

**ECONOMIC, SOCIAL AND CLINICAL EVALUATIONS OF DIABETES SELF  
MANAGEMENT PROGRAM AT UNIVERSITI SAINS MALAYSIA HEALTH  
CENTER: COMPARISON BETWEEN STRUCTURED AND LESS  
STRUCTURED EDUCATIONAL PROGRAMS**

**by**

**MAHMOUD SA'DI MOHAMMAD AL-HADDAD**

**Thesis submitted in fulfillment of the  
requirements for the degree  
of Doctor of Philosophy**

**MAY 2008**

## **Dedication**

I would like to dedicate this work with lots of love and respect to my father Sa'di Al-Haddad and my mother Intesar Al-Haddad

## **ACKNOWLEDGEMENT**

First and foremost, my heartfelt gratefulness goes to the Almighty, the One who has no finality for answering my prayers in many ways and blessing me with the abilities that have enabled me to achieve this success.

I would like to express my deepest gratitude to my supervisor Assoc. Prof Dr. Mohamed Izham Mohamed Ibrahim for his invaluable guidance, advice, patience, as well as my co-supervisor Assoc. Prof. Dr. Syed Azhar Syed Sulaiman for his constructive criticism and assistance given to me throughout this work. This research would have been impossible without their help, concern and consistent encouragement.

I also would like to express my gratitude to the Secretariat of USM Healthy Campus program for their financial support of this research. Special thanks to the director of USM Health Center, Dr. Nurulain bt Abdullah Bayanuddin for her full assistance in facilitating data collection during this research.

My sincere thanks also extend to all the educators of DSMP, especially Dr. Norlela bt Maarup, Assoc. Prof. Dr. Mohd Baidi Bahari, Mr. Azaharudin b. Awang Ahmad, Ms. Sulastri bt Samsudin, Ms. Asdariah bt Misnan, Ms. Che Gayah bt Omar, Ms. Che Rubia and Ms. Jameaton who mainly contributed for the success of this program.

Also I express my sincere thanks to Dr. Awad Mataria for his continuous advices and support. Special thanks to my friends Ahmed Metani, Khaled Amayreh, Ala' Khader, Younis Hammouda, Ahmad Klaib, Homam Eltaj, Ahmed Eid, Mahmoud Ideas, Ashraf Amro, and all my friends in the Discipline of Social and Administrative Pharmacy. Special thanks to all the friends who have directly or indirectly assisted me in this study.

Last but certainly not least, I express my gratitude to my parents, brothers and sisters for their prayers and support at home.

## TABLE OF CONTENTS

<b>Title</b>	<b>Page</b>
<b>DEDICATION</b>	i
<b>ACKNOWLEDGEMENT</b>	ii
<b>TABLE OF CONTENTS</b>	iii
<b>LIST OF TABLES</b>	ix
<b>LIST OF FIGURES</b>	xiii
<b>ABBREVIATIONS</b>	xiv
<b>ABSTRAK</b>	xvi
<b>ABSTRACT</b>	xix
<b>CHAPTER ONE - GENERAL INTRODUCTION</b>	1
1.0 Introduction	2
1.1 Background	2
1.2 Problem statement	7
1.3 Rationale of the study	7
1.4 Significance of the study	9
1.5 Study objectives	11
<b>CHAPTER TWO - DIABETES SELF MANAGEMENT PROGRAM</b>	14
2.1 Introduction	15
2.1.1 Background	15
2.1.2 Problem statement	16
2.1.3 Literature review	16
2.1.4 Rationale of the study	20
2.1.5 Study objectives	21
2.1.6 Significance of the study	22
2.2 Materials and Methods	23
2.2.1 Study population	23
2.2.2 Program structures	23
2.2.3 Patients' recruitment	25

	<b>Title</b>	<b>Page</b>
2.2.4	Program educators	25
2.2.5	Program sessions	26
2.2.5.1	Session one: Diabetes overview and diet	26
2.2.5.2	Session two: Diabetes medications	26
2.2.5.3	Session three: Diabetes complications	26
2.2.5.4	Session four: Exercise and foot care	27
2.2.6	Data collection procedure	27
2.2.7	Statistical analysis	28
2.3	Results	29
2.3.1	Study participants	29
2.3.2	Type and number of drugs used in each group	29
2.3.3	HbA1c level for the less structured and structured groups	32
2.3.4	Body mass index level for the less structured and structured groups	34
2.3.5	Fasting blood sugar level for the three groups	35
2.3.6	Random blood sugar level for the three groups	37
2.3.7	Systolic blood pressure level for the three groups	40
2.3.8	Diastolic blood pressure level for the three groups	42
2.3.9	Comparison between the three groups	45
2.4	Discussion	46
2.4.1	HbA1c level	47
2.4.2	Body mass index level	49
2.4.3	Fasting blood sugar level	51
2.4.4	Random blood sugar level	52
2.4.5	Systolic blood pressure	53
2.4.6	Diastolic blood pressure	54

<b>Title</b>	<b>Page</b>
2.5 Conclusion	55
 <b>CHAPTER THREE - EVALUATION OF DIABETIC PATIENTS' PSYCHOLOGICAL AND SOCIAL BEHAVIORS BEFORE AND AFTER DIABETES SELF MANAGEMENT PROGRAM</b>	 56
3.1 Introduction	57
3.1.1 Background	57
3.1.2 Problem statement	59
3.1.3 Literature review	59
3.1.4 Rationale of the study	65
3.1.5 Study objectives	68
 3.2 Methodology	 69
3.2.1 Study design	69
3.2.2 Study population and sample	69
3.2.3 Sampling method	69
3.2.4 Questionnaire design	70
3.2.5 Data analysis	70
 3.3 Results	 71
3.3.1 Patients' characteristics	71
3.3.2 Understanding	73
3.3.3 Control problem scale	79
3.3.4 Social and personal factors	80
3.3.5 Attitudes toward diabetes	85
3.3.6 Care ability	92
3.3.7 Importance of care	95
3.3.8 Self care adherence	98
3.3.9 Diet adherence	101
3.3.10 Long term care benefits	104

