without using translators during interviews (as well as questionnaire), thereby enhancing the quality of the data.

Furthermore, the extent of nonadherence to medications and other diabetes self-care behaviours in this particular population has never been estimated before. This research provided important data in this regard which would serve as the basis and frame of reference for future intervention studies aiming to improve adherence to medications among this particular population. This chapter will discuss how this thesis have contributed to the knowledge and understanding of nonadherence to medications among Kuwaiti T2DM patients, highlighting the main findings, limitations, implications for practice and policy, recommendations for future research, and ending with conclusions.

4.1 Main findings

This research suggests that about 43% of Kuwaitis with type 2 diabetes mellitus (T2DM) are nonadherent to medications. Almost half (45%) of nonadherent Kuwaiti T2DM patients make a cognitive decision not to take their medications as prescribed (intentional nonadherence). Most of the time this is related to context (e.g., travel, social situations) but about a third (32%) reduce their doses as a result of fear of adverse effects. Further, about half (52%) of nonadherent Kuwaiti T2DM patients inadvertently don't take the medications as prescribed (unintentional nonadherence). In these cases, forgetting was

cited as the most common reason for this (42%) , but travel or being away from home was also commonly cited (30%). Moreover, a significant proportion of Kuwaiti T2DM patients run out of medications (13%), or get distracted from taking their medications (8%) which also inadvertently prevents them from taking their medications as prescribed. Despite an overlap between intentional and unintentional nonadherence, data obtained from both the qualitative and quantitative analyses suggests that there are significant challenges to appropriate medicines use in Kuwaiti T2DM patients with the potential for therapeutic, financial and social implications.

In general, there was no consistent pattern or relationship between demography, clinical variables and medication nonadherence among Kuwaiti T2DM patients, excepting younger age and presence of diabetes complications. This suggests that nonadherence to medications among this particular population was associated with poor health outcomes; however the role of age in predicting nonadherence may not be clinically significant as the mean difference in age between adherers and nonadherers was small. Nevertheless, the variety of reasons offered for both intentional and unintentional nonadherence (e.g. personality traits, resource constraints, lack of knowledge, beliefs about medicines, etc.) suggests that multiple, tailored interventions may need to be tested.

In qualitative interviews participants spoke of many inaccurate beliefs about medicines that might have influenced their adherence to medications. As reported in Chapter 2, Section 2.4.4.1.2.2, on many occasions, the influence of these beliefs was direct and explicit as participants admitted to altering their use of medications a result of these beliefs, which led to the necessity of assessing beliefs about medicines, and testing the impact on medication adherence in the quantitative part of the research. Similarly, participants' perceptions of their doctors' support were evident and consumed a significant part of most interviews, which necessitated assessing these perceptions, and their influence on medication adherence in the quantitative part of the research.

Therefore, based on findings from the qualitative study, it was expected that participants' beliefs about medicines, and perceptions of healthcare providers support would influence their adherence to medications. For example, having strong beliefs in the necessity of taking diabetes medicines, or low beliefs of concerns regarding taking these would be associated with an increase in adherence to medications. Similarly, having strong

beliefs in benefits of medicines in general, low beliefs about harm that can result from taking medicines, and low beliefs that medicines are overused by doctors, would be associated with an increase in participants adherence to medications. In terms of perceptions of doctors' support, it was expected that participants who had strong perceptions of support provided by their doctors would be more adherent to their medications, and vice versa.

Nevertheless, when testing these assumptions on a larger scale, data from the quantitative survey revealed that participants' beliefs about medicines, and perceptions of support provided by doctors, were not predictive of their adherence to their medications. This was unexpected and in contrast to the literature, where beliefs about medicines were found to be the strongest predictors of medication adherence (Butler et al., 2004b; Horne et al., 2007; Horne and Weinman, 2002b; Hunot et al., 2007), and perceptions of healthcare provider support were found to influence adherence to medications (Nguyen et al., 2009; Schneider et al., 2004; Wroth and Pathman, 2006). This may have been related to the use of instruments developed and validated for use among a Western, English speaking population to measure beliefs about medicines and perceptions of healthcare provider support in the target population.

Despite the lack of association between patients' beliefs about medicines, perceptions of doctor support, and adherence to mediations in this study, this research revealed interesting findings in this regard. For example, participants held a number of beliefs that were important and needed to be addressed by healthcare providers to ensure that patients fully understand their medications to ensure appropriate medication use (Section 4.1.1). Similarly, the study provided evidence that support received from healthcare providers was suboptimal and needs to be addressed to improve medication adherence among Kuwaiti patients with T2DM (Section 4.1.2). In addition, other important findings were also revealed in this research, in terms of participants' perceptions of the healthcare system, their attitudes towards diabetes, and perceptions of family support. These variables, and their potential impact on medication adherence, are discussed in more details with specific reference to the existing literature in Section 4.1.3 to Section 4.1.5. Findings related to adherence to other diabetes self-care behaviours are discussed in section 4.1.6.

In this research, psychological models which have been frequently used to assess adherence to medications were not tested. Although most of these models can help explain nonadherence, data from the qualitative interviews suggested that some of these models may be more relevant than others, and could be used to predict nonadherence to medications among the Kuwaiti T2DM patients for future research purposes. The Self-Regulatory Model of Illness (SRM) was particularly relevant, as participants in interviews often rationalized their nonadherence taking behaviour, applying common-sense in perceiving their illness (or treatment), illustrating and signifying the five components of the illness representation in Leventhal's SRM: identity, consequences, timeline, control/cure and cause. To illustrate this using the example of one participant who experienced severe diarrhea as a result of his Glucophage® tablets: the participant identified the problem as diarrhea (I used to get severe diarrhea), perceived it to be temporarily as a result of taking the tablets (I think the tablets were causing it), so he decided to stop taking his Glucophage® tablets (I stopped my Glucophage® tablet and now I only take the Daonil tablets®), then he evaluated whether his actions have controlled/cured his problem (stopping my Glucophage® tablets resolved the issue) and so he kept on doing this, resulting in nonadherence to medications. A central component of the SRM is the feedback loop, where people test specific actions (e.g. taking less of the medications to decrease dizziness for example), test the impact of the action (has it resolved the dizziness?), and changing their action if necessary. This was clearly evident in qualitative interviews.

In addition to the SRM, God's locus of control was also relevant among participants in qualitative interviews, as most participants mentioned God's will at some point during the interviews suggesting a high degree of fatalism among participants which sometimes led to reluctance to use medications altogether. Nevertheless, application of psychological models to predict adherence to medication among Kuwaiti T2DM patients must be made with caution, as the use of already available tools which are developed for use among an English-speaking population to assess these models may be problematic. Findings from this research suggest that full validation of instruments may be warranted before using them in a culturally different population.

4.1.1 Beliefs about medicines

One of the most interesting findings of this research was related to the set of beliefs about medicines held by some Kuwaiti T2DM patients. In the qualitative study, Western

brands of medications were perceived by some participants as superior to local alternatives, they were specifically perceived to have better effectiveness, better quality, and fewer adverse effects. This finding is not adequately described in the literature, although similar perceptions were cited by British Pakistani and British Indian T2DM patients about their oral hypoglycaemics compared to those which could be obtained from the Indian subcontinent (Lawton et al., 2005). In this research, although some preferred Western brands, others preferred local brands of medicines for their perceived freshness, or a general lack of trust in the Western world. Findings from the quantitative study provided further evidence for the relevance of these themes among the wider population of Kuwaiti T2DM patients. Over a third (38%) of Kuwaiti T2DM patients, at least to a certain extent, did not trust Western brands of medications and believed they were poisons promoted by the West.

In this regard, this research highlighted difficulties presented by the ethics committee for medical research which limited comprehensive assessment of Kuwaiti T2DM patients' opinions about local brands of medications supplied by the Ministry of Health. For the questionnaire item "Availability of certain brands of medication affects the way I take my medications"; the ethics committee prevented the use of the word "brands" and required it to be changed into "types", so the final item was reworded into "The ministry of health provides the appropriate types of medicines for diabetic patients". This may not have reflected the original idea this item was set out to test. Nevertheless, about a third (30%) of Kuwaiti T2DM patients, at least to a certain extent, were not happy about the types of medications provided by the Ministry of Health. This suggests that local brands of medications currently provided may not be appreciated by a significant proportion of Kuwaiti T2DM patients and that Western brands of mediations may be more preferred. Healthcare providers, particularly doctors and pharmacists, are in great position to identify patients' preferences regarding specific brands of medications. Taking into account patients' preferences by prescribing and dispensing the preferred brands of medications, where possible, may avoid the waste of expensive medications and ensure that patients would adhere to their prescribed medications. However, in real practice this may not always be possible. In this case, healthcare providers need to address patients' concerns and assure them about the bioequivalence of alternative brands.

Furthermore, this research revealed that about 13% of Kuwaiti T2DM patients do not believe that they would be very ill without their diabetes medicines, and about one in five Kuwaiti T2DM patients (22%) are uncertain whether their health in the future depends on their diabetes medicines. This suggests that a significant proportion of Kuwaiti T2DM patients do not believe in the necessity of their diabetes medicines. This research also revealed that nearly half (46%) of Kuwaiti T2DM patients are concerned about the long-term adverse effects of their diabetes medicines, and a similar proportion are worried about becoming too dependent on their diabetes medications (44%). This suggests a need for patient education and counseling about adverse effects of diabetes medicines (especially long-term adverse effects). Patients also need to be assured that diabetes medications do not cause dependency, but must be taken indefinitely to halt disease progression and prevent its complications.

4.1.2 Perceptions of healthcare provider support

Despite the key role played by doctors in providing T2DM patient care in Kuwait, data from this qualitative study suggests that healthcare providers such as doctors, pharmacists and dieticians failed to provide sufficient support to the Kuwaiti T2DM patients. This was attributed to a general lack of communication between doctors as well as pharmacists and their T2DM patients. Participants cited that the doctors' role was limited it to prescribing medications, whereas the pharmacists' role was limited to dispensing medications, often with unclear labeling instructions. This provoked confusion by the patients suggesting that even basic professional roles were not adequately performed, and that more support was needed from both doctors and pharmacists. Consequently, if patients are unsure how to take the medications, they might use them the wrong way or not take them altogether resulting in unintentional nonadherence to their medications.

In addition, results from qualitative data revealed that some healthcare providers were perceived to have unethical attitudes, such as favoritism and inequality of care provision. Participants reported that doctors, or pharmacists, treated people they knew better and provided them with better medications and better treatment. This finding has not been adequately described in the literature, and maybe deeply rooted in the culture of Kuwaiti people, which similar to many countries in the Middle East, is highly influenced by tribal customs. There is the feeling that a family or a tribe will always look after each

other. If you are from tribe X, and you meet someone else from tribe X, you are expected to help them.

Moreover, and in line with other qualitative studies of diabetes patients (Greenhalgh et al., 1998; Vermeire et al., 2003; Vinter-Repalust et al., 2004), Kuwaiti T2DM patients perceived their doctors' attitudes as paternalistic, and cited that medical consultations were brief and rushed, with little regard for the patient's perspective.

Furthermore, this research showed that Kuwaiti T2DM patients suffered a general lack of education and counselling by all healthcare providers (e.g. doctors, pharmacist, dieticians, etc.) resulting in deficient knowledge about diabetes and its treatment, which is in line with findings of other studies of diabetes patients (Adams, 2003; Hernandez et al., 1999; Vermeire et al., 2003). As a pharmacist, it was particularly disappointing to find that pharmacists did not appear to play a significant role in providing medication education and counselling for T2DM patients in Kuwait. Evidence from the quantitative study confirmed this finding, as over half of all respondents disagreed that pharmacists provided sufficient information about their medications (56%). A similar proportion disagreed that pharmacists played a role in educating them about their medications (48%). This may have been merely related to time constriction, as patients in qualitative interviews have cited and complained of long waiting times at the pharmacies. Another possible explanation could be related to the perceived higher authority of doctors in Kuwait, dominating and undermining all other healthcare professionals. This may have resulted in pharmacists' lack of confidence and their reluctance to provide information that would interfere with the doctors' advice. As a pharmacist with a 2-year practicing experience at an outpatient pharmacy of a large Kuwaiti hospital, challenging the doctor's decisions was not always welcomed by doctors. Some doctors perceived any interference by pharmacists as stepping into their responsibility and taking over of their role. Embracing a teamwork spirit between healthcare providers is much needed for the benefit of the patients. This research suggests that more pharmacist involvement may have a great potential for improving diabetes care in Kuwait.

