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A STUDY ON THE USE OF CLINICAL PRACTICE GUIDELINES (CPG) ON MANAGEMENT OF TYPE 2 DIABETES MELLITUS IN KELANTAN

by

DR. NOR AZLINA BINTI A.RAHMAN

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ABBREVIATIONS

ADA	=	American Diabetes Association
AHA	=	American Heart Association
BMI	=	Body Mass Index
BP	=	Blood pressure
CHD	=	Coronary heart disease
CI	=	Confidence interval
CME	=	Continuing medical education
CPG	=	Clinical Practice Guideline
CVD	=	Cardiovascular disease
DALYs	=	Disability adjusted life years
DCCT	=	Diabetes Control and Complications Trial
DCDCP	=	Diabetes Care Data Collection Project
DCT	=	Diabetes care team
DM	=	Diabetes Mellitus
DPP	=	Diabetes Prevention Program
DREAM	=	The Diabetes REduction Assessment with ramipril and rosiglitazone Medication
EMM	=	Estimated marginal mean
ESRD	=	End stage renal disease
FBG	=	Fasting blood glucose
FDA	=	Food and Drug Administration
FLP	=	Fasting Lipid Profile
FMS	=	Family Medicine Specialist
Freq.	=	Frequency
HbA_{1c}	=	Glycaeted haemoglobin
HC	=	Health Centre
HDL	=	High-density lipoprotein
HUSM	=	Hospital Universiti Sains Malaysia
ICR	=	*Internal consistency reliability*
ITC	=	Item-total correlation
IDDM	=	Insulin-dependent diabetes mellitus
IDF	=	International Diabetes Federation
IFG	=	*Impaired fasting glycaemia*
IGT	=	Impaired glucose tolerance

IRLS	=	Iteratively reweighted least square
JKNK	=	Jabatan Kesihatan Negeri Kelantan (Kelantan State Health Department)
KAP	=	Knowledge, attitude and practice
LDL	=	Low-density lipoprotein
MA	=	Medical assistants
PDM	=	Malaysian Diabetes Association
MEMS	=	Malaysian Endocrine and Metabolic Society
M&HO	=	Medical and Health Officer
MLR	=	Multiple linear regression
mls	=	milliliters
MLT	=	Medical laboratory technician
mmHg	=	Millimeter mercury
mmol/L	=	millimoles per litre
MOH	=	Ministry of Health Malaysia
MODY	=	Maturity onset diabetes of the young
NADI	=	National Diabetes Institute
NGOs	=	Non-governmental organisations
NHMS	=	National Health Morbidity Survey
NIDDM	=	Non-insulin-dependent diabetes mellitus
OGTT	=	Oral glucose tolerance test
OHA	=	Oral hypoglycaemic agents
OR	=	Odds ratio
PAHI	=	Pan American Hypertension Initiative
RBP4	=	Retinol-binding protein 4
RCT	=	Randomised controlled trial
RM Anova	=	Repeated Measure Anova
SD	=	Standard deviation
SLR	=	Simple linear regression
SMBG	=	Self-monitoring of blood glucose
SSGCYD	=	Scottish Study Group for the Care of the Young Diabetic
TC	=	Total cholesterol
TG	=	Triglycerides
UKPDS	=	United Kingdom Prospective Diabetes Study
USA	=	The United States of America
WHO	=	World Health Organization
YLD	=	Years lived with disability

ABSTRAK

TAJUK

Kajian Penggunaan Garispanduan Praktis Klinikal Pengurusan Diabetes Mellitus Jenis 2 Di Kelantan.

PENGENALAN

Prevalen diabetes di Malaysia semakin meningkat dan kebanyakan pesakit dilaporkan mempunyai kawalan glukosa yang tidak baik. Garispanduan Praktis Klinikal (GPK) diwujudkan untuk memperbaiki pengendalian pesakit oleh kakitangan kesihatan bagi menghasilkan kesihatan yang baik kepada para pesakit.