<b>Title</b>	<b>Page</b>
3.3.11 Before-After comparisons	107
3.3.12 Patients' feedback	109
3.4 Discussion	111
3.5 Conclusion	118
<b>CHAPTER FOUR - ECONOMIC EVALUATIONS OF DIABETES SELF MANAGEMENT PROGRAM AT UNIVERSITI SAINS MALAYSIA HEALTH CENTER</b>	<b>120</b>
4.1 Introduction	121
4.1.1 Background	121
4.1.1.1 Major willingness to pay eliciting methods	123
4.1.2 Cost effectiveness analysis	125
4.1.3 Problem statement	126
4.1.4 Literature review	126
4.1.4.1 Uses of willingness to pay in cost benefit analysis	132
4.1.5 Rationale of the study	136
4.1.6 Objectives of the study	139
4.1.7 Significance of the study	139
4.2 Materials and methods	140
4.2.1 Study design	140
4.2.2 Questionnaire design	140
4.2.3 Willingness to pay amounts	141
4.2.4 Study population and participants	142
4.2.5 Study location and timeline	142
4.2.6 Cost benefit analysis study perspective	142

<b>Title</b>	<b>Page</b>
4.2.7 Cost benefit analysis benefits and diabetes self management program costs calculations	142
4.2.8 Cost effectiveness analysis evaluations	143
4.2.9 Sensitivity analysis	144
4.2.10 Statistical analysis	145
 4.3 Results	 146
4.3.1 Sensitivity analysis	156
4.3.1.1 Costs incurred by healthcare providers assuming that classes are given by medical doctor and three pharmacists	157
4.3.1.1 Costs incurred by non healthcare providers based on seven years of life expectancy	159
4.3.1.2 Costs incurred by non healthcare providers based on three years of life expectancy	161
4.3.2 Cost benefit analysis ratios	164
4.3.3 Costs saved from preventing the development of one case of end stage renal failure	170
4.3.4 Cost effectiveness ratios	172
4.3.4.1 Cost effectiveness analysis for the less structured group	174
4.3.4.2 Cost effectiveness analysis ratios for the structured group	177
4.3.4.3 Cost effectiveness analysis ratios for the control group	179
4.3.4.4 Cost effectiveness analysis ratios for the three groups	181
 4.4 Discussion	 182
 4.5 Conclusion	 188



<b>Title</b>	<b>Page</b>
<b>CHAPTER FIVE - GENERAL CONCLUSION</b>	189
5.1 Conclusion	190
5.2 Recommendations	192
5.3 Limitations of the study	193
 <b>BIBLIOGRAPHY</b>	 194
 <b>APPENDICES</b>	 210
Appendix A: English version of diabetes care profile (pre-questionnaire)	211
Appendix B: Malay version of diabetes care profile (pre-questionnaire)	217
Appendix C: English version of diabetes care profile (post-questionnaire)	224
Appendix D: Malay version of diabetes care profile (post-questionnaire)	230
Appendix E: English version of willingness to pay questionnaire	237
Appendix F: Malay version of willingness to pay questionnaire	238

## LIST OF TABLES

	<b>Title</b>	<b>Page</b>
2.1	Gender distribution and mean of age in the three groups	29
2.2	Percentage of drug usage in each group	30
2.3	Percentage of the number of drugs used in each group	30
2.4	Mean number of antihyperglycemic medications during the study periods in the three groups	31
2.5	Percentage and type of antihyperglycemic medications changes in the three groups	31
2.6	HbA1c level for the less structured and structured groups	32
2.7	BMI level for the three groups	34
2.8	FBS level for the three groups	36
2.9	RBS level for the three groups	38
2.10	Systolic BP level for the three groups	41
2.11	Diastolic BP level for the three groups	43
2.12	Comparison between the three groups	46
3.1	Patients' characteristics	72
3.2	Less structured group understanding	74
3.3	Structured group understanding	77
3.4	Control problem for the less structured group	79
3.5	Control problem for the structured group	80
3.6	Social and personal factors for the less structured group	81
3.7	Social and personal factors for the structured group	83
3.8	Attitude toward diabetes for the less structured group	86
3.9	Attitude toward diabetes for the structured group	89

<b>Title</b>	<b>Page</b>
3.10 Care ability for the less structured group	93
3.11 Care ability for the structured group	94
3.12 Importance of care for the less structured group	96
3.13 Importance of care for the structured group	97
3.14 Self care adherence for the less structured group	99
3.15 Self care adherence for the structured group	100
3.16 Diet adherence for the less structured group	102
3.17 Diet adherence for the structured group	103
3.18 Long term care benefits for the less structured group	105
3.19 Long term care benefits for the structured group	106
3.20 Pre-post results for the less structured group	107
3.21 Pre-post results for the structured group	108
3.22 Comparison between both intervention groups before and after the intervention	108
3.23 Patients' feedback	110
3.24 Patients' suggestions for program schedule	111
4.1 Pre-post WTP amounts for both groups	149
4.2 Before-after WTP difference for both groups	151
4.3 WTP difference between both groups at the baseline and at the end of the program	151
4.4 Healthcare providers costs if program is given by a medical physician, a pharmacy lecturer and trained pharmacists	153
4.5 Costs incurred by non healthcare providers based on five years of life expectancy	154

	<b>Title</b>	<b>Page</b>
4.6	Health care providers cost if the program is given by a medical physician and trained pharmacists only	158
4.7	Costs incurred by non healthcare providers based on seven years of life expectancy	159
4.8	Costs incurred by non healthcare providers based on three years of life expectancy	162
4.9	Net benefit of DSMP if given by a medical physician, a pharmacy lecturer, two pharmacists and life expectancy of equipments = five years	165
4.10	Net benefit of DSMP if given by a medical physician, a pharmacy lecturer, two pharmacists and life expectancy of equipments = seven years	166
4.11	Net benefit of DSMP if given by a medical physician, a pharmacy lecturer, two pharmacists and life expectancy of equipments = three years	167
4.12	Net benefit of DSMP if given by a medical physician and three pharmacists and life expectancy of equipments = five years	167
4.13	Net benefit of DSMP if given by a medical physician and three pharmacists and life expectancy of equipments = seven years	168
4.14	Net benefit of DSMP if given by a medical physician and three pharmacists and life expectancy of equipments = three years	169
4.15	Net benefit of DSMP if given by a medical physician, a pharmacy lecturer and pharmacists and life expectancy of equipments = five years and the DSMP resulted from delaying the development of ESRF or one patient for one year	170
4.16	Net benefit of DSMP if given by a medical physician, a pharmacy lecturer, two pharmacists and life expectancy of equipments = five years and the DSMP resulted from preventing the development of ESRF for one patient	172
4.17	Mean patients' costs for cost effectiveness evaluations	173
4.18	Medicines' costs for the three groups	174
4.19	Cost effectiveness ratios of the less structured group	176

