# ECONOMIC AND BEHAVIOURAL ASSESSMENT OF A DIABETES SELF-MANAGEMENT EDUCATION PROGRAMME AMONG TYPE 2 DIABETES PATIENTS AT DIABETES CENTRE IN RIYADH, SAUDI ARABIA

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# ECONOMIC AND BEHAVIOURAL ASSESSMENT OF A DIABETES SELF-MANAGEMENT EDUCATION PROGRAMME AMONG TYPE 2 DIABETES PATIENTS AT DIABETES CENTRE IN RIYADH, SAUDI ARABIA

**by**

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| | |
|---|---|
| A/E DMSES | Australian English diabetes management self-efficacy scale |
| BC | Basic Care |
| BMI | Body Mass Index |
| CAD | Coronary Artery Disease |
| CEA | Cost-Effectiveness Analysis |
| CERs | Cost-Effectiveness Ratios |
| CHD | Coronary Heart Disease |
| CHWs | Community Health Workers |
| DBP | Diastolic Blood Pressure |
| DM | Diabetes mellitus |
| DMSES | Diabetes Management Self-efficacy Scale |
| DSME | Diabetes Self-Management Education |
| ESRD | End Stage Renal Disease |
| EQ-5D | European Quality of Life -5 –Dimensions |
| EQ-Vas | European Quality of Life Visual Analogue Scale |
| FPG | Fasting Plasma Glucose |
| GDM | Gestational Diabetes Mellitus |
| GDP | Gross Domestic Product |
| HbA1c | glycosylated haemoglobin |
| HBM | Health Belief Model |
| HCV | Hepatitis C virus |

| | |
|---|---|
| HDL-C | High-Density Lipoprotein-Cholesterol |
| HRQoL | Health Related Quality of Life |
| ICER | Incremental Cost-Effectiveness Ratio |
| IDF | International Diabetes Federation |
| IGT | Impaired Glucose Tolerance |
| IMB | Information Motivation Behavioural Skills |
| IRB | Institutional Review Board |
| ISRFNCD | Iranian Surveillance Of Risk Factors Of Non-Communicable Disease |
| KSA | Kingdom of Saudi Arabia |
| LDL-C | Low-Density Lipoprotein-Cholesterol |
| MAU | A Multi Attribute Utility |
| MDKT | Michigan Diabetic Knowledge Test |
| MDRTC | Michigan Diabetes Research and Training Centre |
| MNT | Medical Nutrition Therapy |
| NCDEG | National Centre of Diabetes, Endocrinology and Genetics |
| OGT | Oral Glucose Tolerance |
| PDA | Personal Digital Assistant |
| PE | Patient Education |
| PGC | Practice Guideline Care |
| PHC | Primary Healthcare Centres |
| QALY | Cost Per Quality-Adjusted Life-Year |
| SBP | Systolic Blood Pressure |

| | |
|---|---|
| SDSCA | Summary Of The Diabetes Self-care Activities Scale |
| TC | Total Cholesterol |
| TG | Triglyceride |
| The AADE | American Association of Diabetes Educators |
| UKPDS | United Kingdom Prospective Diabetes Study |
| WHO | World Health Organization |

## LIST OF APPENDICES

**PENILAIAN EKONOMI DAN PERLAKUAN DARIPADA PROGRAM PENDIDIKAN PENGURUSAN-DIRI DIABETES DALAM KALANGAN PESAKIT DIABETES JENIS 2 YANG MENGHADIRI PUSAT DIABETES AWAM DI RIYADH, SAUDI ARABIA**

## ABSTRAK

Prevalens diabetes mellitus meningkat secara mendadak dalam kalangan populasi Arab Saudi sejak beberapa dekad yang lalu, yang secara tidak langsung menjadi beban ekonomi utama terhadap sistem penjagaan kesihatan. Justeru, objektif kajian ini adalah untuk menilai keberkesanan program Pendidikan Pengurusan-Diri Diabetes (Diabetes Self-Management Education, DSME) dalam usaha meningkatkan natijah atau keputusan klinikal, perlakuan penjagaan-diri dan kualiti hidup. Di samping itu, kajian ini juga berobjektif melaksanakan penilaian ekonomi DSME dalam kalangan pesakit diabetes jenis 2. Kajian ini dijalankan di Pusat Diabetes King Abdulaziz Hospital Universiti, Riyadh, Arab Saudi. Kajian ini melibatkan tiga fasa, iaitu analisis keratan rentas daripada pemboleh ubah atau variabel kajian, praintervensi dan pascaintervensi, dan pendidikan ekonomi. Data diperoleh daripada semakan semula ringkasan Skala Aktiviti Penjagaan-Diri Diabetes (Diabetes Self-care Activities Scale, SDSCA), Skala Kecekapan-Diri Pengurusan Diabetes (Diabetes Management Self-efficacy Scale, DMSES), dan Ujian Pengetahuan Diabetes Michigan (Michigan Diabetes Knowledge Test (MDKT). EQ-5D digunakan bagi penilaian kualiti hidup. Min skor EQ-5D dalam kalangan pesakit diabetes jenis 2 adalah 0.71, min skor MDKT adalah 8.96 ± 2.1, dan purata skor atitud adalah 6.38