OBJEKTIF

Objektif kajian ini adalah untuk menentukan penggunaan GPK diabetes di kalangan pasukan kawalan diabetes (PKD), mengkaji keberkesanan kursus intensif GPK yang diberikan kepada PKD ke atas pengetahuan, sikap dan amalan (PSA) mereka serta PSA dan kawalan diabetes pesakit mereka serta faktor-faktor yang berkaitan dengan paras HbA_{1c} di kalangan pesakit diabetes dengan kawalan glukos yang tidak baik.

KAEDAH

Kajian ini dijalankan di semua klinik kesihatan (KK) di Kelantan dari Ogos 2005 hingga Mac 2006. Kajian keratan rentas digunakan untuk menentukan penggunaan GPK dan faktor-faktor yang berkaitan dengan paras HbA_{1c} di kalangan pesakit diabetes. Kajian kawalan secara rawak digunakan untuk menentukan kesan intervensi ke atas PSA PKD serta PSA dan kawalan diabetes pesakit mereka. Kumpulan intervensi dan

kumpulan kawalan dipilih secara rawak berdasarkan daerah atau jajahan di negeri Kelantan. Pengukuran semula dibuat selepas empat bulan intervensi dijalankan.

KEPUTUSAN

Sejumlah 176 PKD menyertai kajian ini. Dari segi penggunaan GPK, cuma 40.4% hingga 83.1% mengaku selalu melakukan mana-mana proses pengendalian pesakit diabetes mengikut GPK. Purata markah pengetahuan mereka adalah 23.6 (SD = 3.41) daripada jumlah 30 atau 78.7%, median markah sikap adalah 29 (IQR = 8) daripada jumlah 35 atau 82.9% dan median markah amalan adalah 27 (IQR = 4) daripada jumlah 30 atau 90%.

Sejumlah 208 pesakit diabetes dengan kawalan glukosa yang tidak baik menyertai kajian ini. Purata markah amalan mereka adalah 21.9 (SD = 2.49) daripada jumlah 32 atau 68.4%, median markah pengetahuan adalah 42 (IQR = 8) daripada jumlah 48 atau 87.5% dan median markah sikap adalah 14 (IQR = 2) daripada jumlah 15 atau 93.3%. Pesakit yang berkahwin, tidak menerima pendidikan formal dan menerima rawatan diabetes di KK yang tidak mempunyai Pakar Perubatan Keluarga (PPK) mempunyai paras HbA_{1c} yang lebih tinggi. Paras glukosa darah berpuasa juga meningkat secara bermakna dengan meningkatnya paras HbA_{1c}.

Sejumlah 88 orang peserta PKD dari kumpulan intervensi dan 55 orang dari kumpulan kawalan menyempurnakan kajian ini. Di dalam kumpulan intervensi, peningkatan yang bermakna di dalam markah pengetahuan mereka dapat diperhatikan berbanding kumpulan kawalan. Sejumlah 86 orang peserta pesakit dari setiap kumpulan

menyempurnakan kajian ini. Markah amalan mereka menurun lebih banyak di dalam kumpulan intervensi daripada kumpulan kawalan.

KESIMPULAN

Kebanyakan peserta PKD di Kelantan mengetahui tentang adanya GPK diabetes. Walaubagaimanapun, penggunaan GPK di kalangan mereka adalah kurang memuaskan. PSA PKD dan pesakit adalah agak baik tetapi ianya tidak membawa kepada kawalan diabetes yang baik kepada pesakit. Faktor-faktor yang berkaitan dengan paras HbA_{1c} di dalam pesakit ini adalah paras glukosa darah berpuasa, taraf pendidikan dan perkahwinan serta menerima rawatan di KK yang mempunyai PPK. Kursus intensif yang dijalankan cuma berjaya memperbaiki markah pengetahuan PKD secara minima. Kemungkinan kursus intensif sehari yang diberikan tidak mencukupi untuk mengubah PSA ahli-ahli PKD dan pendidikan berstruktur yang berterusan perlu untuk memberi penekanan tentang PSA kepada PKD. Tempoh masa empat bulan mungkin tidak mencukupi bagi PKD menguruskan pesakit mereka dengan baik bagi memberikan kesan perubahan yang bermakna kepada PSA serta kawalan diabetes pesakit.

ABSTRACT

TITLE

A Study On The Use Of Clinical Practice Guidelines (CPG) On Management of Type 2 Diabetes Mellitus In Kelantan.