<b>Title</b>	<b>Page</b>
4.20 Cost effectiveness ratios of the structured group	178
4.21 Cost effectiveness ratios of the control group	180
4.22 Summary of CEA ratios for the three groups	181

## LIST OF FIGURES

	<b>Title</b>	<b>Page</b>
Figure 2.1	Less structured group HbA1c level	33
Figure 2.2	Structured group HbA1c level	33
Figure 2.3	BMI level for the less structured group	34
Figure 2.4	BMI level for the structured group	35
Figure 2.5	FBS values for the less structured group	36
Figure 2.6	FBS values for the structured group	37
Figure 2.7	FBS values for the control group	37
Figure 2.8	RBS values for the less structured group	39
Figure 2.9	RBS values for the structured group	39
Figure 2.10	RBS values for the control group	40
Figure 2.11	Systolic BP values for the less structured group	41
Figure 2.12	Systolic BP values for the structured group	42
Figure 2.13	Systolic BP values for the control group	42
Figure 2.14	Diastolic BP values for the less structured group	43
Figure 2.15	Diastolic BP values for the structured group	44
Figure 2.16	Diastolic BP values for the control group	44

## ABBREVIATIONS

BG	Bidding Game
BMI	Body Mass Index
BP	Blood Pressure
CBA	Cost Benefit Analysis
CE	Cost Effectiveness
CEA	Cost Effectiveness Analysis
CV	Contingent Valuation
CVD	Cardio Vascular Diseases
DC	Dichotomous Choice
DCP	Diabetes Care Profile
DSMP	Diabetes Self Management Program
ESRF	End Stage Renal Failure
FBS	Fasting Blood Sugar
Ft	Feet
HbA1c	Hemoglobin A1c
lb	Pound
M	Meter
Max	Maximum
Min	Minimum
OE	Open-Ended
PC	Payment Card
QALY	Quality Adjusted Life Years
QOL	Quality of Life
RA	Referendum Approach
RBS	Random Blood Sugar
SD	Standard Deviation
SG	Standard Gamble
SMBG	Self Monitoring Blood Glucose
TTO	Time Trade Off
TV	Television

UK	United Kingdom
US	United States
USM	Universiti Sains Malaysia
WTP	Willingness to Pay



**PENILAIAN EKONOMI, SOSIAL DAN KLINIKAL PROGRAM PENGURUSAN  
KENDIRI DIABETES DI PUSAT KESIHATAN UNIVERSITI SAINS MALAYSIA:  
PERBANDINGAN DI ANTARA PROGRAM PENDIDIKAN BERSTRUKTUR DAN  
KURANG BERSTRUKTUR**

**ABSTRAK**

Kes-kes penyakit diabetes mellitus (DM) di dunia meningkat dengan banyaknya masa kini. Tambahan lagi, banyak komplikasi yang serius boleh berlaku akibat penyakit DM dan ini boleh memberi kesan negatif ke atas kualiti hidup individu serta meningkatkan beban ekonomi negara. Oleh itu, objektif utama kajian ini adalah untuk menyelidiki hasil akhir klinikal, psikologikal, tingkah laku dan ekonomi dua Program Pengurusan Kendiri Penyakit Diabetes (DSMP) yang berbeza (berstruktur dan kurang berstruktur) di Pusat Kesihatan Universiti Sains Malaysia. Dalam penyelidikan ini, reka bentuk kajian kuasi sebelum-selepas telah digunakan. Nilai-nilai HbA1c, BMI, paras gula dalam darah semasa berpuasa (FBS), paras gula dalam darah rawak (RBS) dan tekanan darah pesakit telah diambil sebelum, selepas dan 4 bulan dalam tempoh susulan. Selain itu, satu soal selidik untuk penilaian psikologi dan kesanggupan untuk membayar (WTP) telah diberikan kepada pesakit sebelum dan selepas program. Kumpulan berstruktur menunjukkan penurunan yang signifikan dari segi nilai HbA1c dan RBS, sebaliknya BMI, FBS, dan tekanan sistolik dan diastolik tidak signifikan. Kumpulan yang kurang berstruktur pula menunjukkan peningkatan nilai HbA1c yang tidak dijangka, manakala nilai-nilai FBS, RBS dan tekanan darah sistolik menurun

secara signifikan. Ukuran-ukuran yang lain tidak menunjukkan keputusan yang signifikan. Pesakit menunjukkan pemahaman yang baik berkaitan penyakit DM di mana jawapan-jawapan mereka adalah di antara nilai baik dan sangat baik bagi semua item yang diukur. Hanya kumpulan yang berstruktur menunjukkan peningkatan yang signifikan selepas program bagi 'penjagaan DM secara keseluruhan'. Walau bagaimanapun, kes-kes hipoglisemik dan hiperglisemik menurun dalam kumpulan berstruktur manakala meningkat dalam kumpulan yang kurang berstruktur. Kuantiti dan kualiti makanan yang diambil oleh pesakit bertambah baik dengan signifikan bagi kedua-dua kumpulan selepas intervensi. Sikap negatif meningkat sedikit dan sikap positif menurun sedikit dalam kumpulan yang kurang berstruktur. Sebaliknya, bagi kumpulan berstruktur, sikap positif meningkat sedikit dan sikap negatif menurun sedikit selepas intervensi. Penilaian ekonomi telah menunjukkan bahawa kumpulan berstruktur mempunyai nilai WTP lebih tinggi selepas program berbanding dengan kumpulan yang kurang berstruktur. Sebaliknya, DSMP memberikan faedah bersih yang lebih tinggi dalam kumpulan yang berstruktur bagi semua anggapan yang digunakan dalam analisis sensitiviti. Walau bagaimanapun, faedah bersih akan meningkat kepada lebih daripada RM204,341 jika DSMP mencegah dari berlakunya satu kes kegagalan renal tahap akhir (ESRF). Tambahan lagi, program berstruktur didapati paling berkesan kos dalam kebanyakan pembolehubah yang digunakan dalam penilaian. Oleh itu, ia boleh disimpulkan bahawa DSMP yang berstruktur akan menyebabkan hasil akhir yang lebih baik dan penjimatan bersih yang lebih berbanding kepada program kawalan dan kurang berstruktur. Oleh itu, adalah disarankan supaya DSMP yang berstruktur dapat terus dilaksanakan, disusul dan dipantau.