± 2.11. Min skor kecekapan-diri total adalah 6.97 ± 1.49 dan min skor perlakuan penjagaan-diri total adalah 3.64 ± 1.06. Korelasi linear menunjukkan bahawa subskala diri adalah peramal (predictor) yang signifikan daripada perlakuan penjagaan diri masing-masing. Kecekapan-diri bagi pemantauan gula darah adalah peramal yang sangat kuat terhadap kawalan glisemik. Bagi fasa intervensi, seramai 75 orang pesakit diabetes jenis 2 terlibat sama dari April 2012 hingga Julai 2012. Setiap pesakit menjalani susulan selama tiga bulan dengan pengukuhan pada bulan keenam intervensi. Sesi bagi setiap kumpulan dijalankan selama lima hari berturut-turut, dengan kehadiran pesakit lelaki dan perempuan adalah secara berasingan. Kajian intervensi menunjukkan suatu peningkatan yang signifkan pada tahap HbA1 ($p < 0.001$) dan pengurangan dalam BMI, HDL-C, SBP dan DBP daripada garis dasar bagi susulan pascaintervensi. Terdapat peningkatan yang signifikan dalam skor kecekapan-diri total ($p = 0.004$) dan skor perlakuan penjagaan-diri ($p = 0.012$). Kajian semasa menunjukkan bahawa kos total yang diperlukan oleh kumpulan intervensi adalah Saudi Riyal (SAR) 1351.38, yang lebih rendah daripada kos bagi kumpulan kawalan, iaitu sebanyak SAR 1933.59 bagi setiap peserta selama enam bulan kajian. ICER per unit penambahbaikan dalam serum TC dan tahap LDL-C adalah 0.14 dan 0.17 (<1.0 GDP per kapita), masing-masing. Hal ini menunjukkan bahawa program DSME adalah suatu kaedah berkesan-kos bagi menambah baik tahap TC dan LDL-C dari perspektif penyedia penjagaan kesihatan adalah berkesan-kos jika dilaksanakan di Arab Saudi.

**ECONOMIC AND BEHAVIOURAL ASSESSMENT OF A DIABETES SELF-MANAGEMENT EDUCATION PROGRAMME AMONG TYPE 2 DIABETES PATIENTS AT DIABETES CENTRE IN RIYADH, SAUDI ARABIA**

## ABSTRACT

The prevalence of diabetes mellitus has increased tremendously among the Saudi population during the last decade. This represent as a major economic burden in health care system. The objective was to evaluate the effectiveness of the Diabetes Self-Management Education (DSME) programme in improving clinical outcomes, self-care behaviours and Health Related Quality of Life and to perform an economic evaluation of DSME on health status in type 2 diabetes patients at the Diabetic Centre in King Abdulaziz University Hospital, Riyadh, Saudi Arabia. The study include three phases a cross sectional, pre and post interventional and economic study. The data were obtained by using questionnaires completed during face-to-face interviews. The revised summary of the Diabetes Self-care Activities Scale (SDSCA), the Diabetes Management self-efficacy Scale (DMSES), the University of Michigan Diabetes Research and Training Centre (MDRTC) knowledge test and the diabetic care profile of the University of Michigan were used to measure attitudes towards diabetes. The Health Related Quality of Life was assessed at baseline using The Quality of Life scale (EQ-5D). In cross sectional descriptive study, the mean of EQ-5D score in type 2 diabetic patients was 0.71, which is considered a moderately low score. The mean score of the MDKT was 8.96 ± 2.1, indicating that overall, the patients had moderate knowledge about diabetes. The average attitude score

of all respondents in this study was overall, positive of 6.38 ± 2.11. The mean scores of total self-efficacy were moderately low, at 6.97 ± 1.49 of 10.00 as the maximum score. The mean scores of the total self-care behaviours were low, at 3.64 ± 1.06 of 7.00 as the maximum score. Linear correlations showed that self-efficacy subscales were significant predictors of their respective self-care behaviours. The self-efficacy for blood sugar monitoring seemed to be a stronger predictor of glycaemic control. A total of 75 type 2 diabetes patients were enrolled from April 2012 to July 2012 (over four months) as a baseline study and each patient was followed up for three months with reinforcement and at six months after intervention. Group sessions were conducted for five consecutive days with males and females attending separately. The interventional study revealed a significant improvement in HbA1c levels ($p < 0.001$) and reduction in BMI, HDL-C, SBP and DBP from baseline to post-intervention follow-up. There is also a significant increase in the total self-efficacy ($p = 0.004$) and the total self-care behaviours scores ($p = 0.012$). The present study demonstrated that the total cost incurred by the intervention group was Saudi Riyal (SAR) 1351.385, which was lower than the cost incurred by the control group (SAR 1933.596) per participant over the 6-month study period. The ICER per unit improvement in serum TC and LDL-C levels were 0.14 and 0.17 (<1.0 GDP per capita in Saudi Arabia), respectively indicating that the DSME programme as a highly cost-effective method of improving TC and LDL-C levels from the perspective of health care providers that would be cost-effective if implemented in Saudi Arabia.

# CHAPTER 1

# INTRODUCTION

## 1.1 Background of the study

Diabetes refers to a group of metabolic diseases characterized by chronic hyperglycaemia that results from defects in insulin secretion, insulin action, or both. The autoimmune destruction of pancreatic β-cells is one of the pathogenic processes that cause the development of diabetes. This disease is associated with disturbance in carbohydrate, fat and protein metabolism caused by the deficient insulin action on target tissues. Deficient insulin action results from inadequate insulin secretion (American Diabetes Association, 2014a). Type 2 diabetes, or non-insulin-dependent diabetes, is one of the 3 types of diabetes and affects 90-95% of diabetic patients (American Diabetes Association, 2014a).

Diabetes is the most common chronic endocrine disorder, affecting around 5–10% of the adult population in industrialized countries throughout the world (Wild, Roglic, Green, Sicree, & King, 2004). The International Diabetes Federation (IDF) has estimated that 246 million adults had diabetes at 2007 in the seven regions of the IDF. This value had increased by 52 million from that of 2003, and the number is projected to increase to 380 million by 2025 (International Diabetes Federation, 2013).