Moreover, several important findings were revealed regarding Kuwaiti T2DM patients' perceptions of healthcare provider support, with over a half (51%) of Kuwaiti T2DM patients not being involved in making decisions about their diabetes management by their doctor, and about 24% are not being clearly told what they need to do to manage their

diabetes. A further 6% of patients complained that doctors never listened carefully to what they had to say about their diabetes, and another 8% reported that doctors never addressed their questions and concerns about diabetes or medications. These findings illustrate that doctors (and other healthcare providers) in Kuwait do not implement a patient-centred approach in delivering diabetes care which is unfortunate, as the evidence suggests that supporting patient participation in diabetes care can lead to better functional outcomes and more normal blood glucose levels (Greenfield et al., 1988).

In chronic diseases such as diabetes, patients are likely to need a considerable amount of support by healthcare providers beyond what can be provided at routine clinic appointments, however this research highlighted that the majority (92%) of Kuwaiti T2DM patients never receive any support between their appointments. Furthermore, in qualitative interviews, participants cited long time-gaps between appointments, and discontinuity of care, having to see different doctors at different appointments as problematic. These issues can be improved by assigning a regular doctor to patients, decreasing time-gaps between appointments and providing support to patients between appointments, such as routine telephone calls, district visits particularly to those from the older aged group and limited mobility.

4.1.3 Family support

In accordance with the literature (Lohri-Posey, 2006; Puavilai and Stuifbergen, 2000; Xu et al., 2008; Stone et al., 2005), qualitative interviews in this research highlighted that Kuwaiti T2DM patients' families were an important source of support for patients in terms of managing diabetes and taking medications. Findings from the quantitative study confirmed this finding as about two thirds of participants (65%) agreed, at least to a certain extent, that their family and friends helped to make sure they took their medications properly. This may be linked to the strong familial and social relations held within the Kuwaiti society and can therefore be utilized by healthcare providers through involving family members in the management of T2DM patients. Based on this research, including patients' families in discussions and decisions about diabetes treatment have the potential to promote adherence to medications in T2DM.

In addition, qualitative interviews revealed that Kuwaiti T2DM patients considered family members and friends with diabetes as sources for information and learning about diabetes and its treatment. Further support for this finding was provided by the quantitative

study; about one in three participants (30%) turned to other people with diabetes for information, admitting being affected by them in the way they managed their illness. This confirmed findings of other researchers reporting that diabetes patients often use and get influenced by lay sources of information about their disease (Adams, 2003; Greenhalgh et al., 1998; Stone et al., 2005). Therefore, healthcare providers in Kuwait need to explore patients' lay sources of information and whether knowledge obtained from these sources is accurate to promote proper use of medications.

4.1.4 Perceptions of the healthcare system

Kuwaiti T2DM patients reported in qualitative interviews of this research that there was a lack of organisation and coordination in diabetes services provided by different healthcare providers within the Ministry of Health. For example, the prescribing and dispensing of some diabetes medications being limited to hospitals were perceived as irrational and inconvenient. Furthermore, diabetes care was provided in places which were perceived to be inconveniently distanced from each other, and this was cited to present access difficulties especially in rural areas of the country. In addition, the availability of diabetes medications varied between different districts, with rural areas of the country being perceived as disadvantaged in this regard. This can be explained by the over-populated nature of rural areas of Kuwait, resulting in higher strain on clinics and hospitals in these regions of the country. The results of the quantitative survey confirmed that about two thirds of participants (60%), at least to a certain extent, were not happy about the organization and coordination between different parts of the healthcare system. There are three possible explanations for this finding. Firstly, while the Kuwaiti population continued growing at a rapid rate, the number of healthcare centers and hospitals remained constant since the 1980s which increased the load and pressure on healthcare facilities in Kuwait. Secondly, due to the shortage of diabetes specialists, the availability of certain diabetes care services and procedures was limited to certain centers, inflicting a sense of confusion and lack of coordination in the healthcare system among Kuwaiti T2DM patients. Thirdly, up to date, healthcare providers in Kuwait depend on manual medical records. Consequently, there is potential for misfiling and or loss of hard copies of records, potentially causing an enormous waste of time and a sense of lack of organization. Indeed, this has been reported by participants in qualitative interviews.

The evidence from the literature suggests that improving care and outcomes for patients with chronic disease depends on reshaping and organizing healthcare systems, so that patients would receive planned, regular interactions with healthcare providers, with prevention of disease exacerbation and complications being the focus of the interaction. Further, systematic assessments of patients, adhering to treatment guidelines, supporting the patient's role as a self-manager and continuous follow-up are all necessary components of an organized healthcare system that would improve the care for patients with chronic disease (Wagner et al., 1996; Wagner, 1998).

4.1.5 Attitudes towards illness

In the qualitative interviews, certain attitudes towards illness were salient among participants and appeared to have an impact on their adherence to medications. These attitudes influenced adherence either in positive or in a negative direction. Particularly, denial, down-playing severity of diabetes, fatalism /God-centered locus of control, social stigma, and perceptions of expertise with diabetes and body awareness appeared to hinder participants' adherence to their medications. Conversely, fear of diabetes, perceptions of self-efficacy, having a doctor-centered locus of control and perceptions of social support appeared to improve adherence to medications.

Further support for some of these findings was provided by the quantitative study, where about one in five participants (20%) agreed that they avoided taking their medications, at least to a certain extent, in situations where they could be overseen by others. This confirmed the role of social stigma in precipitating nonadherence to medications, and was consistent with findings of other studies (Utz et al., 2006; Adams, 2003)

Furthermore, and consistent with findings of other studies (Adams, 2003; Devlin et al., 2006; Greenhalgh et al., 1998; Hernandez et al., 1999; Puavilai and Stuifbergen, 2000; Utz et al., 2006) this research highlighted that God-centered locus of control and religion played an important role in the way some Kuwaiti T2DM managed their diabetes. This may be related to the patients' strong religious Muslim views which shape and influence all aspects of life of the Kuwaiti people. The Islamic faith constitutes a major support system for Muslims, providing the strength and hope which allows people to cope with illness. To Muslims, everything is explained in terms of God's will. This has implications for healthcare providers in terms of supporting patients who turn to their faith to help them

cope with their disease, as patients' with a God-centered locus of control may underestimating the role of medications and demonstrate nonadherence. Nonetheless, Islamic religion supports the notion of integrity and wellbeing of the human soul and body, and therefore educational programmes to raise religious and health awareness can be implemented to prevent nonadherence to medications as result of fatalism and a God-centred locus of control.

4.1.6 Other diabetes self-care behaviors

Findings presented in this thesis revealed that adherence to other diabetes self care behaviours is also problematic among Kuwaiti T2DM patients. This research illustrated that about two thirds of Kuwaiti T2DM patients are nonadherent to diet plans (66%) or exercise (68%), and about half (49%) of Kuwaiti T2DM patients are nonadherent to self-blood glucose monitoring (SBGM). Furthermore, about 18% of Kuwaiti T2DM patients do not adhere to foot care, and about 15% are nonadherent to smoking cessation advice. As effective diabetes management rests upon patients' commitment to all of these behaviours, these findings suggest that nonadherence to medications may not be the sole issue which requires attention. Interventions aimed at improving Kuwaiti diabetes patients' outcomes must also target other aspects of the diabetes management.

Furthermore, findings of this research revealed that adherence to other diabetes self care behaviours was not associated with medication adherence among Kuwaiti T2DM, with the exception of adherence to smoking cessation advice. Moreover, about two thirds of Kuwaiti T2DM patients found adherence to diet or exercise more difficult than adherence to medications.

In the qualitative study, reported barriers preventing adherence to the diabetes self-care behaviours were generally similar to barriers to medication adherence (e.g. lack of education and counselling by healthcare providers, paternalism, low self-efficacy, fatalism/having a God-centred locus of control, perceptions of social support or lack of it, etc.).

However, some barriers reported were related to specific behaviours, such as social gatherings or food cravings preventing diet adherence and weather or comorbidity preventing exercise adherence.

In the quantitative part of this research, reasons for nonadherence to specific diabetes self-care behaviours were revealed. About 44% of Kuwaiti T2DM do not adhere to diet plans as

a result of food cravings, or a lack of motivation (41%). Further, over a third (38%) of Kuwaiti T2DM patients do not adhere to diet plans as a result of not being confident in their ability to stick to diet plans, or because of difficulties in finding healthy food choices.

In terms of exercise, about half of Kuwaiti T2DM patients cited not being confident in their ability to exercise (48%), and comorbidity (45%) as the most common reasons for their nonadherence to exercise. Moreover, about a third (28%) of Kuwaiti T2DM patients do not exercise because they have no time for it, and about one in ten do not exercise because of the weather (10%).

As for SBGM, about 43% of Kuwaiti T2DM patients do not adhere because they do not have a monitoring device, and about a third (29%) do not adhere because of the lack of awareness regarding the need for SBGM. One in five (20%) do not perform SBGM because they prefer clinic testing, or because of a lack of motivation, and about one in ten Kuwaiti T2DM patients (11%) do not perform SBGM because they would feel stressed about its results.

In terms of foot care, the majority (75%) of Kuwaiti T2DM do not adhere to this aspect of diabetes self-care behaviours as a result of a lack of awareness of its importance. This suggests that doctors may have never educated patients about the need to perform foot checks. The role of doctors in orienting patient behaviour can be crucial, it has been shown that patients who had received foot care education and who had their feet examined by their doctor were more likely to check their feet regularly (De et al., 2004).

In the quantitative part of this research, adherence to diabetic clinic appointments was also assessed, and it was found that 23% of Kuwaitis with T2DM were nonadherent to their appointments. However, patients' adherence to appointments was not associated with their adherence to medications.

4.2 Limitations

One of the limitations of this research is that, in both the qualitative and quantitative studies, participants were mostly recruited from clinics, polyclinics and hospitals while they attended their outpatient diabetes clinic appointments. This sample may not be representative of all patients with T2DM in Kuwait. Those who access medical care may be more concerned about their health, and thus are likely to be more adherent to their medications or facing a different set of barriers to medication adherence than those who do not access medical care or attend their appointments.

Nonadherence to medications (and other diabetes self care behaviours) was assessed using self-report. Therefore, patients may have responded in a way to provide socially desirable responses which might have underestimated the true extent of nonadherence. Nevertheless, careful attention was given to phrase questions related to nonadherence in a non-judgemental manner. The high prevalence of nonadherence reported in this study suggests that social desirability may not have been an issue.

Self report scales (e.g., Morisky, MARS) were designed to provide a convenient, valid and reliable mechanism for identifying nonadherence. The results of this research, however, suggest several limitations in using these with the target population of this research. The Morisky scale was shown to be insensitive to intentional nonadherence, to distinguishing between continuous and one-off nonadherence or for nonadherence resulting from taking more medicines than prescribed. The MARS was shown to be less useful for distinguishing the type of nonadherence. Further, the MARS fared worse at identifying nonadherence compared to direct self-report. Because all methods of assessing nonadherence shown limitations (Chapter 2; Section 2.4.2.5 and Section 2.4.2.7; and Chapter 3, Section 3.4.4.5), it may still be reasonable to use one of these methods as part of multiple measures but their advantages over self-report were not clear from this work. In this study, simple direct questioning of patients about their last episode of nonadherence that occurred within the last week was practical for assessing nonadherence to medication and a useful indicator to the type of nonadherence patients had. With direct self-report participants have the freedom to report any reason for their nonadherence, which can then be categorised as intentional/unintentional or continuous/contextual/one-off.

The beliefs about medicines (BMQ) scale and the physician and health care team support subscale of the Chronic Illness Resources Survey (CIRS) were of limited use in this study in terms of identifying predictors for medication nonadherence. Similar to the MARS and the Morisky scales, these scales were developed, tested and validated for use among a predominantly English speaking population. The lack of association between medication adherence and beliefs about medicines or perceptions of healthcare provider support as measured by these scales may have been due to their inappropriateness for use among the target population. Full validation of the instruments was not sought in this research. Nevertheless, several steps were taken to ensure the validity and reliability of these instruments before their use in the target population.