Kekunci: Universiti Sains Malaysia, Pendidikan Diabetes, Penjagaan Diabetes,  
Analisis Faedah Kos, Kesanggupan Membayar, HbA1c

**ECONOMIC, SOCIAL AND CLINICAL EVALUATIONS OF DIABETES SELF  
MANAGEMENT PROGRAM AT UNIVERSITI SAINS MALAYSIA HEALTH  
CENTER: COMPARISON BETWEEN STRUCTURED AND LESS STRUCTURED  
EDUCATIONAL PROGRAMS**

**ABSTRACT**

Diabetes mellitus is increasing tremendously in the world. In addition, many serious complications could result from diabetes which would affect on the quality of life and would increase the economical burden in the country. Thus, the main objectives of this study are to investigate the clinical, psychological and behavioral and economical outcomes of two different Diabetes Self Management Programs (DSMP) (structured and less structured) at the Health Center of Universiti Sains Malaysia. In this study, a quasi before-after study design was used. Patients' HbA1c, BMI, FBS, RBS and blood pressure values were taken before, after and after 4 months of follow up period. In addition, a questionnaire for psychological and WTP evaluations was given to patients before and after the programs. Structured group showed significant reduction in HbA1c and RBS values whereas BMI, FBS, systolic and diastolic blood pressure did not reach the significance level. On the other hand, less structured group resulted in unexpected significant increase in HbA1c values while FBS, RBS and systolic blood pressure reduced significantly whereas other measures did not reach the significance level. Patients showed good understandings of diabetes where their responses were between good and very good for all items measured. Only structured group showed

significant increase after the program in 'over all diabetes care'. However, hypoglycemic and hyperglycemic cases reduced in the structured group while increased in the less structured group. Patients' quantity and quality of food consumption were significantly improved for both groups after the intervention. In addition, negative attitudes toward diabetes were slightly increased and positive attitudes were slightly decreased in the less structured group. In contrast, structured group has slightly increased their positive attitudes and decreased their negative attitudes after the intervention.

Economic evaluations showed that structured group had higher WTP values after the program compared to the less structured group. On the other hand, DSMP resulted in net benefits which were higher in the structured group in all of the assumptions considered in the sensitivity analyses. However, net benefit would reach up to more than RM204,341 if DSMP prevent the development of one case of ESRF. Furthermore, structured program was found to be the most cost effective in most of the variables considered in the evaluations. Therefore, it has been concluded that structured DSMP would result in better outcomes and more net benefits compared to the control and less structured programs. Thus, it is recommended to continue implementing, following up and monitoring the structured DSMP.

Key words: Universiti Sains Malaysia, Diabetes Education, Diabetes Care, Cost-Benefit Analysis, Willingness to Pay, HbA1c.

# **CHAPTER ONE**

## **GENERAL INTRODUCTION**

## **Introduction**

### **1.1 Background**

Diabetes mellitus is “a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both” (American Diabetes Association, 2005). Another definition by Japan Diabetes Society is “a group of diseases of heterogeneous etiology, characterized by chronic hyperglycemia and other metabolic abnormalities, which are due to deficiency of insulin effect” (Kuzuya et al., 2002). Diabetes could be symptomatic like polyuria, weight loss, thirst, polydipsia and blurred vision while sometimes it could be asymptomatic. Being symptomatic or asymptomatic depends on the severity of the metabolic abnormalities. (Kuzuya et al., 2002; American Diabetes Association, 2005).

Diabetes is known to human kind since tens of centuries and is of high prevalence among populations in the world. This prevalence varies from country to country since it is mainly caused by environmental and heredity factors that differ from population to another (Gutteridge, 1999). It was estimated that the prevalence of diabetes in US was 20.8 million in October 2005 with an increase of 2.8 million from 2003 estimates. According to Vinicor (the director of division of diabetes translation at the centers of disease control and prevention in Atlanta), “every 24 hours, 4100 new diabetes cases are diagnosed in the US, at least 810 people die, 230 undergo amputation, 120 learn they need kidney dialysis or transplant, and 55 go blind”. The prevalence of diabetes among aged group >60 years in the U.S. is 21% compared to 10% for those aged 40-59 years and 2% of those 20-39 years (Beckley, 2006).

A study of estimating the lifetime risk of diabetes development in different age groups was conducted in the US. It was found that in 2000, the lifetime risk of developing diabetes in individuals born in US was 33% for men and 39% for women (Riddle, 2004). On the other hand, variety of metabolic or genetic disorders may cause insulin resistance. Obesity is considered the most etiological factor for insulin resistance (Lebovitz, 1999). A cluster of metabolic disorders are associated with insulin resistance. They include glucose intolerance, increase macrovascular diseases and hypertension (Lebovitz, 1999). In addition, urbanization, aging, population growth, and physical inactivity are other major causes of the increase of the prevalence of diabetes worldwide (Wild et al 2004; Wing et al., 2001).

Significant complications are associated with diabetes mellitus such as retinopathy and neuropathy. These complications have significant impact on the patients' quality of life due to the increase of morbidity and mortality ratios (Cusick et al., 2005). Since the increase of morbidity rates among diabetes patients, such as Cardio Vascular Diseases (CVD) (Fox et al., 2004), blindness, kidney failure, extremity amputations and others, diabetes has been listed as the fifth leading cause of death by disease in the US. (Cefalu, 2004).

On one hand, a cohort study compared causes of mortality in diabetes patients with non-diabetes patients in the UK population. During the 6 years follow up, it was found that mortality rates among diabetes patients due to cardiovascular and renal diseases were significantly higher than non-diabetes patients (Roper et al., 2002). On the other hand, 40% of young onset diabetes patients develop severe kidney diseases at the age of 50 years. In developed countries, stroke and heart diseases account 75% of all deaths of diabetes patients in which presence of



diabetes increases the incidence of death 3 folds due to stroke, heart diseases and renal failure. (The Western Pacific Declaration on Diabetes- A Strategic Alliance, Kuala Lumpur, 2000). Therefore, it is important to control diabetes which leads to the prevention or delay of the development of many severe complications (Hardy and Bell, 2004).