In the Kingdom of Saudi Arabia, rapid economic growth during the last four decades and urbanization have led to changes in lifestyle characterized by unhealthy diets and diminished physical activity; accordingly, the prevalence of diabetes has continually risen over the last two decades, representing a major clinical and public health problem (Alqurashi, Aljabri, & Bokhari, 2011). In the late 1970s and early 1980s, the prevalence

of diabetes in Saudi Arabia was similar to that in other countries. In the last three decades, diabetes has become an epidemic chronic disease in Saudi Arabia (Elhadd, Al-Amoudi, & Alzahrani, 2007).

Improvements in socioeconomic status and urbanization, which are related to rapid changes in lifestyle, diet, obesity, and physical activity, are important risk factors for diabetes. Accordingly, in most developing countries, the prevalence of diabetes is two-fold higher in urban areas than in rural areas (King & Rewers, 1993).

There are many barriers to optimal diabetic care; these include educational barriers, including lack of knowledge and low awareness of services. External physical barriers, such as poor quality of services and inappropriate diabetic care, also play a role in diabetic care. Psychosocial barriers include a lack of public awareness, a lack of community support and psychological factors such as health beliefs, poor motivation, low self-efficacy and emotional stress (Simmons, 2001).

Quality of Life is an important health outcome that is assessed via measures of social functioning and perceived physical and mental well-being (Testa & Simonson, 1996). Accordingly, effective health education programmes based on increasing diabetes awareness, promoting behavioural changes and overcoming all barriers are needed for optimal diabetes management, which in turn will lead to improvements in health outcomes and Quality of Life (Al-Shehri, Taha, Bahnassy, & Salahc, 2008). In general, the Quality of Life of an individual with diabetes is worse than that of a similar age person without diabetes, and an increase in the number of complications is associated with a poorer Quality of Life (Grandy & Fox, 2008; Holmes et al., 2000).

The economic burden of diabetes for patients and for society is tremendous. The IDF has reported that expenditures for diabetes care has increased, constituting 11.6% of all health care expenditures in 2010 (International Diabetes Federation, 2008). In the Middle East, the economic burden of diabetes has risen consistently with the increased prevalence of diabetes (Al-Maatouq et al., 2010), and the majority of diabetes-related costs are due to complications of the disease (Gray et al., 2000).

Among the most important educational approaches for diabetic patients are diabetes self-management education (DSME) programmes, which are an essential part of diabetes care (International Diabetes Federation, 2013). Studies have demonstrated that didactic approaches for educating diabetic patients should not be supported (Steed et al., 2005); effective education for type 2 diabetes patients has been shown to incorporate DSME (Rickheim, 2002).

The AADE7$^{TM}$ Self-care Behaviours form the framework for diabetes education. These behaviours include healthy eating, physical activity, medication consumption, blood sugar monitoring, problem solving, reduction of chronic and acute complications and healthy coping; all of these behaviours are essential for successful and effective diabetic self-management (Austin, 2006). Thus, diabetic education that focuses on these seven self-care behaviours is important for improving health status and Quality of Life (American Association of Diabetes Educators, 2008).

## 1.2 Problem statement

The prevalence of diabetes in the Saudi population has increased significantly to approximately 23.7%, which is one of the highest rates in the world (Al-Nozha et al., 2004) and almost one in every 11 Saudi people had been diagnosed with diabetes. This prevalence is set to increase to one in five by 2020 if the current prevalence rate continues without change over time and there is no adoption of diabetes education programmes (Alhowaish, 2013); moreover, the WHO has estimated that the prevalence of diabetes in the Middle East will be the highest in the world by the year 2030, increasingly by 163% (Wild et al., 2004). In addition, the prevalence of multiple diabetic complications such as cardiovascular disease is extremely high, and the progression of End Stage Renal Disease (ESRD) is rapid. Moreover, all of these factors lead to an overwhelming economic burden because of the consumption of the majority of health care economic resources by diabetic patients (Jamal, Durdana, Al Suwaida Abdulkaraem, Nawaz, & Fathia, 2009); and patients with diabetes account for 2.6% of all hospital admissions and 3.5% of all hospital stays in Saudi Arabia. The cost of diabetes was approximately $0.9 billion of the total healthcare expenditure in 2010, which accounts for ten times more expenditure than for people without diabetes (Alhowaish, 2013).

In the last three decades, diabetes mellitus has become an epidemic disease in Saudi Arabia as a consequence of the development and socio-economic transformation of the country during that time from a tribal and nomadic to a modern lifestyle, which in turn has led to changes in dietary habits and a high prevalence of obesity due to reduced physical activity (Azab, 2001; Elhadd et al., 2007).

The lack of proper diabetes education and awareness programmes in Saudi Arabia exacerbates gaps in knowledge and inadequacies in compliance, and also inadequacies in self-management which affects glycaemic control (Saadia, Rushdi, Alsheha, Saeed, & Rajab, 2010; Uddin, Ahmad, Kurkuman, & Iftikhar, 2001). Because this lack of literacy is more prevalent among uneducated and older people (Al-Baghli, Al-Ghamdi, et al., 2010; Midhet, Al-Mohaimeed, & Sharaf, 2010), therefore, improving knowledge of diabetes in will not be an easy task.

Most diabetic patients are unaware of their disease status, which leads to poor glycaemic control and more complications, resulting in decreased productivity; consequently, Saudi Arabia has an urgent need for structured programmes to educate the public and improve awareness about diabetes and its complications to improve Quality of Life and control diabetes (Al-Nozha et al., 2004; Amer, Attia, Ahmed, & Mohammad, 2008; Azab, 2001; El-Hazmi, Warsy, Al-Swailem, Al-Swailem, & Sulaimani, 1998).