INTRODUCTION

The prevalence of diabetes is increasing in Malaysia. Majority of the patients were reported to have poor glycaemic control. CPG were developed to improve the practice of health care providers for better health outcomes in patients.

OBJECTIVE

The objective of this study was to determine the use of diabetic CPG among diabetes care team (DCT), to evaluate the effectiveness of intensive training on the CPG given to DCT in Kelantan on their knowledge, attitude and practice (KAP) and patients' KAP and diabetic control, and to determine the factors associated with HbA_{1c} levels in type 2 diabetic patients with poor control in Kelantan.

METHODS

This study was conducted in all health centres (HC) in Kelantan from August 2005 till March 2006. Cross-sectional study design was used to determine the characteristics of DCT and their use of diabetic CPG, and the characteristics of type 2 diabetic patients with poor control and the factors associated with their HbA_{1c} levels. To determine the effect of intensive course on diabetic CPG given to DCT on their KAP and their patients' KAP and diabetic control, randomised controlled trial was used where the

participants were randomized into intervention and control group by cluster according to the districts in Kelantan. The participants were all DCT members and diabetic patients with poor control. Post-intervention data were collected four months after the intervention was completed.

RESULTS

A total of 176 DCT members participated in this study. Most of the participants knew about the existence of diabetic CPG (79.5%) or have ever read it (71.6%). In term of the use of CPG, only 40.4% to 83.1% of them claimed always practice according to the diabetes care measured. The mean total knowledge scores were 23.6 marks (SD = 3.41) from the total score of 30 or 78.7%, and the median total attitude and practice scores were 29 (IQR = 8) from the total score of 35 and 27 marks (IQR = 4) from the total score of 30 or 82.9% and 90%, respectively.

A total of 208 diabetic patients with poor control participated in this study. Their mean total practice scores were 21.9 (SD = 2.49) from the total score of 32 or 68.4%, and the median of total knowledge and attitude scores were 42 (IQR = 8) from the total score of 48 and 14 (IQR = 2) from the total score of 15 or 87.5% and 93.3%, respectively. Patients who were married, had no formal education and receiving their diabetic care in HC without Family Medicine Specialist (FMS) were significantly associated with poorer HbA_{1c} levels. Fasting blood glucose (FBG) levels were significantly increased with increasing levels of HbA_{1c}.

A total of 88 DCT participants in intervention and 55 in control group completed this study. In the intervention group, significant improvement was observed in knowledge

scores as compared to control group. A total of 86 patient participants in each group completed this study. Their practice scores were significantly reduced more in intervention compared to control group. However the changes observed here were minimal. No significant changes were observed in all the other outcome variables measured in DCT or patient participants.

CONCLUSION

Majority of the DCT members in Kelantan knew about the existence of diabetic CPG. However, their use of the CPG was not very satisfactory. The KAP of DCT and patients were quite good but that did not translate into good diabetic control of the patients. Factors associated with HbA_{1c} levels in the diabetic patients with poor control FBG, educational level, marital status and receiving care in HC with FMS. After intervention, significant improvement was only seen in the knowledge score of DCT, albeit minimal. One day intensive course may not be enough to change DCT's KAP and regularly structured continuing medical education (CME) might be needed to reinforce their KAP. Four months duration may not be enough for the DCT to properly manage their diabetic patients for observable changes in the patients' KAP and diabetic control measures.

1 INTRODUCTION AND LITERATURE REVIEW

1.1 Diabetes Mellitus

Diabetes mellitus (DM) is a group of metabolic diseases characterized by a chronic hyperglycaemic state and disturbances of carbohydrate, fat and protein metabolism. It is caused by insufficient or absence of the hormone insulin, or defect in the insulin action or insulin resistance, or both (WHO, 1994, WHO, 1999, Gavin *et al.*, 2003). The disease has high morbidity and mortality. High cost is needed in order to manage it, in monetary terms or socially, to the patients, their family or to the health care providers and government (Olsson *et al.*, 1994, AACE, 2002).