In this study, nonadherence to medications was associated with presence of diabetes complications. However, the direction of causality could not be confirmed, and can only be ascertained with a longitudinal study design. A longitudinal study design might also be advantageous as repeated measurement would allow the assessment of the consistency of adherence/nonadherence, beliefs about medicines, and perceptions about healthcare providers over time.

The sample of this research included Kuwaiti patients with T2DM, therefore, results may not be transferrable to patients with other diseases, or non-Kuwaitis. Although barriers related to healthcare providers or the healthcare system may be applicable to patients with other diseases, careful attention must be paid before transferring the conclusions to other contexts.

4.3 Implications for practice and policy

Findings of this research can be used to provide the foundation of programme development and aid in the design of culturally sensitive adherence interventions. Where limited resources are available, targeted interventions may be most useful. It is recommended that interventions need to be guided by research findings, and that targeted interventions are formulated based on these findings (MRC, 2008). Results of this study showed that medication nonadherence was associated with poor diabetes outcomes, i.e. presence of diabetes complications. Therefore, it might be useful to adapt a preventive approach which focuses on improving patients' adherence to medications prior to the development of the diabetes complications.

However, interventions to improve adherence to medications must be preceded with an assessment of the type of nonadherence that is problematic, as different types of nonadherence warrant different types of interventions. While reminders may help with unintentional barriers (e.g. forgetting, distractions, running out of medications), educational interventions may be more appropriate to resolve intentional barriers resulting from a lack of awareness (e.g. skipping or taking less medications to avoid adverse effects, taking drug holidays to relieve body/avoid dependence, switching from insulin to tablets for convenience while travelling/being away from home).

Healthcare providers, especially doctors and pharmacists, should make medication adherence assessment a standard part of the consultation process. A simple direct self-assessment tool involving direct questioning of patients about their last episode of

nonadherence that occurred within the last week may provide an indication to the type of nonadherence present so that targeted interventions may be tailored according to different patinets' needs on an individual basis.

Diabetes education packages can be designed to address the knowledge deficits found among Kuwaiti T2DM patients, particularly in relation to the nature of diabetes, seriousness of the disease and its potential complications. Perhaps this can be achieved through interventions whereby patients are given the opportunity to live the experience of having diabetes complications before their occurrence. This may achieved through joining diabetes support groups and sharing sound experiences with identified group leaders and other unfortunate members who had already developed advanced diabetes complications. Sharing experiences with those who have lost their sight or limbs due to diabetes may allow others to appreciate the severity of T2DM complications and adopt preventive approaches and healthier lifestyles including better adherence to their medications.

With regards to patients' education, findings from this research revealed that doctors may not always have the time to perform this task properly. Therefore, it might be more useful to prioritize information given to patients, providing the "need to know" information first, and setting up multiple shorter appointments over the first weeks of diagnosis. This approach has been recommended (Lautenschlager and Smith 2006) and may be more applicable for real practice in Kuwait. In addition, it might be useful to involve more healthcare personnel in this educational process. This can involve training nurses to provide one-to-one as well as telephone support to patients, especially over the first weeks of diagnosis suppoted by continous follow-up to emphasize and reiterate the information. It is argued that effective education should be a planned and continuous experience with opportunities for repetition and follow-up (Dietrich, 1996). The establishment of a diabetes helpline to provide further information and educational support to patients at the convenience of their homes can be handy, particularly to those with reduced mobility and increased morbidity. This may also ensure that patients can have access to professional advice regarding their diabetes throughout the day regardless of the working hours of the hospital.

A family-centred approach to education would be beneficial as findings of this research showed that the family constitutes a vital source of support to Kuwaiti T2DM patients. Given that Kuwaiti T2DM patients in this study showed a strong influence of

verbal advice from family and friends, educational programmes via different media sources such as radio, television, and lecture courses are recommended and might be more useful within the Kuwaiti culture. These can also help to correct the religious misconceptions and alter patients' attitudes that have the potential to result in intentional nonadherence to medications among Kuwaiti T2DM patients.

Targeted interventions must also address nonadherence to other diabetes self-care behaviours (i.e., diet, exercise, SBGM, foot care and smoking cessation) in order to achieve better control of diabetes and maximize therapeutic benefit of medications. Doctors in collaboration with other healthcare personnel must advocate and emphasize the importance of such lifestyle changes which are needed for the effective management of diabetes. They must also identify specific barriers to the implementation of diabetes self-care behaviours, and provide advice/support to minimize these barriers.

Results from this research suggest the need for strengthening the doctor-patient partnership through improved communication and appropriate time allocations to individual patients. Adopting a patient-centred approach in delivering diabetes care is highly recommended, whereby doctors would involve patients as equal partners in all decisions about their treatment, especially in relation to medication selection and prescription. Patients are more likely to adhere to their medications if they were involved in and agreed on the decisions about their medications. A possible way of helping patients being more adherent is perhaps by eliciting their priorities, identifying their expectations towards diabetes and its treatment and translating these into realistic objectives for the individual patient (Wens et al., 2005). That way, doctors could learn about the context in which patients experience and manage their diabetes. Cultural beliefs and lifestyle priorities should be addressed and incorporated into patients' medical records, as recommended by the FIP in the statement of professionals standards on the role of pharmacists in encouraging adherence to long-term treatments (International Pharmaceutical Federation, 2003). For the successful contribution of all different healthcare personnel in the management of all T2DM patients in Kuwait, the vital role of establishing electronic databases for patients' medical records cannot be underestimated. Such databases would allow access and sharing information among to all healthcare providers involved in diabetes care, which would allow the provision of a more coherent treatment approach to

T2DM patients. This in turn can allows patients to be managed in a more efficient way and increase their confidence in the healthcare system altogether.

This study highlighted several areas for improving the current practice of pharmacists to improve health care provision for Kuwaiti T2DM patients. With regards to the basic tasks of labelling and dispensing of medications, pharmacists need to provide clear oral information about medication use, and reinforce this by clear labeling of medications including at least the generic name, strength of medicine, and individual dosage instructions. Abbreviations and unfamiliar expressions should be avoided, and labels must be computer-generated where possible. Graphic symbols can be used for providing instructions for illiterate patients, however these must be always be supported by written instructions.

More importantly, findings of this study highlighted the need for greater involvement of pharmacists in the care of Kuwaiti T2DM patients through much-needed patient education and counselling. With patient counselling pharmacists are in a great position to identify and correct any false beliefs patients might have about medications and address any concerns they might have to make sure they have a better understanding of their medications. In the qualitative interviews, some participants felt that adverse effects are an inevitable by product of taking medications therefore they may not present to their healthcare providers to report these, which would prevent resolution of these adverse effects and possibly induce nonadherence. Pharmacists are in great position to resolve such issues by probing patients about any adverse effects and stressing the importance of presenting back to the clinic if problems arise. Further, this research revealed that lay sources of information were frequently cited as a major influence on behaviour and medication use in particular. Pharmacists can identify negative learning experiences and substitute any misconceptions patients may have with more accurate information. This can reduce intentional nonadherence to medications. On the other hand, practical support by pharmacists using reminders, and special adjustment of dosage regimens to fit with individual patient's lifestyle can help in reducing unintentional nonadherence.

Findings of this study highlighted several implications for health authorities responsible for planning and implementing health regulations (e.g., The Ministry of Health and professional organisations). In particular, the development of national guidelines for the appropriate management of diabetes might be most useful, including the evidence for

the benefits of improving medication adherence in T2DM patients, and highlighting effective strategies to support patients' adherence to their medications. Perhaps these guidelines could also state objective, explicit and assessable standards of performance for healthcare providers relating to promoting adherence. Providing incentives for patients or healthcare providers involved in promoting adherence may also be useful. Further, health authorities might benefit from providing professional education and training courses for pharmacists, doctors, and other healthcare providers regarding the appropriate management of diabetes drawing from the international evidence. In these courses, the importance of team work in optimizing patient outcomes must be emphasized and effective strategies to ensure coordination of care and services by different healthcare providers must be illustrated. This highlights the importance of implementing electronic databases. Moreover, regulations must be in place to ensure continuity of care offered to patients with T2DM. Findings of this study suggest that patients can be better supported if they have steady contact with the same doctor. Regulations must also focus on establishing an effective appointment system to patients with T2DM. Perhaps, the electronic databases may be used in identifying patients who frequently miss their appointments so that they could be better supported via telephone reminders. Regulations must also be in place to detect and discipline healthcare providers who demonstrate evidence of lack of respect, favourtisitm and discrimination in providing patient care. Efforts must also be taken to reduce disparity in access to healthcare and medications between different districts in Kuwait. This may involve increasing the number of diabetes clinics as well as medication supplies in rural areas of the country to meet the demands of a more rapidly growing population in these regions of the country.

In the qualitative interviews, some participants reported they would have preformed SBGM if they had testing-strips, perhaps these could be provided by the Ministry of Health. The Ministry of Health in collaboration with professional and academic organizations may benefit from organizing public campaigns for raising awareness regarding the seriousness of T2DM, management strategies, benefits of adherence, and encouraging patients to participate fully in discussions with their healthcare providers to ensure maximum benefits from medication, as recommended by the FIP (International Pharmaceutical Federation, 2003). These campaigns must also encourage patients to engage more with pharmacists and ask questions about their medications.

4.4 Recommendations for future research

Future research could focus on evaluating interventions targeted at identifying and resolving Kuwaiti T2DM patients' inaccurate beliefs about medicines and assessing whether these would improve medication adherence. Alternatively, future research could focus on the patient- provider relationship. Perhaps, patient-provider consultations could be video-taped and analysed to explore the content of information provided and the style of communication currently used by doctors involved in the care of Kuwaiti T2DM patients. Findings can help inform the design of interventions targeted at improving patient-provider relationship. The impact of such interventions on adherence to medications and clinical outcomes of diabetes (e.g. HbA1c levels) could then be assessed. Researchers are also encouraged to identify specific variables that are predicative of nonadherence to medications among Kuwaiti T2DM. Values, norms and expectations of this unique population must be identified, and appropriate interventions must be devised and targeted at these variables to improve adherence and health outcomes for this particular population. Cost-effectiveness studies of adherence interventions are also needed, as they would provide evidence for the importance of this area of research and build the case for the need to direct health resources at decreasing nonadherence to medications. Future work may also explore barriers to medication adherence among non-Kuwaitis, as they may have different issues given their different cultural backgrounds, and that healthcare services are less accessible to this particular population.

With regards to the use of scales in languages other than those they were tested for, several solutions may be helpful for future research purposes. Refining scales and validating them fully in a culturally similar population before their use in a culturally different context may be needed. Alternatively, new scales can be developed from grounded qualitative research involving the same population. This has the advantage of eliminating the need for translation. Alternatively, future studies may need to test different measures for performance on this particular sample, e.g., social support received from family/friends, knowledge about disease, etc.

To facilitate recruitment of research participants for future research, careful attention must be given as extensive paperwork may cause patients to become anxious and reluctant to participate in research. Tape/digital recording of interviews might be

intimidating, research participants must be assured about the confidentiality of data and any concerns must be addressed to ensure obtaining their honest views.

4.5 Conclusions

This thesis provided evidence that nonadherence to medications among Kuwaiti patients with T2DM is a significant problem of a striking magnitude. About two in five (43%) Kuwaiti T2DM patients are nonadherent to their medications. About half of the time (45%) nonadherence is intentional. The underlying reasons that discourage or motivate patients to adherence to medications are complex and often inter-linked. Patient, doctor and systemic-related factors influence adherence and in turn are influenced by each other. Moreover, nonadherence to medications is associated with poor health and diabetes outcomes. Furthermore, this research showed that adherence to other diabetes self-care behaviours (i.e., diet, exercise, SBGM, foot care and smoking cessation advice) is also poor (15%-68% are nonadherent) depending on the specific behaviours.

There is evidence that patients held a range of specific beliefs about their diabetes medications or about medications in general that might be problematic. These beliefs must be addressed by healthcare providers to ensure that patients are aware of the necessity of their medications, and reassured about any concerns regarding taking them. There was also evidence that support received from doctors, pharmacists or other health care providers was suboptimal and there is a need towards a more patient-centred approach and more involvement of patients in their disease management targets and strategies, resulting in concordant models of patient-provider communication. It is also important to include family members in these plans as the study showed that family members may be an important asset in patients' life. In addition, the study highlighted the importance of finding other predictors of nonadherence to medications among this particular population.