### 1.3 Rationale of study

The prevalence of diabetes in Middle East countries is much higher than that in other parts of the world, and it is projected to more than double by 2025 (International Diabetes Federation, 2013). Moreover, the WHO projects that the number of diabetic patients in Saudi Arabia will nearly triple from 890,000 in 2000 to 2,523,000 by 2030 (Wild et al., 2004). Poor glycaemic control is common among the Saudi diabetic population; studies indicate that only 24% of patients attain the target glycaemic control, compared to 32% with poor glycaemic control, and only 4.5% of patients achieve glucose, blood pressure and LDL cholesterol control (Eledrisi et al., 2007). The dramatic increase in the incidence

of diabetes is related to several factors, such as advancing age. This can be seen in the rising proportion of sufferers according to age: 21% for people aged 30–39 years, 23% for those aged 40–49 years, 33.8% for those aged 50–59 years and 36.5% for those aged 60–70 years (Al-Nozha et al., 2004). It is well established that obesity is a strong risk factor for the development of diabetes (Daniel, Rowley, McDermott, & O'Dea, 2002; Gordon et al., 1999). In the Kingdom of Saudi Arabia, obesity is increasing at a similar rate to diabetes (Al Nuaim, 1997; Warsy & El-Hazmi, 1999).

It appears that urbanization and changes to the modern lifestyle have resulted in increased sedentary activity and consumption of high calorie foods, indicating the significance of these changes in the increased frequency of diabetes mellitus and hence their association with the expanded prevalence of micro- and macro-vascular complications (El-Hazmi et al., 1998; Elhadd et al., 2007). Several unhealthy dietary patterns are responsible for the rising incidence of diabetes, such as unhealthy items (kabsa, French fries and bakery items) that are commonly consumed by the Saudi population (Midhet et al., 2010). This pattern is consistent with the findings of a 12-year prospective study in the U.S. that revealed the development of diabetes to be associated with Western dietary habits, including the high consumption of red meat, French fries, high-fat products and sweets (van Dam, Rimm, Willett, Stampfer, & Hu, 2002).

It is well recognized that physical inactivity and sedentary living habits are major threats to the health of the world's population (WHO, 2003). The prevalence of inactivity in the Saudi population is high and ranges from 43 to 99.5% among Saudi children and adults (Al-Hazzaa, 2004). Diabetes management requires compliance and adherence, because non-compliance, non-adherence, poverty, lack of knowledge and low rates of follow-up are the main factors related to poor glycaemic control (Kalyango, Owino, & Nambuya,

2008); therefore, many factors, including demographic, psychological and social aspects, affect compliance and adherence. Healthcare providers, treatment-related factors and the social support provided by the health care team are important for promoting the adherence of diabetic patients to their diets, medications, self-monitoring of blood glucose levels and physical activity (Sherbourne, Hays, Ordway, DiMatteo, & Kravitz, 1992), indicating the importance of the patient-doctor relationship in adherence and compliance.

On the other hand, satisfaction is the most important factor that aligns patients with their doctor's recommendation, promoting a positive outcome and ultimately termination of the patient-doctor relationship: diabetic patients who are more satisfied with their physician's humanity and communication are more likely to be compliant and adhere to treatment and, consequently, have better glycaemic control (Sherbourne et al., 1992; Viinamäki, Niskanen, Korhonen, & Tähkä, 1993). In addition, patients' satisfaction with their doctors is related to the characteristics of the patients themselves rather than those of their healthcare providers (Franciosi et al., 2004).

A study conducted in Saudi Arabia revealed that 33% of patients received satisfactory health education, whereas 67% received unsatisfactory care. It appears that a lack of literacy and education results in dissatisfaction regarding the information received and poor glycaemic control (Al-Khaldi & Khan, 2000), which explains the wide gap between effective diabetic interventions and their implementation in practice (Eledrisi et al., 2007). The Ministry of Health in Saudi Arabia has provided detailed guidelines for health education for diabetic patients, but their implementation requires further reinforcement (Ministry of Health, 2002).

Diabetes can be managed through lifestyle changes and adherence to medication; therefore, it is very important to adopt education programmes for diabetic patients to reduce the growing burden of diabetes-related morbidity and mortality. Through diabetes education programmes, patients can acquire knowledge and skills, develop the confidence needed for appropriate self-care behaviours, and learn problem-solving and coping skills to overcome any barriers to effective self-care. Patients can improve their ability to achieve effective self-care, including appropriate and effective physical activity, what and when to eat, how much to eat, how to reliably monitor blood glucose levels, how to use those results to adjust dietary habits, and appropriate exercise and treatment choices, which in turn enhance clinical outcomes and, consequently, improve quality of life.

### 1.4 Conceptual Framework

This conceptual framework will highlight the diabetes self-care behaviours that influence measures of outcome for DSME and determine the effectiveness of DSME programs. A diabetes self-management education program is a collaborative process through which people with diabetes gain knowledge, acquire skills, improve motivation and learn how to solve problems.

The immediate objective of DSME programmes is to help diabetic patients to improve self-care knowledge and develop psychosocial mediators, such as attitude, self-efficacy, and coping skills. These immediate outcomes of knowledge and psychosocial mediators are not direct predictors of health per se; however, these mediators are supposed to work through self-care behaviours, and hence are directly linked to clinical outcomes.

Diabetes self-care behaviours, including a healthy diet, physical activity, medication consumption, blood glucose monitoring, problem solving (particularly regarding blood glucose high and low levels and sick days), reducing the risk of diabetic complications and living with diabetes (psychosocial adaptation), are primary outcomes of DSME programmes. Consequently, healthy eating to reduce fat intake, optimizing physical activity, overcoming barriers to attain glycaemic control and improving problem-solving skills lead to improved short-term clinical outcomes (e.g. HbA1c level blood pressure, body mass index (BMI), and lipid level). These improvements in clinical outcomes lead to improvements in health status, which in turn result in enhanced Quality of Life and economic benefits for people with diabetes and society (figure 1.1).