According to Simmons, (2001) there are many factors which play as barriers for optimal diabetes care. These barriers are educational barriers such as low diabetes knowledge and low awareness of services. There are also internal physical barriers which are the physical effects of treatment. External physical barriers play another role like own finance issues, limited range of services, poor physical access to the service, insufficient community based services, low quality of services, need for more supportive health professionals and improper diabetes care. Psychosocial barriers are group pressure, prejudice, and insufficient public awareness, inadequate family support, family demands, inadequate community support, communication difficulties and deficiency of cultural support. The last barriers that affect on optimal diabetes care are psychological barriers such as health beliefs, public health beliefs, low motivation, low self-efficacy, negative perceptions, and emotions. On the other hand, it has been found that stressors such as family loss and workplace play an important role on the onset and control of both type 1 and type 2 diabetes. Depression was found to negatively affect on diabetes patients, which may affect on their behaviors such as healthy eating or blood glucose testing and monitoring. Stress negatively affect on diabetes control and management such as regularly monitoring blood glucose level, planning for healthy meals, and taking of insulin doses or oral medications on time which are

difficult to be controlled during stress (Lloyd et al., 2005). Moreover, some of the foremost barriers to use effective medication therapy were the fear of many patients to start diabetes medications and medications regimens. Furthermore, physicians were keen to start medications regimens (Skovlund and Peyrot, 2005). In addition, The Diabetes Attitudes Wishes, and Needs (DAWN) program was conducted in 11 different countries to improve the outcomes of diabetes care focusing on the main barriers of effective diabetes management. One of the main objectives of this study was to measure the psychological distress and levels of diabetes self-management among diabetic patients. Another objective was to measure the barriers behind effective medical therapy for diabetes. It was found that patients' adherence to medications, food, exercise and glucose testing was poor. Diabetes related distress was found to be high among diabetes patients. Problems found to rise with diabetic patients after 15 years mainly due to the fear of developing complication and social disabilities (Skovlund and Peyrot, 2005). Thus, promoting life style changes among diabetes patients and overcoming all the barriers for optimal management would be achieved by diabetes education.

The economical burden of diabetes is high worldwide. In Mexico, the annual cost per diabetic patients was US\$708 while the total annual cost for diabetes was US\$2,618,000 and the percentage of health spending was 15.48% (Villarreal-Rios et al., 2000). Moreover, Caro et al., (2002) have calculated the lifetime costs of complications resulting from type 2 diabetes in U.S. They have found that 85% of cumulative costs of complications for the first five years were due to macrovascular disease which found to be the largest cost component. A total of US\$47,240 was estimated to be the costs of diabetes complications over 30 years. 52% of the total

costs were for managing macrovascular disease, followed by 21% for nephropathy, 17% for neuropathy and lastly 10% for retinopathy. Furthermore, the impact of diabetes on hospital resources in patients admitted to hospital due to cardiovascular diseases was measured from 1998 to 1999 in Puerta del Mar university hospital in south of Spain. It was found that 35.1% of total admissions were due to diabetes. Diabetes patients accounted 39% of direct medical costs, have longer hospital stay and direct in-patient costs and have more readmissions than nondiabetic patients (Carral et al., 2003). On the other hand, an observational study was conducted to compare time spent by diabetes patients visits to community family physicians. It was found that visits for diabetes were longer than both chronic and acute conditions. It was found that diabetic patients discuss on the average of 2.5 problems each visit. Most time spent was to get feed back about the tests, exercise and nutritional advices and health education (Yawn et al., 2001). Longer visits, longer time spent by carers, more work off days, longer hospital stays, more medications consumption and more use of resources, lead to increase the economical burden of uncontrolled diabetes and emphasize on the importance of diabetes education and management.

## **1.2 Problem statement**

Diabetes adherence is not an easy task since the chronic nature of the disease, the daily decisions patients need to take, the difficulty of diabetes management and the serious complications of the disease. Patients must be able to plan for their objectives and take daily effective decisions that meet their values and lifestyles to manage their diabetes successfully (Funnell and Anderson, 2004). Therefore, professionals' responsibility is to help patients to take decisions that meet with their goals and overcome barriers through professional advices, education and support (Funnell and Anderson, 2004). On the other hand, number of diabetic patients is increasing throughout the years as well as the expenses of the healthcare center. Therefore, there is a need to develop educational self management programs for chronic diseases especially for diabetes. The impacts of this program on patients' psychological and behavioral attitudes need to be understood for better designing and improving the way of treating and dealing with them. Moreover, due to the limited budgets and scarce resources, decision makers need comprehensible reports about the effectiveness of these programs in relation to dollars and cents.

## **1.3 Rationale of the study**

Diabetes mellitus is an increasing problem in the western pacific region which has a great impact on the quality of life. It is estimated that by the year 2025, 60 million patients will have diabetes compared to an estimate of 30 million diabetes patients in year 2000. This increase is due to unhealthy life styles, overweight and unhealthy diet. Study of 12 countries showed that the prevalence

of diabetes among adults exceeds 8%. In 1993, the prevalence of diabetes in Malaysia was 8.2% in urban areas and 6.7% in rural areas, 8.9% in Singapore and 10.9% in Japan. (The western pacific declaration on diabetes- a strategic alliance, Kuala Lumpur, 2000). While the first and second National Health and Morbidity surveys found that the prevalence of diabetes increased from 6.3% in 1985 (First national health and morbidity survey, 1985) to 8.3% in 1996 (Second national health and morbidity survey, 1996).

Aging and life style changes are major contributors for diabetes explosion. In 1970, Malaysians over 65 years old were 5.2% of the total population while it is projected to reach 9.5% by the year 2020. Besides, life expectancy for men in 1970 was 61.4 years and 64.7 for women. This figure is projected to increase to 75.4 years for men and 80.4 years for women in 2020. All of these factors, with the estimated increase of Malaysian population in 2020 to 33.7 million, make Malaysia a suitable place for diabetes explosion (Zaini, 2000).