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APPENDICIES

Appendix 1: Interview Topic Guide (English and Arabic versions)

Interview Topic Guide

1-Diagnosis
• Could you tell me when and how were you diagnosed? • How did you experience the diagnosis of diabetes?
2-Knowledge about diabetes and medications
• In your opinion what causes diabetes? • In your opinion, how should diabetes best be treated? • How do you describe your health at the present, and what do you think it is going to be like in 10-20 years' time? • Could you describe the consequences of diabetes in the future? *(probe: complications)* • How do you know when you are sick with your diabetes? *(probe: describe symptoms of hypoglycemia, hyperglycemia)* • Could you describe what do you do when you are sick with diabetes? *(probe: hyperglycemia, hypoglycemia, foot problems)* • What is/are the source(s) of your information/knowledge about diabetes/its medications?
3-Views and experiences with diabetes medications
• Are you currently treated with tablets, insulin or both for your diabetes? • What medications are you currently taking for your diabetes? • How do you take your medications? • What do you think of your medications? *(probe: effectiveness in the short term and in the long-term)* • Could you describe your experience of taking your diabetes tablets/insulin? *(probe: effectiveness, practical difficulties, adverse effects)* • Have you ever experienced difficulties taking your mediations for diabetes? if yes, please describe. • Can you remember a time where you couldn't take your medications as prescribed by your doctor? If yes, can you tell me what happened? • Some people alter the use of their medications and find their own way of using their medications for many reasons. Can you think of a time when you have done so? • If yes, how do you feel about this? Do you tell anyone about these decisions?

4-Views and experiences with alternative/herbal medicines
• Do you use herbal/complimentary medicines for your diabetes? • If yes, could you describe your experience with such therapy? • If yes, how do feel about these compared to your regular medications? *(probe: adverse effects, effectiveness)*
5-Views and experiences with healthcare providers (doctors, pharmacists, nurses, dieticians)
• Could you describe your views and experiences with your doctor? *(Probe: type of relationship, communication style)* • How do you feel about the education and counseling provided by your doctor about diabetes/medications? *(probe: sufficiency of information received about your diabetes/medications/other treatment behaviours)* • Has your doctor involved you in decisions relating to your own treatment plan? *(probe: to what degree?)* • If your doctor has decided on your therapeutic regimen, how do you feel about that? *(probe: degree of control and responsibility for own treatment desired)* • Do you always get the chance to be followed-up with the same doctor? If not, how do you feel about that? • Could you describe your experience with pharmacists? • How do you feel about the education and counseling provided by your pharmacists? • Could you describe your experience with other healthcare providers who were involved in your diabetes, e.g. nurses, dieticians, etc.? *(probe: who? What do you think of them in terms of diabetes care provided)*
6-Views and experiences with current health care system at the Ministry of Health
• What is your view of the current health care system? *(probe: health services provided)* • How do you feel about access to healthcare providers or medications? *(probe: describe ease/ difficulty?)* • What should the Ministry of Health do to help patients with type 2 diabetes? *(probe: sufficiency of what it currently provided)*
7-Impact of diabetes on participant's life
• In what way have diabetes changed your life? *(probe: describe living with diabetes on a daily basis, how does your life differ from someone who doesn't have diabetes?)* • How do you feel about these changes?

8-Actual/ perceived social support
• Do you receive any kind of support from your family in terms of managing your diabetes *(probe: help with medications, SBGM, preparation of diabetic meals, etc.)* • If yes, could you describe the role of your family in management of your disease? *(probe: practical or moral support)*
9-Adherence to other diabetes self-care behaviours (diet, exercise, SBGM, foot care)
DIET • Do you have a healthy diet plan to follow? • If yes, please describe your daily meal plan? *(probe: type of food on main meals, snacks, type of food in social gatherings)* • If not, what are the reasons? EXERCISE • Do you exercise? • If yes, what kind of exercise do you do and how often? • If not, what are the reasons? MONITORING OF BLOOD GLUCOSE LEVELS • Do you monitor your blood glucose levels at home? • If yes, how often do you do it? • If yes, when do you do it? • If not, what are the reasons? FOOT CARE • Do you check your feet usually? *(probe: do you take care of your feet?)* • If yes, please describe how do you take care of your feet? • If not, what are the reasons?
Is there anything else you think that you wanted to say? THANK AND CLOSE

دليل المواضيع للمقابلة

1- التشخيص
• هل تستطيع أن تخبرني متى و كيف تم تشخيصك بمرض السكري؟ • كيف كانت تجربتك عندما تم تشخيصك؟
2- معلومات المريض عن مرض السكري و الأدوية الخاصة به
• ما هي أسباب الاصابة بمرض السكري برأيك؟ • ما هي أفضل طريقة لعلاج مرض السكري برأيك؟ • كيف تصف وضعك الصحي بالوقت الحالي و ماذا تعتقد أن يؤول اليه حالك بعد 10-20 سنة من الان؟ • هل تقدر أن تصف لي العواقب المستقبلية التي قد تترتب على الأصابة بمرض السكري؟ *(تحفيز: ما هي المضاعفات؟)* • كيف تعلم مرض السكر لديك مرتفع أو غير مستقر؟ *(تحفيز: صف لي أعراض الهبوط و ارتفاع مستوى السكر لديك، مشاكل القدم)* • ما أين تحصل على معلوماتك الشخصية بالنسبة لمرض السكري و أدوية السكر؟
3- الأراء الشخصية و تجربة المريض مع أدوية السكر
• بالنسبة لعلاجك الخاص بمرض السكري، حاليا هل تأخذ حبوب، ابر، أم الاثنان معا؟ • ما هي الأدوية التي تأخذها حاليا؟ • كيف تأخذ هذه الأدوية؟ • ما هو رأيك بأدويتك الخاصة بمرض السكري؟ *(تحفيز: فعاليتها على المدى القريب و على المدى البعيد)* • هل تستطيع أن تصف لي تجربتك مع أخذ حبوب أو ابر مرض السكري؟ *(تحفيز: الفعالية، الصعوبات العملية، الأثار الجانبية)* • هل واجهت أي صعوبة بتناول أدوية مرض السكري؟ في حال نعم، الرجاء وصف ذلك. • هل تستطيع تذكر مرة لم تستطع بها أن تأخذ أدويتك الخاصة بمرض السكري كما وصف لك الطبيب؟ في حال نعم، الرجاء وصف ما حدث. • هناك اناس يغيرون طريقة استخامهم لأدويتهم بما يتناسب معهم و يتبعون طريقتهم الخاصة في تناول الأدوية لأسباب عديدة، هل تذكر أنك قمت بذلك و لو لمرة؟ • في حال نعم، ما هو شعورك لفعل ذلك؟ و هل تخبر أحدا بقراراتك هذه بتغيير طريقة أخذ الدواء؟
4- الأراء الشخصية و تجربة المريض مع أدوية الطب البديل أو الأعشاب
• هل تستخدم اية أعشاب/أدوية الطب البديل لعلاج مرض السكري؟ • في حال نعم، هل تستطيع وصف تجربتك مع هذه الأدوية؟ • في حال نعم، ما هو شعورك من ناحية هذه الأدوية بالمقارنة مع أدويتك الخاصة بمرض السكري العادية؟ *(تحفيز: الأثار الجانبية، الفعالية)*

5- الأراء الشخصية و تجربة المريض مع الفريق الطبي (الأطباء، الصيادلة، الممرضات، اخصائيي التغذية)

- هل تستطيع وصف رأيك الشخصي و تجربتك مع طبيبك الخاص بمرض السكري؟ *(تحفيز: نوع العلاقة بينكم، طريقة التواصل)*
- ماذا رأيك بالمشورة الطبية التي تتلقاها من طبيبك بخصوص مرض داء السكري و الأدوية الخاصة به؟ *(تحفيز: كفاية المعلومات عن الأدوية و المرض و عن الأساليب الأخرى لعلاج مرض السكري كالرياضة و الحمية، الخ)*
- هل يشركك طبيبيك بالقرارات المتعلقة بخطة علاجك؟ *(تحفيز: الى أي مدى)*
- اذا كان طبيبك هو من يقوم بأخذ القرارات الخاصة بعلاجك، ماذا تشعر حيال ذلك؟ *(تحفيز: ما مقدار السلطة و المسئولية التي تريد أن تتلقاها بخصوص أخذ القرارات الخاصة بعلاجك)*
- هل تسنح لك الفرصة لمتابعة حالتك لدى نفس الطبيب كل مرة؟ في حال لا، ما هو شعورك حيال ذلك؟
- هل تستطيع أن تصف لي تجربتك مع الصيادلة؟
- ماذا رأيك بالمشورة الصيدلانية المقدمة من قبل الصيدلاني الذي تتردد عليه لصرف أدوية السكرى؟
- هل تستطيع أن تصف لي تجربتك مع الأخرين من الفريق الطبي المختصين بتقديم الرعاية الصحية لك بخصوص مرض السكري مثل الممرضات، أخصائيي التغذية،الخ *(تحفيز: من هم؟ ما رأيك بهم و بما يقدمونه من الرعاية الصحية لمرضى السكري)*

6- الأراء الشخصية و تجربة المريض مع النظام الصحي الحالي بوزارة الصحة

- ما هو رأيك بالنظام الصحي الحالي المقدم من قبل وزارة الصحة؟ *(تحفيز: الخدمات الصحية)*
- ما هو رأيك بسهولة الحصول على الخدمات الصحية أوالأدوية المقدمة من قبل الفريق الطبي ؟ *(تحفيز: صف مقدار السهولة/الصعوبة)*
- ما الذي تستطيع وزارة الصحة القيام به لمساعدة مرضى السكري؟ *(تحفيز: هل الخدمات الصحية المقدمة حاليا كافية)*

7- تأثير مرض السكرى على حياة المريض

- صف لي كيف تغيرت حياتك بعد الأصابة بمرض السكري؟ *(تحفيز: صف لي حياتك اليومية في ظل مرض السكري، كيف تختلف حياتك عن غيرك من غير المصابين بالمرض؟)*
- ما هو شعورك ناحية هذه التغيرات؟

8- الدعم الأسري العملي أو المعنوي

- هل تقدم لك أسرتك أي نوع من الدعم من ناحية علاج مرض السكري؟ *(تحفيز: مساعدة من ناحية الأدوية، الفحص الشخصي لمستوى السكر بالدم، تحضير وجبات غذائية مناسبة لمرض السكري، الخ)*
- في حال نعم، صف لي الدور الذي تلعبه أسرتك في مساعدتك من ناحية علاج مرضك بالسكري *(تحفيز: الدعم الحقيقي، المعنوي)*

9- الالتزام بأساليب علاج مرض السكري الأخرى (الحمية الغذائية، الفحص الشخصي لمستوى السكر بالدم، الرياضة، رعاية القدم)

الحمية الغذائية:

- هل تتبع نظام للحمية الغذائية الصحية؟
- في حال نعم، الرجاء وصف ما تتناوله في يومك العادي (*تحفيز: نوعية الطعام المكون للوجبات الأساسية، الوجبات الخفيفة، نوعية الطعام الذي تتناوله في التجمعات العائلية أو المناسبات*)
- في حال لا، هل هناك ما يمنعك من ذلك؟ و ما هي الأسباب؟

الرياضة:

- هل تمارس الرياضة؟
- في حال نعم، ما نوعية الرياضة التي تمارسها، و ما مدى استمراريتك عليها ؟
- في حال لا، هل هناك ما يمنعك من ذلك؟ و ما هي الأسباب؟

الفحص الشخصي لمستوى السكر بالدم:

- هل تقوم بالفحص الشخصي لمستوى السكر بالدم في المنزل؟
- في حال نعم، كم مرة تقوم بذلك؟
- في حال نعم، متى تقوم به؟
- في حال لا، هل هناك ما يمنعك من ذلك؟ و ما هي الأسباب؟

رعاية القدم:

- هل تقوم بفحص و ملاحظة قدمك باستمرار؟ (*تحفيز: هل تحرص على رعاية قدميك؟*)
- في حال نعم، صف كيفية ذلك.
- في حال لا، هل هناك ما يمنعك من ذلك؟ و ما هي الأسباب؟

هل هناك ما تود اضافته حول الموضوع؟

شكر المريض و انهاء المقابلة

Appendix 2: Ethics Approval Documents

STATE OF KUWAIT
MINISTRY OF HEALTH

دولة الكويت
وزارة الصحة

Reference : الرقم :

Date : التاريخ :

السيد الدكتور/ وكيل الوزارة المحترم

تحية طيبة وبعد ،،

يرجى الإحاطة بأن اللجنة الدائمة لتنسيق البحوث الطبية والصحية قد ناقشت بروتوكول مشروع البحث المقدم من الباحثة/ فاطمة باقر جراغ الحداد (مبعوثة لدراسة الدكتوراه/ جامعة لندن) وعنوان الحث:

مدى إلتزام مرضى السكر من النوع الثاني بأخذ أدوية السكر والصعوبات التي تواجههم عند أخذ الدواء.