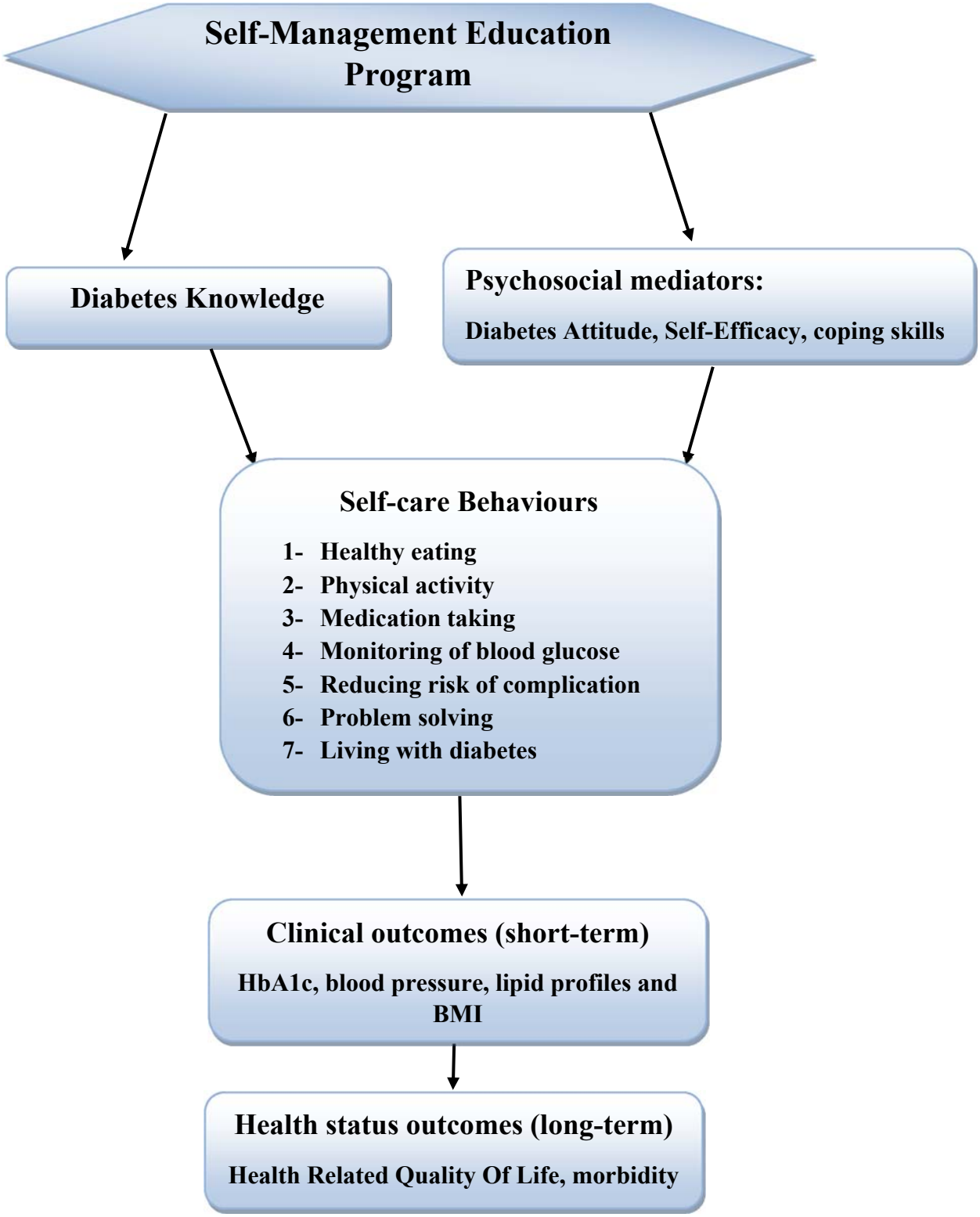


**Figure 1.1: Conceptual framework**

## 1.5 Significance of the Study

Because of the nature of diabetes as a non-communicable chronic disease, it is difficult for most diabetic patients to cope with their lifestyle changes, complying with treatment and attaining sustainable glycaemic control. Moreover, the high prevalence of diabetes in Saudi Arabia due to unhealthy diets and low physical activity combined with multiple diabetic complications has led to an overwhelming economic burden because of the consumption by diabetes care of the majority of the economic resources for healthcare. Therefore, DSME programmes are required to help diabetic patients manage their condition. In addition, the cost and effectiveness of DSME programmes need to be compared with those of usual care. Therefore, at the end of this study, decision makers in the Saudi Ministry of Health will have clear findings regarding the clinical outcomes and benefits of this programme.

Clinical outcome measures, such as HbA1c, blood pressure, cholesterol and BMI, will help the decision makers to evaluate the current status of diabetic patients and assist them in understanding the improvements in clinical outcome measures and health status after the implementation of this programme.

On the other hand, the psychosocial outcomes in this study, such as attitude and self-efficacy, will help physicians in general hospitals and primary healthcare clinics to help diabetic patients cope with barriers and solve problems to attain better glycaemic control. The economic evaluation of this programme will be performed via an assessment of the cost-effectiveness per unit improvement of glycaemic control of HbA1c. This economic evaluation will provide a clear view of the effectiveness of this programme and its potential application on a countrywide basis.

The American Diabetes Association (2014b) has reported that a 1% reduction in HbA1c levels reduces the risks of cardiovascular complications, diabetes-related death, all-cause mortality, and combined fatal and non-fatal myocardial infarction by 35%, 25%, 7% and 18%, respectively. Accordingly, the Saudi Arabian Ministry of Health may wish to adopt the DSME programme to facilitate health gains, high Quality of Life and better glycaemic control, which will decrease the diabetes healthcare expenditures across all health sectors in Saudi Arabia.