There are three major different ethnic groups in Malaysia with genetic and cultural differences. A study was conducted in seven states in Malaysia to measure the prevalence of diabetes in Malaysians under the age of 40 years, and to measure diabetes control in relation with sociodemographic factors and access to trained diabetes personnel. Results showed that 35.5% were type 1 diabetes while 64.5% were type 2 diabetes. It was found that diabetes control among all diabetes patients was poor with the average HbA1c more than 8%. It was found that glycemic control varies based on ethnic group. Chinese were found the best ethnic group in terms of glycemic control if compared with Malays and Indians. Income,

sexes and educational status showed no significant differences in glycemic control (Ismail et al., 2000).

Compliance or adherence is a major factor for successful diabetes management. Many factors are strongly related to adherence or compliance problems. Some of these factors are social, healthcare provider, demographics, psychological, disease and treatment related factors (Delamater, 2006). Thus, management of diabetes is a challenge for both healthcare provider and patients. This challenge rises to patients since they need to change the lifestyle they are used to, changing their daily food habits and physical activities (Sarkadi and Rosenqvist, 2001), learn how to deal with diabetes medications, how to deal with complications and how to monitor blood glucose level, (Venkat et al., 2000) make diabetes management more difficult. Healthcare providers believe that if patients follow their recommendations, they would avoid diabetes related complications. Healthcare providers face many challenges. First challenge is time limitation during busy hours. It is a challenge to listen to patients and find out what is important for them. The second challenge is to achieve congruence with patients' readiness to change. Furthermore, reducing patients' resistance to change is another challenge faced by healthcare provides (Delamater, 2006).

#### **1.4 Significance of the study**

Due to the chronic, silence nature and the serious complications of diabetes as well as the difficulties to cope with lifestyle changes, difficulties to cope with medications and changing behaviors, the importance of diabetes education has been raised. Moreover, cost of diabetes complications and limited budgets, make

decision makers require a need to compare the effectiveness of diabetes self management programs with normal care and find the net savings which could be achieved by implementing these programs. Therefore, at the end of this study, decision makers at USM health center will have a clear picture of the clinical outcomes of DSMP. These outcomes will assist decision makers in evaluating the current status of diabetic patients in terms of HbA1c, FBS, RBS, BMI and blood pressure. Moreover, at the end of DSMP, decision makers will be able to understand the clinical improvements gained by patients due to the DSMP. Therefore, they will be able to improve the current programs and develop new techniques for better controlling glucose level and avoiding the development of diabetes complications. On the other hand, evaluating patients' psychological and behavioral attitudes and barriers, will assist decision makers in improving the way that medical physicians deal with patients during their regular visits and assist them to improve the way diabetes educators conduct the educational sessions.

Finally, the economical evaluations of this study will help decision makers to understand the real costs and benefits of developing educational programs. Knowing the cost of improving HbA1c, FBS, RBS, and blood pressure values in the intervention groups and compare them with normal care, give decision makers a good idea about the effectiveness of the educational programs. On the other hand, comparing the outcomes and costs of the programs in monetary values, make it easier for decision makers to understand the net savings of these programs. Therefore, they will be able to compare the net savings of this program with other programs which give different outcomes. Therefore, it would be easy for decision makers to rank all the interventions and programs which have been proposed to be

implemented based on the amount of the net benefits these programs can achieve. Thus, their limited resources can be utilized effectively. Therefore, costs and effectiveness of DSMP resulted from this study can be used by the authorities in Malaysia as baseline data for developing such educational programs at the national level since Malaysia is projected by the year of 2020 to be a suitable place for diabetes explosion (Zaini, 2000).

### **1.5 Study objectives**

The main objective of this study is to evaluate Diabetes Self Management Program which has been developed at Universiti Sains Malaysia Health Center from three different perspectives which are clinical, social and economical perspectives.

The main objectives of the clinical perspective in which this research tries to answer are:

1. To evaluate diabetic patients' HbA1c, FBS, RBS, BMI and blood pressure at USM main campus.
2. To compare the impact of two different educational programs on patients' HbA1c, FBS, RBS, BMI and blood pressure at USM main campus.
3. To compare patients' HbA1c, FBS, RBS, BMI and blood pressure values of the intervention groups with those on the normal care group.



On the other hand, this research has the following social objectives:

1. To evaluate psychological behaviors, social, knowledge, and attitudes of diabetic patients at USM health center.
2. To measure the impact of two different educational programs on patients' psychological behaviors, social, knowledge, and attitudes of diabetic patients at USM health center.
3. To compare the impact of the two different interventions on patients' psychological behaviors, social, knowledge, and attitudes toward diabetes and its management.

Furthermore, the economical perspective of this study tries to measure the following:

1. To measure patients' WTP amounts for joining Diabetes Self Management Program.
2. To determine the total costs of developing Diabetes Self Management Program.
3. To conduct cost benefit analysis for developing Diabetes Self Management Program.
4. To measure the impact of two different Diabetes Self Management Programs on patients' WTP amounts.
5. To conduct cost benefit analysis for Diabetes Self Management Program after patients being involved in the two programs.
6. To conduct cost benefit analysis (CBA) for the two Diabetes Self Management Programs after assuming that the programs can prevent the

development of End Stage Renal Failure (ESRF) or delay the development of ESRF for one patient for one year.

7. To perform cost effectiveness analysis (CEA) for reducing one unit of HbA1c, CEA for reducing one unit of FBS, CEA for reducing one unit of RBS, CEA of reducing one unit of systolic blood pressure and CEA for reducing one unit of diastolic blood pressure in the normal care group and the intervention groups.
8. To compare between all CEA ratios.

In this thesis, the second chapter will evaluate the key measurements (Hba1c, BMI, FBS, RBS, and blood pressure) for diabetic patients and the impact of DSMP on those measurements. Chapter three will evaluate the psychological and social factors of diabetic patients and evaluate the impact of DSMP on those factors. The fourth chapter will evaluate the costs and benefits of DSMP and measure CBA and CEA for running DSMP. In the final chapter, conclusion about the study findings was highlighted along with some further recommendations.