وقد أوصت اللجنة باجتماعها السابع عشر المنعقد بتاريخ 2008/2/10 بالموافقة على هذا البحث مع مراعاة تعهد الباحثة بالمحافظة على حقوق المرضى بشأن سرية البيانات الشخصية وعدم استخدام أي معلومات خارج نطاق الدراسة والحصول على الموافقة المستنيرة المسبقة من المشاركين بالبحث (informed consent) .

ونظرا لكون البحث يتم بعيادات السكر بالمستشفيات وبمراكز الرعاية الصحية الأولية، يرجى الاطلاع ومخاطبة السيد/ وكيل الوزارة المساعد لشئون الرعاية الصحية للعمل على تسهيل مهمة الباحثة وفقا للضوابط والإجراءات المتبعة والإمكانيات المتاحة بهذا الشأن.

وتفضلوا بقبول فائق الاحترام ،،،

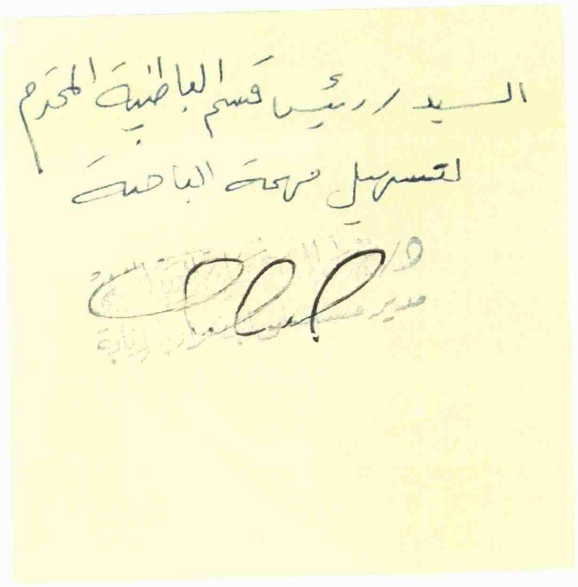
الدكتور علي يوسف السيف
وكيل الوزارة المساعد
لشئون الصحة العامة

رئيس اللجنة الدائمة
لتنسيق البحوث الطبية والصحية

+ المرفقات

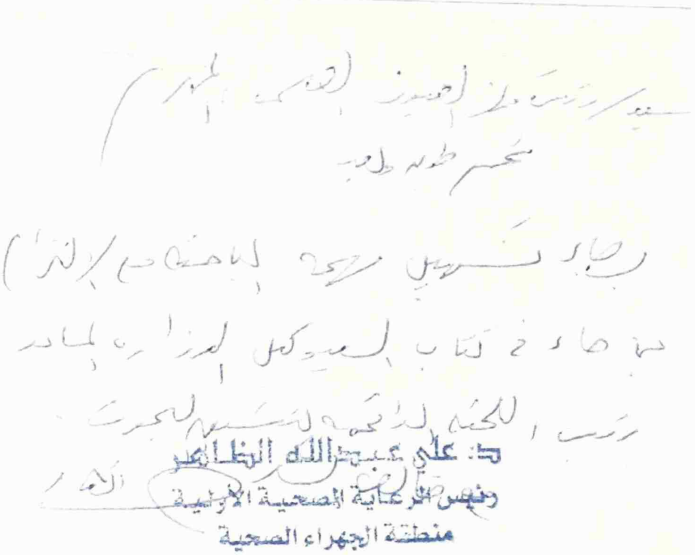
Cables : HEALTH KUWAIT
Admin. Financial Affairs Medical Stores
P.O.Box : 5 1519 22575
Zip Code : 13001
E-Mail:health@moh.gov.kw

برقيا : صحة الكويت
الوزارة المالية
الرمز البريدي



السيد / رئيس قسم الباطنية المحترم

لتسهيل مهمة الباحث



د. علي عبدالله الظاهري
رئيس الرعاية الصحية الأولية
منطقة الجهراء الصحية

Appendix 3: Healthcare Provider Information Leaflet for the Exploratory Study

(English and Arabic versions)

Healthcare Provider Information Leaflet

Purpose of the Study and Brief Description of the Process

In diabetes, many patients do not adhere to their medications, which can lead to significant consequences such as disease progression, poor outcomes and development of preventable complications of the disease.

I am working on a research project at the School of Pharmacy in London which aims to understand the barriers that Kuwaiti patients with type 2 diabetes face when adhering to their medications. Uncovering these barriers can help us design pharmaceutical interventions to help patients take their medications.

The study will involve interviewing patients at a place of their convenience to understand their personal experiences regarding their medications. Interviews will take 30 minutes to 1 hour on average, depending on what they have to say.

We are kindly asking for your help to recommend a sample of patients who might be interested in talking to us about their experiences with their medications. We are specifically interested in those who are likely to be facing difficulties when adhering to their medications.

This study has been approved by the Ministry of Health Committee for Facilitation of Medical Research and by Kuwait University.
If you have any questions about the project, please contact:

ملخص و أهداف البحث (للقسم الأول من البحث)

نسخة الدكتور المعالج

عزيزي الدكتور(أوالدكتورة) المعالج،

إن العديد من مرضى السكري لا يلتزمون بأخذ أدويتهم حسب التعليمات الطبية مما يؤدي إلى العديد من النتائج السلبية كتقدم المرض، تدهور صحة المريض وحصول مضاعفات المرض الجسيمة كالعمى، قطع الأطراف، و تدهور وظائف الكلى...الخ.

إنني باحثة من جامعة لندن (مدرسة الصيدلة) أهدف إلي معرفة أسباب عدم أخذ مرضى السكري من النوع الثاني لأدوية السكر الخاصة بهم، كما أهدف إلى معرفة العوائق الحقيقية التي تمنعهم من أخذ الدواء حسب تعليمات الطبيب. إن معرفتنا لهذه العوائق سيكون لها دور مهم في تصميم دراسة مستقبلية على مستوى الدولة يقوم بها الصيدلي بأخذ خطوات فعلية من أجل تحسين التزام مرضى السكري من النوع الثاني بأخذ أدويتهم.

تتطلب الدراسة إجراء مقابلة شخصية لعدد من مرضى السكري الكويتيين يتم اختيارهم عند حضورهم لمواعيدهم في العيادات الخارجية. بعد اختار كل مريض (أو مريضه) و ابلاغه بأهداف و متطلبات البحث سيتم تحديد موعد مناسب له لاجراء تلك المقابلة في مكان مناسب حسب اختياره (مثل غرفة محاضرات في مركز العلوم الطبية، الجمعية الصيدلية، أو مكان مناسب ضمن المستشفى أو مركز الرعاية الأولية، كما يمكن إجرائها في منزل المريض الخاص ان رغب في ذلك). سيتم من خلال هذه المقابلة سؤال المريض عن تجربته مع مرض السكري و أدوية السكري و سيكون الوقت المتوقع للمقابلة ما بين 30 دقيقة إلى ساعة، حسب ما عند المريض من المعلومات.

نحن نرجو تعاونكم معنا في بداية الدراسة بتحديد عدد من المرضى الذين تتوقعون أنهم يواجهون صعوبات في أخذ أدويتهم.

لقد تمت الموافقة على هذه الدراسة من قبل وزارة الصحة (اللجنة الدائمة لتنسيق البحوث الطبية و الصحية) و جامعة الكويت.

إذا كنت ترغب بمعلومات إضافية أو في حال وجود أي استفسار يرجى الاتصال بالباحثة الأساسية للبحث:

فاطمة جراغ الحداد (ماجستير صيدلة اكلينيكية، جامعة لندن)
[redacted]

Appendix 4: Patient Information Leaflet and Consent Form for the Exploratory Study (English and Arabic versions)

Patient Information Leaflet

Purpose of the Study and Brief Description of the Process

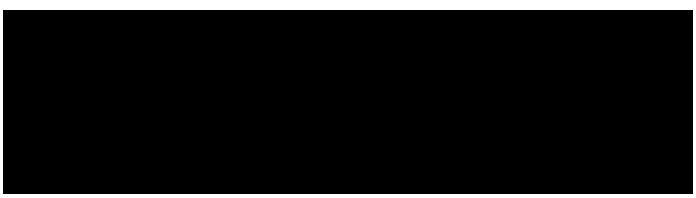
Some patients may experience problems when taking their medications. To learn more about this, pharmacists at Kuwait University are working together with pharmacists at the School of Pharmacy in London on a research project to understand how Type 2 diabetic patients like yourself feel about taking their medications and the barriers they may face whilst doing so. The results of this research will help us to uncover any difficulties or barriers you may face so that we can design solutions to help you take your medication more easily so that you could expect better outcomes of your diabetes.

If you choose to participate in the project, we will ask you to spend some time answering questions about your illness and medications during the course of an interview. The interview will be held at a place of your convenience and the time will not be limited (you will be allowed to talk freely for as long as you wish). However, we estimate that it will take 30 minutes to an hour of your time. You will be contacted sometime after the interview to check if our findings truly represent what you meant to convey in your interview. Interviews will be tape-recorded to ensure that we are not missing anything you tell us and to help us analyse the information more effectively. We will protect the confidentiality of any information you share with us. All the information you give us will be private and we won't include your name or any identifying information on any of the report about this project. The information you give us will not be part of your medical record or shared with your doctor or anyone else in the clinic.

Your decision to participate in this research project is voluntary. You may decide not to take part in the project, and you may decide to withdraw from the interview at any time whenever you feel uncomfortable. The study will not affect the health care you are receiving at this clinic.

The study has been approved by the Ministry of Health Committee for Facilitation of Medical Research and by Kuwait University.

If you have any questions about the project, please contact:



If you are willing to participate, please fill in and sign the consent form attached.

The Consent Form

Title of Study: The experience of Kuwaiti patients with type 2 diabetes milletus with their illness and the medications used to treat it.

Name of Researcher: Fatima Jeragh Alhaddad, MSc. Clinical Pharmacy, International Practice and Policy, School of Pharmacy University of London.

Co-researchers: Prof. Nick Barber (School of Pharmacy, London), Dr. Tina Brock (School of Pharmacy, London), Dr. Mohammad Waheedi (Kuwait University)

The study has been explained to me and I agree to take part in the study

Name of the participant:.....

Date:.....

Signature:.....

ملخص و أهداف البحث (للقسم الأول من البحث)

نسخة المريض

بعض المرضى قد يجدون صعوبة في أخذ أدويتهم حسب تعليمات الطبيب لأسباب عديدة. للتعرف على أسباب هذه المشكلة نقوم نحن مجموعة من الصيادلة من جامعة لندن بالتعاون مع جامعة الكويت (كلية الصيدلة) بعمل دراسة تهدف إلى معرفة كيفيه أخذ الدواء لمرضى السكري من النوع الثاني بالكويت و إذا كانت هناك أي صعوبات تواجههم عند أخذ الدواء.
الغرض الأساسي من هذه الدراسة هو عمل دراسة أخرى يقوم بها الصيدلي بأخذ خطوات فعلية من أجل تحسين التزام مرضى السكري بأخذ دوائهم حتى ينعموا بحياة أفضل في ظل مرض السكري.