## 1.6 Study Objectives

### 1.6.1 Main objective

The main objective of this study is to evaluate the effectiveness of the Diabetes Self-Management Education (DSME) programme in improving clinical outcomes, self-care behaviours and Health Related Quality of Life and to perform an economic evaluation of a diabetic self-management education programme on health status in type 2 diabetes patients at the Diabetic Centre in King Abdulaziz University Hospital, Riyadh, Saudi Arabia.

### 1.6.2 Specific objectives:

1- To evaluate the effect of DSME programmes in improving short-term outcomes, including HbA1c levels, blood pressure, lipid profile and body mass index (BMI), of patients with type 2 diabetes.

2- To evaluate the effect of DSME programmes in improving knowledge, attitude and self-efficacy of patients with type 2 diabetes.

3- To evaluate the effects of DSME programmes in facilitating self-care behavioural changes after intervention in patients with type 2 diabetes.

4- To evaluate the effects of DSME programmes in improving the Health Related Quality of Life of patients with type 2 diabetes.

5- To determine the proportion of patients with diabetes achieving improved glycaemic control after the completion of a DSME programme.

# CHAPTER 2

# LITERATURE REVIEW

## 2.1 Diabetes Mellitus

### 2.1.1 Definition of diabetes mellitus

Diabetes mellitus (DM) is a common disease involving a heterogeneous group of diseases of various aetiologies characterized by an increase in blood glucose level termed hyperglycaemia. The chronic hyperglycaemia of diabetes is associated with metabolic abnormalities of carbohydrate, fat and protein with related defects of insulin action on target tissue or its secretion, or both (American Diabetes Association, 2014a). DM occurs when the body fails to absorb glucose due to inadequate or inefficient insulin secretion.

### 2.1.2 Classification of diabetes

DM based on aetiology was classified into four groups according to an international expert committee. The classification specified four types of diabetes mellitus: type 1, type 2, gestational diabetes and other specific type (The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2002).

Type 1 diabetes is associated with β-cell damage or destruction caused by an autoimmune destruction, resulting in reduced insulin or absolute insulin deficiency (Falorni, Kockum, Sanjeevi, & Lernmark, 1995; The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2002). This type of diabetes affects 5–10% of diabetic patients

(American Diabetes Association, 2014a). The aetiology of the autoimmune destruction of type 1 diabetes is still not well defined, but the development of the disease is related to multiple genetic predispositions and environmental factors (Peng & Hagopian, 2006; Visalli et al., 2003). Over 95% of individuals with type 1 diabetes mellitus develop the disease before the age of 25; it can be managed with a combination of pharmacological and non-pharmacological treatments such as insulin, diet and exercise (Franz et al., 2004). In this type of diabetes, patients need exogenous administration of insulin for survival (American Diabetes Association, 2014b).

While the incidence of type 1 diabetes is highest in children and adolescents, type 2 also affects younger adults and adolescents in addition to adults (King, 1999). Type 2 diabetes is associated with a family history of diabetes and is more prevalent in females, especially those with a history of gestational diabetes and over 40 years old. Also, the incidence of this type of diabetes increases in younger people with obesity and lack of physical activity (Alberti, Zimmet, & Shaw, 2007; American Diabetes Association, 2000; Silverstein & Rosenbloom, 2001). This type of diabetes encompasses individuals who have a defect in insulin secretion and insulin resistance; these patients do not need treatment with insulin for survival. Many previous studies have reported that insulin resistance usually happens in a pre-diabetic state that may persist for many years (American Diabetes Association, 2014a). Type 2 diabetes is associated with a strong genetic predisposition and have a three-fold increase risk of DM in comparison to non-diabetic people (McIntyre & Walker, 2002). Previous studies reported that liver and skeletal muscles are the key tissues for insulin resistance in type 2 DM (DeFronzo, Gunnarsson, Björkman, Olsson, & Wahren, 1985).

Gestational diabetes refers to glucose intolerance, which is first detected during pregnancy. In the 1960s, O'Sullivan found that the increase in development of diabetes after pregnancy was contributed to by the degree of glucose intolerance (Buchanan & Xiang, 2005). 14% of pregnancies in the U.S. are affected by impaired glucose tolerance and it is a recognized risk factor for mothers with type 2 DM (Jovanovic & Pettitt, 2001). Women who are obese, older than 25 years and unable to compensate for the developing glucose intolerance have a higher risk of developing gestational diabetes mellitus (Kjos & Buchanan, 1999). Women with prior GDM are associated with a higher risk for insulin resistance and hence are more likely to develop diabetes than a normal woman (Ryan et al., 1995).

### 2.1.3 Diagnosis of diabetes

Diabetes is defined as symptomatic or a symptomatic state of abnormalities in carbohydrate metabolism; the diagnosis can be made when one or more symptoms of diabetes are in existence and can be confirmed by a high blood glucose level in a venous blood sample.

The diagnostic criteria for diabetes based on the venous blood sample and laboratory methods are shown in Table 1 (American Diabetes Association, 2014a): a fasting plasma glucose (FPG) level $\geq$ 7.0 mmol/L in concordance with a 2-hour plasma glucose (2hPG) value $\geq$ 11.1 mmol/L in a 75g oral glucose tolerance test (OGT) in regard to the prevalence of retinopathy (Engelgau et al., 1997; Ito et al., 2000; The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 1997). The use of the HbA1c test for

diagnosis of diabetes with the threshold of ≥ 6.5% has been recommended by the International Expert Committee (International Expert Committee, 2009) and there is a relationship between the diagnostic cut-point of HbA1c, FPG and 2hPG concerning the prevalence of retinopathy (Colagiuri et al., 2011; International Expert Committee, 2009).