## **CHAPTER TWO**

### **DIABETES SELF MANAGEMENT PROGRAM (DSMP)**

## **2.1 Introduction**

### **2.1.1 Background**

Diabetes is of high prevalence worldwide. By the year 2005, number of diabetic patients in US reached up to 20.8 million (Beckley, 2006). The estimated lifetime risk for developing diabetes in US was found to be 33% for men and 39% for women (Riddle, 2004). On the other hand, many factors play major role in the increase of the prevalence of diabetes. Some of these factors are aging, over weight, stress, and large amounts of unhealthy food intake. In addition, estimating the increase of life expectancy in Malaysia, make it an appropriate place for diabetes explosion (Zaini, 2000).

Many serious complications are associated with diabetes such as CVD (Fox et al., 2004), nephropathy, neuropathy and blindness (Cefalu, 2004). In peripheral neuropathy which affects many diabetes patients, if not examined regularly, patients would not take actions until the appearance of injury or ulcerations. Lower extremity amputations have a great economic and social burden due to the long hospitalization stays, home special care, loss of employment and productivity (Marks, 2005). The UKPDS study, (1998) found that intensive blood glucose control with sulphonylureas or insulin resulted in significant reduction in the development of microvascular complications compared with normal care in patients with type-2 diabetes. Similar findings were found with intensive treatment with type-1 diabetic patients which resulted in delaying the development of microvascular complications compared to normal care group (The DCCT Research Group, 1993).

Patients' adherence to their healthcare providers' recommendations is one of the main contributing reasons to diabetes management. On the other

hand, improvements of lifestyle would not only benefit patients by avoiding the development of diabetes complications, but it also improves patients' quality of life through improving physical activities and weight reduction (Teutsch, 2003). Therefore, the essence of diabetes management and education has been explored.

### **2.1.2 Problem statement**

Severe complications can develop from diabetes, such as Cardio Vascular Diseases (Fox et al., 2004), blindness, kidney failure, extremity amputations and others (Cefalu, 2004). Due to the chronic and silent nature of diabetes, patients do not take actions until the development of its complications. On the other hand, the number of diabetic patients at USM is increasing annually in which there are more than 350 known diabetic patients among USM staff at the main campus. Therefore, healthcare expenditures for diabetes medications and complications are increasing annually with limited resources and budgets. Thus, there is a need to increase patients' awareness of the proper ways for diabetes management. By doing so, it will help to increase the patients' quality of life and reduce the expenses of the healthcare center on diabetes medications and complications.

### **2.1.3 Literature review**

Several papers in the literature have discussed the impact of diabetes educational programs on patients' clinical outcomes. Some of these interventions were conducted by pharmacists while others were conducted by

physicians and trained nurses. In this section, we will try to summarize some of the previous relevant studies which have been conducted throughout the world.

Diabetes group education has been seen as an effective tool since 1970s (Mensing and Norris, 2003). Group educational program for type 2 diabetes patients was found to be effective in reducing HbA1c and BMI levels. (Sarkadi and Rosenqvist., 2001). Furthermore, a study compared the effectiveness of group and individual diabetes educational programs found that both groups showed similar improvements in knowledge, weight, BMI and self management behaviors while HbA1c improvements were higher in the group educational program (Rickheim et al., 2002). It could be due to sharing experiences in diabetes in the group programs which add to them extra benefits compared to individual education. Therefore, group's education interventions are more effective and cost saving than the individual interventions.

Pharmacists play a good role in patients' education. A one year group diabetes education led by trained pharmacists was conducted in Swedish pharmacies. Results of the study showed reductions in HbA1c levels after 6 months of the study while returned to the baseline after one year of the study. At the end of the study, patients showed satisfaction from the content and the study circles and recommended to be conducted for other diseases (Sarkadi and Rosenqvist, 1999). An additional study conducted in Sweden led by trained pharmacists for a period of 12 months. It was found that HbA1c level reduced significantly by 0.33% less than the baseline after 6 months of initiating the program (from 6.28 to 5.95), while returned to baseline at the end of the program. 12 months after the end of the program results showed that HbA1c level reduced again by 0.15% from the baseline (Sarkadi et al., 2005). Frequent

follow ups and proper reminders to patients after disease educational interventions are very essential for keeping patients following their educators' recommendations.

On the other hand, a 6 months diabetes management program led by a nurse educator was conducted on poorly controlled diabetes patients. At the end of the study, it was found that HbA1c level decreased significantly in the intervention group by 1.3% while control group by 0.2%. In addition, patients' efficacy and satisfaction were significantly improved in the intervention group (Sadur et al., 1999). Furthermore, access to diabetes educator was found to be a major factor in glycemic control than the access to diabetologist or nutritionist. It was found that the only two centers in a study conducted in Malaysia, who had access to nurse educator had the best glycemic control compared to all other centers (Ismail et al., 2000).

Furthermore, diabetes self management program was conducted in USA. Patients were provided with glucometer and 4 hours group education class. In addition, individual consultations with dietitian and monthly support meetings were given to all patients. Patients showed a significant 15% reduction in HbA1c level while body weight increased 1 lb during the follow up period (Banister et al., 2004).

Reducing HbA1c and BMI help patients in delaying or avoiding the development of diabetes complications which results in better quality of life and lower economical burden. A one year staged management diabetes foot program was done in Louisiana public hospital. Foot ulcer costs and utilization were compared with normal care group. Savings were very clear among staged management group. Over the 12 months program period, staged management

group showed lesser foot related inpatient hospitalizations, lesser foot related inpatient days, lesser foot inpatient related charges, lesser emergency department visits and charges. In general, this program showed to be effective in terms of reducing emergency visits, costs and hospital utilization compared to normal care group (Horswell et al., 2003).

Moreover, a one year diabetes educational program was conducted in 10 Latin American countries. All outcomes of this program have been improved significantly within one year. FBS, HbA1c, body weight, systolic BP, total cholesterol and triglycerides were improved significantly during the study period. After calculating the savings resulted from reduction in the pharmacotherapy consumption due to the program, 34% decrease in the annual cost of treatment was achieved by one year (Gagliardino and Etchegoyen, 2001).