في حال موافقتك على المشاركة ستقوم الباحثة الأساسية بسؤالك بعض الأسئلة لمعرفة بعض المعلومات الخاصة بمرضك وكيفية استخدامك لأدويتك الخاصة بمرض السكري. بعد ذلك سوف تقوم بتحديد موعد مناسب لك لإجراء مقابلة شخصية معك في مكان مناسب حسب اختيارك مثل غرفة محاضرات في مركز العلوم الطبية، الجمعية الصيدلية، أو مكان مناسب ضمن المستشفى أو مركز الرعاية الأولية، كما يمكن إجرائها في منزلك الخاص إن رغبت بذلك ، الوقت المتوقع للمقابلة سيكون ما بين 30 دقيقة الى ساعة، و لكن يمكنك التحدث لأكثر من ذلك إن شئت. بعد إجراء المقابلة سيتم الاتصال بك في وقت لاحق لمشاركتك بنتائج الدراسة و للتأكد إذا ما كانت النتائج تعكس وجهة نظرك.

ان المعلومات التي ستدلي بها في هذه الدراسة ستكون سرية و ستستخدم فقط في نطاق البحث و ليس لأي أغراض أخرى، كما نضمن لك بأن مشاركتك بالدراسة لن تؤثر على مستوى الرعاية الصحية التي تتلقاها حيث لن يتم إفصاحها لأي شخص من المستشفى أو العيادة التي تتردد عليها للعلاج.

بالطبع نحن نترك لك حرية الاختيار في المشاركة بهذه الدراسة أو الرفض، كما يمكنك الانسحاب من المشاركة بأي وقت لاحق إن شئت لكن مشاركتك معنا ستعتبر مكسبا لتحسين مستوى الرعاية الصحية و الصيدلانية لمرضى السكري في الكويت.

لقد تمت الموافقة على هذه الدراسة من قبل وزارة الصحة (اللجنة الدائمة لتنسيق البحوث الطبية و الصحية) و جامعة الكويت.
اذا كنت ترغب بمعلومات إضافية أو في حال وجود أي استفسار يرجى الاتصال بالباحثة الأساسية للبحث:

فاطمة جراغ الحداد (ماجستير صيدلة اكلينيكية، جامعة لندن)
نقال 9441914 بريد الكتروني q8pharmacist@hotmail.com

في حال الموافقة على المشاركة يرجى توقيع الإقرار على المشاركة بالمرفق بالخلف

إقرار الموافقة على المشاركة بالدراسة

عنوان الدراسة: تجربة مرضى السكري من النوع الثاني بالكويت مع مرض السكر و الأدوية الخاصة لعلاجه.

اسم الباحثة الأساسية: فاطمة جراغ الحداد (جامعة لندن، مدرسة الصيدلة).

الباحثون المشاركون: البروفيسور\ نك باربر (جامعة لندن، مدرسة الصيدلة)، الدكتورة\ تينا بروك (جامعة لندن، مدرسة الصيدلة)، الدكتور\ محمد وحيدي (جامعة الكويت، كلية الصيدلة).

لقد تم شرح الدراسة لي بشكل وافي و أنا أوافق على المشاركة بهذه الدراسة:

اسم المشترك:.....

التاريخ:.....

التوقيع:.....

Appendix 5: Example Section of a Matrix Used for Charting and Summarizing Interview Data (Framework Analysis)

No	2. Knowledge about diabetes 2.1 Lack of/awareness of seriousness of diabetes	2.2 Mis/conceptions about disease or its treatment	2.3 Hereditary factor involved	2.4 Stress is a major cause for high blood sugar	2.5 Hearsay, others as primary source of information	2.6 Awareness of hyper or hypo situations
No 1	Pt was aware of seriousness of diabetes, having both parents dying from disease (319)	"diabetes doesn't need treatment as much as it needs keeping your spirits high, doing exercise, and limitting food intake, that's it, nothing more or less!" (107) "it might be enough if you could just walk, normally, you see, not so hard" (111), "my friends were able to stop their medicines just by following an exercise plan.. but when they stopped, it (DM) returned" (113-116), "When I travel, I feel that I don't need my medicines, coz I'd be moving so much" (117), "sometimes id check my BG and find it to be within limits" (119) "its is mostly stress-related, and it depends on diet and exercies, and medicines come last, when neither of the previous ways work" (123)	Strongly associated diabetes with herditary "I got it without being overweight, so its mostly hereditary" (107, 121).	Thinks that his blood sugar tends to increase in stressful periods of time (53) Thinks that stress leads to "big increase" in his blood sugar (55).	Had an idea about diabetes from his experience with both parents who died of the disease (39,43). Pt often hears from friends about recent advances in treatment of diabetes, e.g. a friend of pt removed a fatty mass from foot in surgical procedure, and had improvement in BG afterwords so pt was going to undergo the same procedure, til he realized that it doesnt really work, as friend had elevated BG shortly after, apparently the temporary improvement was due to the concomittant diet plan (249) Pt also heard about pancreatic cell transplants from friends (249) Pt learned about diet from experience with parents, who both had DM (39)	Identified dizziness, blurred vision as most frequent signs of hyperglycemia occuring to him, but mentioned that he doesn't get urinary urgencies a lot (59)
No 2	Pt aware of seriousness of diabetes "diabetes damaged my eyes slowly, got me kidney disease,heart disease.. Diabetes ruins the human being" (15). "Hyperglycemia is not as dangerous as hypoglycemia, hypoglycemia is the most dangerous thing, if you dont act on it you would immediately enter a coma and die, but hyperglycemia is, as i told you, can take up the eyes, kidneys, it can take many things.." (15), aware that hyperglycemia can be very dangerous (19-23), aware that diabetics get delayed wound healing (211), aware of seriousness of foot injuries for a diabetic (215).	Aware that diabetes cannot be treated with diet only, though it may be possible in the beginning of the disease (111) Pt is aware that controlling diet is essential to control diabetes (113). Aware that infections can elevate BG (157). Aware that processed or preserved food stuff, lack of exercise can lead to diabetes (235)	recognises the link, but doesn't believe he got diabetes because of this (237)	Pt identified stress as a major cause of elevated BG, thinks its effect is even greater than diet (114), "sometimes (*when im stressed)* even whenI don't eat, and I find it high" (117)	When pt started ahaving symptoms,friends suggested he much have had diabetes, checked with DR and it turned he really had it (11). Heard about nasal insulin from people (163). Heard that herbal medicine can benefit you, and if it doesn't, at least it wont harm you, but Pt is not eaxclty sure of this (205,207)	Identified frequency of urination, blurred vision, thirst, dry mouth as signs of hyperglycemia (25). Identified sweating, esp at back of the neck, shiver, esp hand shivers, increased heart beats, and hunger, anxiousness, general tiredness, a sense of impalance, incoherence in speech as signs of hypoglycemia (27,31). Pt seems positive he could differentiante clearly distinguish signs of hypo from hyperglycemia (29)
No 3	Aware that diabetes can lead to complications, therefore taking precaustions to avoid them (203)	Aware that diabetes is related to lack of exercise, and stress (145). Aware that diet, exercise and medication taking are all needed, combined, to control diabetes (173-176)	ND	Pt identified stress as a major cause of elevated BG, Believes that half kuwaitis got diabetes as a result of stress, esp after the Iraqi invation (145-149)	ND	ND

Appendix 6: Healthcare Provider Information Leaflet for the Quantitative Study

(English and Arabic versions)

Healthcare Provider Information Leaflet

Purpose of the Study and Brief Description of the Process

Review from different countries and across different disease conditions have consistently estimated that 30-50% of prescribed medication is not taken as instructed. The WHO (2003) highlighted that nonadherence to treatment is the single most important modifiable factor that compromises treatment outcome. In diabetes, significant consequences can result from patients' nonadherence to medications including disease progression, poor outcomes and development of complications of the disease, which constitute a considerable financial burden on healthcare systems.

I am working on a research project at the School of Pharmacy in London to estimate the prevalence of nonadherence to medications in Kuwaiti patients with type 2 diabetes mellitus. The results of this research will help us to design pharmaceutical interventions to improve adherence in this particular group of patients in the future.

The study will involve asking a sample of type 2 diabetic patients who are attending their appointments to fill in a questionnaire to assess the level of their adherence to medications. This will be done after explaining the aims of research to patients and obtaining their signed consent.

This study has been approved by the Ministry of Health Committee for Facilitation of Medical Research and by Kuwait University.

If you have any questions about the project, please contact:

Fatima Jeragh Ahaddad

Mobile: 9441914; email: q8pharmacist@hotmail.com

ملخص و أهداف البحث (للقسم الثاني من البحث)

نسخة الدكتور المعالج

عزيزي الدكتور(أوالدكتورة) المعالج،

حسب التقارير العالمية من مختلف أنحاء و دول العالم يقدر بأن حوالي 30-50% من الأدوية المصروفة للمريض لا تؤخذ حسب تعليمات الطبيب، كما تشير منظمة الصحة العالمية (WHO) بأن مشكلة عدم التزام المرضى بالدواء تعد من أهم العوامل القابلة للتغيير التي تهدد علاج المريض.

إذا نظرنا إلى أبعاد المشكلة في مرضى السكري من النوع الثاني، فان النتائج المتوقعة هي تقدم المرض، سوء العواقب و حدوث مضاعفات المرض مما يترتب عليه تدهور في صحة المريض و هدر لأموال الدولة للصرف على هذه العواقب.

أنني باحثة من جامعة لندن (مدرسة الصيدلة) أهدف إلى تقدير حجم مشكلة عدم التزام المرضى بأخذ الدواء الخاص بمرض السكري النوع الثاني في الكويت.
نواتج هذا البحث ستفيدنا لعمل دراسة يقوم بها الصيدلي بأخذ خطوات فعلية من أجل تحسين التزام مرضى السكري بأخذ دوائهم.

تتكون الدراسة من التالي:
سنطلب من المرضى الذين حضروا لمواعيدهم في عيادة السكري الخارجية ملء استبيان قصير لتقدير مدى التزامهم بأخذ أدوية السكر التابعة لهم. بالطبع سيتم ذلك بعد شرح ملخص و أهداف الدراسة للمرضى و قيامهم بتوقيع إقرار موافقة على المشاركة بالبحث.

لقد تمت الموافقة على هذه الدراسة من قبل وزارة الصحة (اللجنة الدائمة لتنسيق البحوث الطبية و الصحية) و جامعة الكويت.
اذا كنت ترغب بمعلومات اضافية أو في حال وجود أي استفسار يرجى الاتصال بالباحثة الأساسية للبحث:

فاطمة جراغ الحداد (ماجستير صيدلة اكلينيكية، جامعة لندن)
نقال 9441914 بريد الكتروني q8pharmacist@hotmail.com

Appendix 7: Patient Information Leaflet and Consent Form for the Quantitative Study (English and Arabic versions)

Patient Information Leaflet

Purpose of the Study and Brief Description of the Process

Some patients may experience problems when taking their medications. To learn more about this, pharmacists at Kuwait University are working together with pharmacists at the School of Pharmacy in London on a research project to estimate the percentage of Kuwaiti patients with diabetes who do not take their medications as prescribed by their doctor. The results of this research will help us provide a better service for patients with diabetes in Kuwait.

If you choose to participate in the project, there will be 2 parts. First, we will ask you to spend about 15-20 minutes answering questions about your diabetes and your medications. Second, we will check your medical records for the results of your blood tests to see how controlled your diabetes is.

Your decision to participate in this research project is voluntary. You may decide not to take part in the project, or you may stop taking part at any time without affecting the health care you are receiving at this clinic. All the information you give us will be private and we won't include your name or any identifying information on any of the reports about this project. Also, the information you give us will not be part of your medical record or shared with your doctor or anyone else in the clinic.

This study has been approved by the Ministry of Health Committee for Facilitation of Medical Research and by Kuwait University. If you have any questions about the project, please contact:

If you are willing to participate, please fill in and sign the consent form attached.

The Consent Form

Title of Study: Nonadherence to Medications in Kuwaiti Patients with Type 2 Diabetes Mellitus

Name of Researcher: Fatima Jeragh Alhaddad, MSc. Clinical Pharmacy, International Practice and Policy, School of Pharmacy University of London.

Co-researchers: Prof. Nick Barber (School of Pharmacy, London), Dr. Tina Brock (School of Pharmacy, London), Dr. Mohammad Waheedi (Kuwait University)

The study has been explained to me and I understand:

1- What the study involves.
2- That relevant sections of my medical notes will be looked at by the researcher. I give permission for the researcher to have access to my records.
3- That refusal to participate will not affect my treatment in any way.
4- That I have the right to withdraw at any time.