The decision of which tests should be used for diagnosis of diabetes is contributed to by clinical judgement. If the patient presents with symptoms of hyperglycaemia, it is preferable that the same test be repeated for confirmation of diabetes. For example, HbA1c is 7% and the repeated result is 6.85%: thus, the diagnosis of diabetes is confirmed. However, if the results of two different tests (FPG and HbA1c) are both above the diagnostic cut-point, this also means that the diagnosis of diabetes is confirmed. On the other hand, when two different tests for an individual are available and the results are conflicting, the test whose result is above the diagnostic thresholds should be repeated, which is the basis of diagnosis of diabetes (Sacks, 2011).

**Table 2.1 Criteria for the diagnosis of diabetes**

| |
|---|
| • A1C ≥ 6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay*. |
| OR |
| • FPG ≥ 126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h.** |
| OR |
| • Two-hour PG ≥ 200 mg/dL (11.1 mmol/L) during an OGTT. The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.*** |
| OR |
| • In a patient with classic symptoms of hyperglycaemia or hyperglycaemic crisis, a random plasma glucose ≥ 200 mg/dL (11.1 mmol/L).<br>• In the absence of unequivocal hyperglycaemia, result should be confirmed by repeat testing. |

* (NGSP) National Glycohemoglobin Standardization Program, (DCCT) Diabetes Control and Complications Trial reference assay. ** (FPG) fasting plasma glucose. *** (OGTT) oral glucose tolerance test.

### 2.1.4 Clinical presentation of diabetes

Diabetes can exhibit symptoms such as marked hyperglycaemia, polyuria, polydipsia, weight loss, polyphagia and blurred vision or be a symptomatic, depending on the severity of the metabolic abnormalities (American Diabetes Association, 2014a). Chronic hyperglycaemia in patients is associated with growth impairment and susceptibility to certain infections. Usually the initial symptoms of diabetes (polyuria, polydipsia and weight loss) are associated with the early diagnosis of diabetes (Ganong & Systems, 1995).

### 2.1.5 Diabetes complications

Long-term diabetes is associated with microvascular complications, such as retinopathy and neuropathy, and macrovascular complications, such as myocardial infarction, angina pectoris and stroke (Grandy & Fox, 2008; Hamadeh, 2000). An epidemiological analysis of the United Kingdom Prospective Diabetes Study (UKPDS) data revealed a continuous relationship between hyperglycaemia and the above microvascular complications (UK Prospective Diabetes Study (UKPDS) Group, 1998). People with type 2 diabetes have a two- to four-fold higher risk of coronary heart disease, peripheral vascular disease and stroke than the general population, and these account for approximately 65% of diabetes mortality. In 2006, diabetes was classified as the seventh leading cause of death in the U.S. (Al-Ajlan, 2007; Dall et al., 2008).

### 2.1.6 Glycosylated haemoglobin

The fasting plasma glucose (FPG) test and the oral glucose tolerance (OGT) test are the most widely used screening tests for measurement of blood glucose. However, both FPG and OGT require the patient to fast for eight hours overnight and diagnosis by FPG requires the test to be performed at least twice to confirm the diagnosis. In addition, diagnosis by FPG is not sensitive, since diabetes remains undetected in one third of sufferers (Barr, Nathan, Meigs, & Singer, 2002). It has been suggested that the glycosylated haemoglobin (HbA1c) test be used as alternative test for type 2 diabetes. It is important that individuals with diabetes know and understand their level of HbA1c. It has been used as the gold standard for the level of mean glycaemic control, representing the percentage of blood glucose that has reacted with a person's haemoglobin. HbA1c can

assess the average blood sugar over two to three months because red blood cells live for that time period (American Diabetes Association, 2014b).

HbA1c is widely accepted as an important marker for assessing chronic hyperglycaemia and should be measured every three to six months to estimate blood glucose after a medication treatment regimen (American Diabetes Association, 2014b; Goldstein et al., 2004; Saudek, Derr, & Kalyani, 2006). Many studies report that there is a relationship between HbA1c and the risk for complications in epidemiological studies and clinical trials in both type 1 (Diabetes Control Complications Trial Research Group, 1995) and type 2 (Stratton et al., 2000). This has helped to establish a widely accepted HbA1c target for diabetes care to delay and prevent the development of different of long-term complications (American Diabetes Association, 2014b; European Diabetes Policy, 1999; Nathan et al., 2006).

Moreover, many previous epidemiological studies reported that patients with level of HbA1c $\geq$ 7% are associated with significantly high risk of microvascular and macrovascular complications (Diabetes Control Complications Trial Research Group, 1995; Stratton et al., 2000; Turner, Holman, et al., 1998). It has been suggested that HbA1c level above the diagnostic threshold for diabetes (6.0% to < 6.5% ) is correlated with high risk for incidence of diabetes (International Expert Committee, 2009) and people with the same this range of HbA1c have 10 times more progression of diabetes than those people with low level of HbA1c (Edelman, Olsen, Dudley, Harris, & Oddone, 2004; Pradhan, Rifai, Buring, & Ridker, 2007; Shimazaki, Kadowaki, Ohyama, Ohe, & Kubota, 2007). Preventive interventions program should be initiated for individuals whose HbA1c values in the range of 5.5% - 6.0% (Knowler et al., 2002; Tuomilehto et al., 2001).