Furthermore, Sidorov et al., (2002) carried out a study to measure the impact of diabetes management on medical costs for patients. They compared the group enrolled in the diabetes management program. They found that program patients had fewer emergency visits compared with the control group. They also found that monthly claims per patients who enrolled in the program were less than those who did not join the program \$394.62 vs. \$502.48, respectively. As a conclusion, it is clear that diabetes educational programs are effective in improving patients' outcomes as found in the previous literature, but it was found that some educational programs failed to improve patients' outcomes (Adolfsson et al., 2007). In the previous literature, diabetes educators were either physicians, pharmacists or nurses. In our study, it is intended to measure the impact of a group diabetes self management program in Health



Center in a university setting given by a mix of educators: physicians, pharmacists and clinical pharmacy lecturers.

#### **2.1.4 Rationale of the study**

It is estimated that by the year 2025, number of diabetic patients will reach up to 250-300 million worldwide (Barrett, 2004). Therefore, the number of people who will develop serious diabetes complications such as cardiovascular disease, end stage renal disease, and visual impairment is estimated to be high. On the other hand, diabetes and obesity are of remarkable increase in US. It is obvious that low physical exercise and large dietary intakes play major role in the development of diabetes. Therefore, there is a need to increase peoples' awareness about the seriousness of diabetes to reduce this fast growing epidemic (Barrett, 2004). Thus, there is a need to find supporting ways additional to the normal care, to better manage the disease and to reduce the expected complications.

Once people are diagnosed as diabetics, they are normally given basic diabetes related information and then left to manage their disease alone for the rest of their life. During normal care, physicians normally have limited time to listen to their patients about their personal life, busy to spend long time with them to strengthen their relationship and busy to follow patients' medical records and history properly. Thus, patients' compliance to their healthcare providers' recommendations stays low and their proper glucose level control stays suboptimal. Patient-physician relationship was evaluated in an Italian nation wide research. Patients' satisfaction from their relationship with their healthcare providers was estimated after the involvement of 2515 patients in the

analysis. Results of the study showed that patients who perceived good relationship with their physicians were most likely meet with their healthcare providers frequently and show more diabetes related worries. On the other hand, patients who reported low level of satisfaction with their healthcare providers were mostly have low level of education, were less satisfied from the information received from their healthcare providers and less satisfied from their participation in diabetes management. Therefore, this study found that the main reasons of patients satisfaction from their relationship with their healthcare providers was more related to patients' characteristics rather than healthcare providers characteristics.(Franciosi et al., 2004) Thus, one to one physician-patients meetings are both time consuming and costly and does not always reach the optimal glycemic control (Sadur et al., 1999).

Diabetes can be managed and controlled through lifestyle modifications as well as using the proper medications. Therefore, the importance of diabetes education has been raised. In diabetes education programs, patients learn how to modify their lifestyles to cope with the disease. In addition, they learn how to properly prepare their food plans, how to perform safe and effective exercises, how to deal with stress, how to deal with family members, friends, and neighbors. Hence, these educational programs give patients the opportunity to better manage their life.

#### **2.1.5 Study objectives**

Patients' education is a necessity for teaching them how to cope with diabetes and how to make changes in their daily meal plans, exercises, and at the end to improve their QOL. Therefore, the main objectives of the Diabetes

Self Management Program are to provide excellent complete diabetes self-management education. Therefore, the specific objectives of this study are:

1. To evaluate diabetic patients' HbA1c, FBS, RBS, BMI and blood pressure.
2. To compare the impacts of two different educational programs on patients' HbA1c, FBS, RBS, BMI and blood pressure.
3. To compare patients' FBS, RBS, and blood pressure values of the intervention groups with those on the normal care group.

#### **2.1.6 Significance of the study**

This study will provide a good baseline data about the current status of diabetic patients at USM Health Center and to which degree they control their glucose level. Knowing patients' glucose level, Body Mass Index (BMI) and blood pressure will help decision makers to evaluate the current epidemic level of diabetes at USM main campus and to consider policies and future steps for better diabetes control in order to prevent any complications associated with it. Moreover, at the end of this study, decision makers at USM Health Center will have a valued data about the effectiveness of two different Diabetes Self Management Programs. After comparing the clinical outcomes of Diabetes Self Management Programs with the normal care, it would be easier for decision makers to know the additional value added by the two different interventions. Thus, this study could be used as a baseline study for developing more comprehensive and beneficial educational program for diabetes and other chronic diseases.

## **2.2 Materials and Methods**

The course included a cluster based one monthly teaching session on the average of 90 minutes for a period of four months. Then, patients were followed four months after finishing their fourth (last) session. During this follow up, males were given a massage class for improving their sexual performance, while females were given a massage class for weight reduction. All materials used in this self management program were validated by the team of educators before starting the program.

### **2.2.1 Study population**

All staff, dependents and pensioners who are type 2 diabetics at USM main campus, patients with other diseases like hypertension, hypercholesterolemia, able to attend all the classes and able to communicate in Malaysian national language, were eligible to be involved in this study. On the other hand, patients who were unable to attend all the classes and unable to communicate in the Malaysian national language were excluded from the study.

### **2.2.2 Program structures**

Diabetes Self Management program started in August 2005. During this period, patients were invited to attend the educational sessions. They were given four different sessions on diabetes education. After they had finished their sessions, researcher made some evaluations for their clinical outcomes before and after the program. Surprisingly, patients' HbA1c levels at the end of the program were higher than the baseline. Therefore, researcher called the educators team and had a meeting to find out the reasons of these negative

outcomes. At the end of the meeting, it was concluded that the way classes were conducted could be the main reason of this negative outcome. Classes were mainly toward one way communication in which patients were mostly receiving information from instructors and had limited time to share their experience and their opinions in the discussion. Furthermore, patients were not followed during the study period and met their instructors only during the sessions. As a result, educators found that there could be barriers between them and their patients. Therefore, in February 2006, researcher and educators decided to improve the way the program was conducted. Main changes were to make the sessions to be conducted in two way communications through encouraging patients to talk and share more their experiences and all the ideas coming to their minds with their colleagues and educators. In addition, researcher used to meet patients outside the sessions at USM campus. Furthermore, researcher and instructors gave their contact numbers to patients to assist them any time they need consultation. By doing this, it led to strengthening provider-patient relationship which was assumed to increase patients' adherence. As expected, patients in this program started to show their care about their health status when they used to call instructors and the researcher and ask them about their latest lab tests results and consult them in many issues regarding their disease. Therefore, the first group who joined the program in August 2005 was referred to as the less structured group while those who joined the program in February 2006 were referred to as the structured group.