I therefore agree to take part in the study

Name of the participant: .....

Date: .....

Signature: .....

ملخص و أهداف البحث (للقسم الثاني من البحث)

نسخة المريض

بعض المرضى قد يجدون صعوبة في أخذ أدويتهم حسب تعليمات الطبيب. للتعرف على أسباب هذه المشكلة نقوم نحن مجموعة من الصيادلة من جامعة لندن بالتعاون مع جامعة الكويت (كلية الصيدلة) بعمل دراسة تهدف إلى تقدير نسبة الكويتيين المصابين بمرض السكري من النوع الثاني الذي يواجهون صعوبة في أخذ أدويتهم لعلاج مرض السكري.

تهدف دراستنا إلى تقديم رعاية أفضل لمرضى السكري في الكويت و تشتمل التالي:

سنطلب منك تعبئة استبيان يحتوي على بعض الأسئلة المتعلقة بمرضك و بأدويتك (قد يستغرق الاستبيان 20-15 دقيقة) ، ثم سوف نطلب منك سؤال طبيبك المعالج عن بعض المعلومات المتعلقة بالمرض و فحوصاتك المخبرية لمعرفة مدى استقرار مرض السكر لديك.

بالطبع نحن نترك لك حرية الاختيار في المشاركة بهذه الدراسة أو الرفض، كما يمكنك الانسحاب من المشاركة بأي وقت لاحق إن شئت.

ان المعلومات التي ستدلي بها في هذه الدراسة ستكون سرية و ستستخدم فقط في نطاق البحث و ليس لأي أغراض أخرى، كما نضمن لك بأن مشاركتك بالدراسة لن تؤثر على مستوى الرعاية الصحية التي تتلقاها حيث لن يتم إفصاحها لأي شخص من المستشفى أو العيادة التي تتردد عليها للعلاج.

بالطبع مشاركتك معنا ستعتبر مكسبا لتحسين مستوى الرعاية الصحية و الصيدلانية لمرضى السكري في المستقبل.

لقد تمت الموافقة على هذه الدراسة من قبل وزارة الصحة (اللجنة الدائمة لتنسيق البحوث الطبية و الصحية) و جامعة الكويت.

إذا كنت ترغب بمعلومات إضافية أو في حال وجود أي استفسار يرجى الاتصال بالباحثة الأساسية للبحث:

فاطمة جراغ الحداد (ماجستير صيدلة اكلينيكية، جامعة لندن)

[redacted]

في حال الموافقة على المشاركة يرجى توقيع الإقرار على المشاركة

إقرار الموافقة على المشاركة بالدراسة

عنوان الدراسة: مدى التزام مرضى السكري من النوع الثاني بالكويت بأخذ أدوية السكري.

اسم الباحثة الأساسية: فاطمة جراغ الحداد (جامعة لندن، مدرسة الصيدلة).

الباحثون المشاركون: البروفيسور\ نك باربر (جامعة لندن، مدرسة الصيدلة)، الدكتورة\ تينا بروك (جامعة لندن، مدرسة الصيدلة)، الدكتور\ محمد وحيدي (جامعة الكويت، كلية الصيدلة).

لقد تم شرح الدراسة لي بشكل وافي و أنا أوافق على المشاركة بهذه الدراسة:

اسم المشترك:.....

التاريخ:.....

التوقيع:.....

Appendix 8: Data Abstraction form

Data to be asked from the doctor by the research participant

Patient file no:.....

Type of diabetes:.....

Duration of diabetes:.....

Current medications <u>prescribed for diabetes</u> and dosage regimen:

.....

.....

.....

(Here I will list the medications and dosage regimens as reported by the patient and the doctor will only confirm the list)

Latest HbA1c level: .....**date of measurement:**.....

Appendix 9: The Questionnaire Instrument (English and Arabic versions)

The School of Pharmacy
University of London

Patients' views about their diabetes medications

Information about yourself

Are you: ☐ Male ☐ Female **What's your year of birth?** 19.....

Health care center providing your diabetes care: .....

Which best describes you?

☐ Employed (full/part-time/self-employed)

☐ Unemployed

☐ Unable to work due to illness

☐ Doing voluntary work

☐ Looking after your home/family

☐ Retired from paid work

☐ At school or in full-time education

☐ Other (please describe).....

Did your education continue after the minimum school-leaving age?

☐ Yes ☐ No

Do you have a degree or equivalent professional qualification?

☐ Yes ☐ No

Information about your treatment

Are you on: □diabetes tablets □insulin □ both

How many diabetes tablets do you take per day in total?.....

Apart from you diabetes, do you have any other disease (please specify)?.....

How many other medication tablets are you currently taking?.....

How long have you been taking diabetes medications? Since 19.....

How long have you been a diabetic? Since 19.....

Do you have any of the diabetes complications (e.g. eye damage, nerve damage, kidney damage, heart disease)? .....

Other information

Dates of the last 6 appointments attended

....,....,....,....,....,.....

Your latest HbA1c level..... Date measured.....

	Diabetes medications currently prescribed	Dosage
	Glucophage® (metformin)	.....
	Daonil® (glibenclamide)	.....
	Diamicron MR® (gliclazide)	.....
	NovoNorm® (repaglinide)	.....
	Avandia® (rosiglitazone)	.....
	Glucobay® (acarbose)	.....
	Amaryl® (glimepiride)	.....
	Minidiab® (glipizide)	.....
	Insulin	.....
	Other – please state:	.....

Your views about your diabetes medications only

	Statements others have made	Agree Strongly	Agree	Uncertain	Disagree	Disagree Strongly
*N1	My health at present depends on this medicine					
*C1	Having to take these medicines worries me					
*N2	My medication controls my diabetes					
*C2	I sometimes worry about the long-term effects of these medicines					
*N3	Without this medicine I would be very ill					
*C3	Diabetes medications are a mystery to me					
*N4	My health in the future depends on this medicine					
*C4	These medicines disrupt my life					
*N5	My medications prevent my blood sugar from becoming too high					
*C5	I sometimes worry about becoming too dependent on these medicines					
N6R	These medicines are less important than other parts of my treatment					
C6	These medicines give me unpleasant side-effects					
N7	I understand why I need to control my blood glucose levels					
C7	I am concerned that taking these medicines regularly will make them less effective in the future					
N8	These medicines effectively control my blood glucose levels					
C8	I worry about how many tablets I need to take to manage my blood glucose levels					
N9	Controlling blood glucose levels is essential for my health					
C9	Having to take these tablets is a big hassle for me					
N10	Keeping my heart healthy in the future will depend on this medicine					

Your views about medicines in general

	Statements others have made	Agree Strongly	Agree	Uncertain	Disagree	Disagree Strongly
BG1	Doctors use too many medicines					
BG2	People who take medicines should stop their treatment for a while every now and again					
BG9	Medicines help many people to live better lives					
BG3	Most medicines are addictive					
BG4	Natural remedies are safer than medicines (e.g. herbs, accupunture, etc.)					
BG11	In most cases the benefits of medicines outweigh the risks					
BG10	In the future medicines will be developed to cure most diseases					
BG6	Most medicines are poisons					
BG5	Medicines do more harm than good					
BG12	Medicines help many people to live longer					
BG7	Doctors place too much trust in medicines					
BG8	If doctors had more time with patients they would prescribe fewer medicines					

Using your diabetes medication

People often miss taking doses of their medicines, for a whole range of reasons. Thinking of the medicines that you take for diabetes (which are_ _ _ _ _ _ _ _ _ _ _ _), When was the last time you missed taking a dose of this medicine(s)?

[ ] days ago [ ] never

If less than 7 days ago:

On how many occasions over the past week have you missed doses of this/these medicine(s)?

[ ] times

On the occasions that you have missed taking doses, why did you miss these doses? *(probe for reasons)*

.....
.....
.....

Many people find a **way of using their diabetes medication** that suits them. This may differ from the instructions on the label or from what their doctor has said. Below are some ways in which other people have said they use their medicines. For each of the statements, **please tick the box that best applies to you. There are no right or wrong answers. We are just interested in your personal views.**

		Never	Rarely	Sometimes	Often	Always
*M1	I forget to take them					
*M2	I alter the dose					
*M3	I stop taking them for a while					
*M4	I decide to miss out a dose					
*M5	I take less than instructed					

Your diabetes self-care activities

Diet

- Do you follow a healthy diet plan for your diabetes? □ Yes □ No
- If yes, over the last three months, to what extent have you followed a healthy diet plan?

  □ Never □Rarely □Sometimes □Often □Always

- If no, what are the reasons or barriers which prevented you?

  .....

Exercise

- Do you exercise regularly for your diabetes? □ Yes □ No
- If yes, over the last three months, to what extent have you exercised regularly?

  □ Never □Rarely □Sometimes □Often □Always

- If no, what are the reasons or barriers which prevented you?

  .....

Self Blood Sugar Monitoring

- Do you monitor your blood sugar levels? □ Yes □ No
- If yes, over the last three months, to what extent have you self-monitored your blood sugar levels regularly?

  □ Never □Rarely □Sometimes □Often □Always

- If no, what are the reasons or barriers which prevented you?

  .....

Foot Care

- Do you usually check your feet? □ Yes □ No
- If yes, over the last three months, to what extent have you checked your feet regularly?

  □ Never □Rarely □Sometimes □Often □Always

- If no, what are the reasons or barriers which prevented you?

  .....

Smoking

- Do you smoke? □ Yes □ No
- If yes, what is your daily average of smoking?.....

About your doctor and health care team

(over the last three months)

		Never	To a little extent	To a certain extent	To a good extent	To a great extent
1	Has your doctor or other health advisor (nurse, dietician) clearly explained what you needed to do to manage your illness? (*If you have not had any doctor visits in the past 3 months, think back to the last visit you had.*	1	2	3	4	5
2	Has your doctor or other health advisor provided support between visits such as phone calls, reminder letters, or newsletters?	1	2	3	4	5
3	Has your doctor involved you as an equal partner in making decisions about illness management strategies and goals?	1	2	3	4	5
4	Has your doctor or other health care advisor listened carefully to what you had to say about your illness?	1	2	3	4	5
5	Has your doctor or other health advisor (nurse, dietician) answered your questions and addressed your concerns during office visits?	1	2	3	4	5
6	Has your doctor or other health care provider thoroughly explained the results of tests you had done (e.g., cholesterol, blood pressure, or other laboratory tests)?	1	2	3	4	5

Your personal views, preferences

	Opinions expressed by patients with diabetes	Strongly agree	Agree	To a certain extent	Disagree	Strongly disagree
1	The ministry of health provides the appropriate types of medicines for diabetic patients	1	2	3	4	5
2	When I'm traveling or when I'm away from home I change the way I take my medications	1	2	3	4	5
3	I avoid taking my medications in situations where others can see me (e.g. family or friends)	1	2	3	4	5
4	My friends or family help make sure I take my medications properly	1	2	3	4	5
5	The pharmacist plays a role in educating me about my medications	1	2	3	4	5
6	The pharmacist provides me with enough information about my medications	1	2	3	4	5
7	The media, such as radio and TV programmes constitute an important resource for educating me about my illness and medications	1	2	3	4	5
8	Adhering to diet is more difficult and problematic than adherence to my diabetes medications	1	2	3	4	5
9	Adhering to exercise is more difficult and problematic than adherence to my diabetes medications	1	2	3	4	5
10	I don't trust Western medications; I believe they are poisons promoted to us by the West.	1	2	3	4	5
11	Other people's experience and advice affect the way I manage my diabetes.	1	2	3	4	5
12	Lack of organization/coordination within the healthcare system diminishes the level of services provided for patients with diabetes	1	2	3	4	5

In the end, is there anything you would like to say about your diabetes medicines?

.....
.....
.....

Thank you very much for your participation

The School of Pharmacy
University of London

أراء المرضى حول أدوية داء السكري الخاصة بهم

معلوماتك الشخصية

الرجاء وضع علامة ☑ عند المربع المناسب.

هل أنت **ما هي سنة ميلادك؟**

☐ ذكر ١٩

☐ أنثى

مكان الرعاية الصحية لعلاج داء السكري:.....