On the other hand, each 1% reduction in HbA1c value is associated with a 37% decrease in the risk of microvascular complications and a 14% decrease in myocardial infarction, as well as fewer deaths related to DM. The Diabetes Control and Complications Trial Research Group (1995) reported that there is a relationship between HbA1c and plasma glucose (PG), since 6% of HbA1c corresponded to a 135 mg/dl (7.5 mmol/L) level of mean plasma glucose. Furthermore, each 1% increase in HbA1c corresponded to a 35 mg/dl (2 mmol/L) increase in mean plasma glucose, and this can help the healthcare providers and their patients with diabetes to adjust targets level of plasma glucose on a day-to-day basis in order to achieve the optimal specific HbA1c goals (Rohlfing et al., 2002).

### 2.1.7 Glycaemic control

Optimal glycaemic control is significant to the management of diabetes. Several clinical trials have reported that improved glycaemic control is associated with a reduction in the microvascular complications of diabetes in both type 1 and type 2 (Stratton et al., 2000; The Diabetes Control Complications Trial Research Group, 1993; UK Prospective Diabetes Study (UKPDS) Group, 1998).

A cross-sectional PANORAMA study of type 2 diabetes was conducted in nine countries (Belgium, France, Germany, Greece, Italy, the Netherlands, Spain, Turkey and the UK) >1 year prior to study entry. In this study, a total of 5817 European patients and 397 physicians were randomly enrolled or consecutively selected from physician's practices between May 2009 and April 2010. The study aimed to examine the number of patients in

those countries who were not achieving the optimal goal of glycaemic control and to evaluate the association between glycaemic control and demographic, clinical and treatment factors. The findings of the PANORAMA study showed that the mean HbA1c of the total patient population was 6.9% and 37.4% of the patients had HbA1c ≥ 7%. The study found that those who were younger, female, unemployed, less educated and with a longer duration of diabetes were more likely to have suboptimal glycaemic control. Furthermore, a multivariate analysis revealed that treatment by a combination of therapy, an oral glycaemic agent and insulin were significant predictors of poor glycaemic control (de Pablos-Velasco et al., 2014).

In Malaysia, the Ministry of Health in Hulu Langat, Selangor, conducted a cross-sectional survey over a seven-month period in seven primary health clinics. The data were collected as a systematic random sample of a total of 557 type 2 diabetic patients who participated in the study. This study was carried out to determine the glycaemic control status and factors, which are, associated with good glycaemic control of type 2 diabetic patients. The study found that the average age of the participants was 56 years, with an average duration of disease of 7.8 years. The mean HbA1c level for all 557 patients was 8.04%. Patients who were receiving an oral hypoglycaemic agent had better glycaemic control than those who were receiving a combination of insulin and an oral hypoglycaemic agent. Finally, this study concluded that older patients, shorter duration of disease, mono-therapy and good adherence to the treatment were found to be significantly associated with good glycaemic control, and healthcare providers in the Ministry of Health in Malaysia should advise patients to reduce their sugar intake, eat healthy food and adhere to their medication

treatment in order to attain better glycaemic control (Ahmad, Islahudin, & Paraidathathu, 2013).

In Saudi Arabia, a cross-sectional study was conducted in diabetic patients visiting King Khalid University Hospital, Riyadh. A total of 1520 participants who were diagnosed by diabetes according to American Diabetes Association (2014a) criteria were selected by a random sampling method. The aim of this study was to evaluate the glycaemic control of diabetic patients. This study found that 90% of patients were older than 40 years old and 90% of them were obese. 60% of patients had fasting blood glucose at more than 7.2 mmol/L and only 40% of patients had achieved the optimal glycaemic control of <7%. Triglyceride levels were normal in only 56% of the patients, while 50% had uncontrolled BP. Finally, there was a significant relationship between HbA1c and age, sex and nationality, in which male, older patients and Saudi nationals had better glycaemic control (Al-Rowais, 2013).

Akbar (2001b) conducted a cross-sectional study of 404 diabetic patients attending King Abdulaziz University Hospital medical clinic from June 1998 to July 2000 to determine the percentage of patients reaching target levels of glycaemic control, blood pressure and serum lipids. This study found that it is more difficult for females to achieve better glycaemic control, the target level of blood pressure, appropriate body mass index and low density lipoprotein than males for both Saudi and non-Saudi participants and recommended that greater effort is needed from both healthcare provider and patients to improve diet habits and drugs compliance in order to reduce the incidence of risk factors.

Finally, a longitudinal observational study was conducted in San Diego, California with type 2 diabetes patients from the Dulce project, a nurse-based diabetes management system. This study aimed to demonstrate the association of glycaemic control with different characteristic variables of type 2 diabetes patients. The study found that longer duration of disease, younger patients, patients who used a combination therapy of oral hypoglycaemic agent and insulin, and high cholesterol level were all associated with poor glycaemic control (Benoit, Fleming, Philis-Tsimikas, & Ji, 2005).

#### 2.1.7.1 Factors associated with glycaemic control

Poor glycaemic control among type 2 diabetics is considered a major health problem and one of the risk factors for the development of different diabetes complications. Koro, Bowlin, Bourgeois, and Fedder (2004) showed that in order to prevent damage to organs and subsequent complications which can arise from diabetes, patients need to attain optimal glycaemic control, which constitutes the major therapeutic goal of healthcare management. Identifying demographic, clinical and psychological characteristics that predict poor glycaemic control may help to improve outcomes by provision of better intervention, which is appropriate for diabetic patients. From published literature, many factors have been found to be associated with poor glycaemic control among type 2 diabetes sufferers. Many previous studies have reported that patients of a younger age, with a higher body mass index (BMI), longer duration of diabetes, and undergoing a combination therapy of an oral hypoglycaemic agent and insulin are associated with a higher level of HbA1c (Benoit et al., 2005; El-Kebbi et al., 2003; Nichols, Hillier, Javor, & Brown, 2000; Nyunt, Howteerakul, Suwannapong, & Rajatanun, 2010; Sanal, Nair, &