ما أقرب ما يصف وضعك الوظيفي؟

☐ موظف (دوام كامل\دوام جزئي\تعمل لحسابك الخاص)

☐ عاطل عن العمل

☐ غير قادر على العمل لسبب طبي

☐ متطوع

☐ رب أو ربة بيت

☐ متقاعد

☐ طالب أو طالبة

☐ أخر (الرجاء الذكر).....

هل واصلت تعليمك بعد اكمال الحد القانوني الأدنى للتعليم؟

☐ نعم ☐ لا

هل لديك شهادة علمية أو ما يعادلها من المؤهلات؟

☐ نعم ☐ لا

معلومات حول علاجك

هل تستخدم؟ ☐ حبوب السكر ☐ ابر أنسولين ☐ حبوب سكر و ابر أنسولين معا

كم مجموع عدد حبوب داء السكري التي تأخذها باليوم الواحد؟ .....

هل تعاني من أمراض أخرى غير داء السكري (الرجاء ذكرها)؟

.....

كم عدد حبوب الأدوية الأخرى التي تأخذها في الوقت الحالي؟ .....

منذ متى و انت تأخذ أدوية داء السكري؟ .....

منذ متى و انت مصاب بداء السكري؟ .....

هل تعاني من مضاعفات داء السكري (مثل اصابة شبكية العين، الأعصاب الطرفية، الكليتين، أمراض القلب)؟.....

معلومات أخرى

تواريخ آخر 6 مراجعات قمت بها للطبيب

.....،.....،.....،.....،.....،.....

أحدث قراءة لمعدل السكر التجسسي HbA1c..... **بتاريخ**.....

	أدوية داء السكري المصروفة لك	الجرعة
	جلوكوفاج® (ميتفورمين) Glucophage® (metformin)	.....
	داونيل® (جليبينكلامايد) Daonil® (glibenclamide)	.....
	دايمكرون ام ار® (جليكلازايد) Diamicron MR® (gliclazide)	.....
	نوفونورم® (ريباجلينايد) NovoNorm® (repaglinide)	.....
	أفانديا® (روسيجليتازون) Avandia® (rosiglitazone)	.....
	جلوكوباي® (أكاربوز) Glucobay® (acarbose)	.....
	أماريل® (جليمبيرايد) Amaryl® (glimepiride)	.....
	ميني دايابَ® (جليبيزايد) Minidiab® (glipizide)	.....
	انسولين Insulin	.....
	دواء أخر- الرجاء ذكره.....	.....

آراؤك حول أدويتك الخاصة بداء السكري فقط

	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					
N6R	هذه الأدوية أقل أهمية من نظم العلاج الأخرى المصروفة لي (مثل الحمية الغذائية، الرياضة...الخ)					
C6	تسبب لي هذه الأدوية أعراض جانبية مزعجة					
N7	أدرك مدى حاجتي لضبط مستوى السكر بالدم					
C7	أنا قلق من أن أخذ هذه الأدوية بانتظام سيقلل من فعاليتها في المستقبل					
N8	تنظم هذه الأدوية مستوى السكر بدمي بشكل فعال					
C8	أنا قلق من كمية الحبوب التي يجب علي تناولها لتنظيم مستوى السكر بدمي					
N9	تنظيم مستوى السكر بالدم شيء أساسي للحفاظ على صحتي					
C9	ضرورة تناول هذه الحبوب تشكل عقبة كبيرة بالنسبة لي					
N10	إبقاء أعضاء جسدي سليمة في المستقبل (مثلا الكلية، العينين، أعصاب القدم...الخ) يعتمد على تناول هذه الأدوية					

آراؤك حول الأدوية بشكل عام (و ليس بالضرورة أدوية داء السكر)

	عبارات رددها الغير	أوافق بشدة	أوافق	غير واثق	أعترض	أعترض بشدة
GO1	يستخدم الأطباء الأدوية بكثرة					
GH1	يجب على الناس الذين يتناولون أدوية أن يتوقفوا عن استخدامها لفترة من حين إلى حين					
GB3	تساعد الأدوية الكثير من الناس لعيش حياة أفضل					
GH2	أغلب الأدوية تسبب الإدمان					
GO2	استخدام الطب البديل أو الأعشاب (كالوصفات الطبيعية، الإبر الصينية...الخ) أكثر أمانا من الأدوية					
GB1	تفوق فوائد الأدوية مخاطرها في أغلب الأحيان					
GB2	سيتم تطوير أدوية لعلاج غالبية الأمراض في المستقبل					
GH3	أغلب الأدوية عبارة عن سموم					
GH4	الأدوية تضر أكثر مما تنفع					
GB4	تساعد الأدوية الكثير من الناس لعيش حياة أطول					
GO3	يثق الأطباء بالأدوية أكثر من اللزوم					
GO4	لو أعطى الأطباء وقت أطول للمرضى لقللوا من الأدوية المصروفة لهم					

استخدام أدويتك الخاصة بداء السكري

غالبا ما يفوّت الناس أخذ جرعات من أدويتهم لأسباب عديدة. بالنسبة لأدويتك الخاصة بداء السكري فقط (التي هي.....) متى كانت آخر مرة لم تأخذ بها جرعة من دوائك\أدويتك؟

☐ قبل (.....) أيام ☐ و لا مرة

إذا كانت هذه المرة قبل أقل من 7 أيام:
خلال الأسبوع الماضي كم مرة فوّت بها أخذ جرعة من دوائك\أدويتك؟.....مرات

في المرات التي فوّت بها أخذ جرعة\جرعات من الدواء، ما الأسباب التي أدّت إلى ذلك؟

.....

.....

.....

- يتبع العديد من الناس **طريقة تناسبهم لأخذ أدويتهم الخاصة بداء السكر** تختلف عن التعليمات المطبوعة أو الموصوفة من الطبيب المعالج.
- في الأسفل ستجد بعض الطرق التي ذكرها بعض المرضى عن طريقة استخدامهم لأدويتهم، **لكل عبارة من العبارات يرجى وضع علامة ☑ أمام المربع المناسب حسب ما تنطبق عليك.**

ليس هناك إجابة صحيحة أو خاطئة، كل ما يهمنا هو رأيك الشخصي فقط.

		أبدا	نادرا	أحيانا	غالبا	دائما
*M1	أنسى أخذ الدواء					
*M2	أغير في الجرعة					
*M3	أتوقف عن أخذ الأدوية لفترة					
*M4	أقرر إلغاء جرعة					
*M5	أتناول كمية أقل مما وصف الطبيب					

النشاطات الشخصية التي تتبعها لمعالجة داء السكري

الحمية الغذائية

- هل تتبع نظام حمية غذائية صحية لمواجهة داء السكري؟ ☐نعم ☐ لا
- في حال نعم، إلى أي مدى خلال الثلاث شهور الماضية اتبعت حمية غذائية صحية؟

أبدا	نادرا	أحيانا	غالبا	دائما

- في حال لا، ما الأسباب أو المعوقات التي أدت إلى ذلك؟

.....

النشاط الرياضي

- هل تقوم بأي نشاط رياضي منتظم لمواجهة داء السكري؟☐نعم ☐ لا
- في حال نعم، إلى أي مدى خلال الثلاث شهور الماضية اتبعت بنشاط رياضي منتظم؟

أبدا	نادرا	أحيانا	غالبا	دائما

- في حال لا، ما الأسباب أو المعوقات التي أدت إلى ذلك؟

.....

الفحص الشخصي لمستوى السكر بالدم

- هل تقوم بالفحص الشخصي لمستوى السكر بالدم؟☐نعم ☐ لا
- في حال نعم، إلى أي مدى خلال الثلاث شهور الماضية قمت بالفحص الشخصي لمستوى السكر بالدم؟

أبدا	نادرا	أحيانا	غالبا	دائما

- في حال لا، ما الأسباب أو المعوقات التي أدت إلى ذلك؟

.....

رعاية القدم

- هل تقوم بفحص قدميك عادة؟☐نعم ☐ لا
- في حال نعم، إلى أي مدى خلال الثلاث شهور الماضية قمت بفحص قدميك بشكل منتظم؟

أبدا	نادرا	أحيانا	غالبا	دائما

- في حال لا، ما الأسباب أو المعوقات التي أدت إلى ذلك؟

.....

التدخين

- هل انت مدخن؟☐نعم ☐ لا
- في حال نعم، ما معدل تدخينك اليومي؟.....

طبيبك وفريق الرعاية الصحية (خلال الثلاث شهور الماضية)

		اطلاقا		الى حد ما		إلى حد كبير
١	هل شرح لك طبيبك أو غيره من الفريق الطبي المعالج (مثل الممرضة أو أخصائيي التغذية) بوضوح ما يجب عليك القيام به للسيطرة على مرضك؟ *(إذا كنت لم تقم بمراجعة الطبيب خلال الثلاث أشهر الماضية، ارجع بالذاكرة إلى آخر مرة قمت بها بمراجعة الطبيب)*	١	٢	٣	٤	٥
٢	هل قدم لك طبيبك أو غيره من الفريق الطبي المعالج وسائل الدعم بين مواعيد مراجعتك (مثل الاتصالات الهاتفية، تذكير بالمواعيد، أو إرسال كتيبات تحوي على أية معلومات)؟	١	٢	٣	٤	٥
٣	هل سمح لك الطبيب بالمساهمة بشكل متساو معه في أخذ القرارات التي تختص بطرق علاج المرض و أهداف العلاج؟	١	٢	٣	٤	٥
٤	هل قام طبيبك أو غيره من الفريق الطبي المعالج بالإصغاء باهتمام إلى حديثك بخصوص مرضك؟	١	٢	٣	٤	٥
٥	هل قام طبيبك أو غيره من الفريق الطبي المعالج (مثل الممرضة أو أخصائيي التغذية) بالاجابة على أسئلتك و كل ما يقلقك خلال وقت المراجعة؟	١	٢	٣	٤	٥
٦	هل قام طبيبك أو غيره من الفريق الطبي المعالج بشرح نتائج تحاليلك المخبرية بشكل واف (مثل فحوصات الكوليستيرول، ضغط الدم، و غيرها من التحاليل المخبرية)؟	١	٢	٣	٤	٥

آرائك و تفضيلاتك الشخصية

	أراء بعض المصابين بداء السكري	أوافق بشدة	أوافق	إلى حد ما	أعترض	أعترض بشدة
١	توفر وزارة الصحة أنواع الأدوية المناسبة لمرضى داء السكري	١	٢	٣	٤	٥
٢	أغير في طريقة استخدامي لأدويتي عندما أسافر أو أبتعد عن المنزل	١	٢	٣	٤	٥
٣	أتجنب أخذ أدويتي على مرأى من الغير(مثلا الأهل أو الأصدقاء)	١	٢	٣	٤	٥
٤	يساعدني الأهل أو الأصدقاء على أخذ أدويتي كما يجب	١	٢	٣	٤	٥
٥	للصيدلاني دور في توعيتي عن أدويتي	١	٢	٣	٤	٥
٦	يقدم الصيدلاني معلومات كافية لي بخصوص أدويتي	١	٢	٣	٤	٥
٧	تشكل وسائل الإعلام مثل الراديو أو برامج التلفيزيون مصدرا أساسيا في توعيتي عن مرضي أو أدويتي	١	٢	٣	٤	٥
٨	الالتزام بالنظام الغذائي يشكل عبء أكبر و أصعب من الالتزام بأدوية السكر بالنسبة لي	١	٢	٣	٤	٥
٩	الالتزام بالرياضة يشكل عبء أكبر و أصعب من الالتزام بأدوية السكر بالنسبة لي	١	٢	٣	٤	٥
١٠	أنا لا أثق بالأدوية الغربية و أعتقد بأنها سموم تصدر إلينا من دول الغرب	١	٢	٣	٤	٥
١١	تؤثر نصيحة و خبرة غيري من المصابين بداء السكري في طريقة معالجتي لمرضي	١	٢	٣	٤	٥
١٢	سوء التنظيم في النظام الصحي بالكويت يضعف مستوى الخدمات الصحية المتوفرة لمرضى داء السكري	١	٢	٣	٤	٥

في النهاية، هل هناك ما تود قوله بخصوص أدويتك الخاصة بداء السكر؟

.....

.....

.....

شكرا جزيلا لك على المشاركة