Diseases with clinical features of diabetes have been recognized since 1550 BC, noted from the ancient Egyptian papyrus discovered by George Ebers (Ekoe *et al.*, 2001). The word 'diabetes' is a Greek word, meaning *siphon*. In the 18th century Matthew Dobson, a Liverpool physician, showed that the sweetness of urine and serum was caused by sugar (Ekoe *et al.*, 2001, Williams and Pickup, 2004). John Rollo (1809) was the first to use the word 'mellitus', a Greek and Latin word for 'honey' as an adjective for 'diabetes' (Williams and Pickup, 2004). In 1889, Oskar Minkowski and Joseph von Mering showed that pancreas disorder caused diabetes (Williams *et al.*, 2002). In 1869, Paul Langerhans found 'islets of Langerhans' which was later known to produce the glucose-lowering hormone, 'insulin' (from Latin word, 'insuline' meaning *island*) (Williams and Pickup, 2004).

1.1.1 Diagnosis and classifications of diabetes mellitus

Diagnosis of DM can be made in:

1. Subjects with signs and symptoms of diabetes, with random plasma glucose of more or equal to 11.1 mmol/L
2. Subjects with fasting plasma glucose (FPG) of more or equal to 7.0 mmol/L.
3. Subjects whose two hours plasma glucose after oral glucose tolerance test (OGTT) using 75 gram load of glucose given by mouth were more or equal to 11.1 mmol/L.

In the absence of unequivocal hyperglycaemia with acute metabolic decompensation, each method above should be confirmed on a different day by any method (ADA, 2006). The detail values for diagnosis of DM and other categories of hyperglycaemia is shown in appendix A.

The classification of DM was previously classified based on clinical descriptive criteria as recommended by the 1985 WHO Study Group (WHO, 1994) and according to the pharmacological treatment used in the management of the disease (Gavin *et al.*, 2003). Classification into insulin-dependent DM (IDDM), non-insulin-dependent DM (NIDDM) and a few other categories were widely accepted at that time (WHO, 1994). Currently, DM is classified according to the aetiology of the disease, resulted from improved understanding of the causes of DM into type 1 diabetes, type 2 diabetes, other specific types of diabetes such as genetic defects of ß-cell or insulin function, drug-induced or chemical-induced and infections, and gestational diabetes (WHO, 1999).

1.1.2 Epidemiology of diabetes mellitus

DM is one of the commonest chronic non-communicable diseases globally. The prevalence varies in different geographic regions and in different ethnic groups, ranging from zero in rural Melanesia (highland population of Papua New Guinea) to 40% in Micronesians (Nauru) and more than 50% in population of Pima Indians of the United States. The prevalence of DM in Europe vary from 1.6% in Northern Ireland to 4.7% in Malta (Ismail and Gill, 1999). DM is epidemic in many developing and newly industrialized countries and the fourth or fifth leading cause of death in most developed nations. It has been referred to as pandemic due to its rapid increase in incidence globally. Type 2 DM is more common and constitutes about 85 to 95% of all diabetes in developed countries and even higher in developing countries (King *et al.*, 1995, Ekoe *et al.*, 2001, IDF, 2003, Taylor, 2004).

The prevalence of DM in Malaysia is steadily increasing, from 0.6% in 1960, to 2.1% in 1982. The first National Health Morbidity Survey (NHMS) done in 1986 reported the prevalence of diabetes in Malaysia was 6.3% (Bakri *et al.*, 1999, Zaini, 2000, Shafie O. *et al.*, 2004, MOH, 2003). The second NHMS in 1996 reported higher prevalence of 8.3% (5.7% known and 2.5% undiagnosed diabetics). Based on that prevalence, it was estimated that there was a total of 700,000 to 900,000 persons with diabetes in Malaysia in 1999 and this figure is expected to increase to two million cases by the year 2025 (MOH, 1998, MOH, 2003, Shafie O. *et al.*, 2004). The prevalence in Kelantan from NHMS II was only 5.3% (3.3% known and 2.0% unknown diabetics) (Bakri *et al.*, 1999). However, Mafauzy *et al.* (1999) reported the prevalence of DM in Kelantan as

high as 10.5%. The difference seen could be due to difference in sampling and diagnosis method, and source population.

Diabetes admission to government hospitals in Malaysia has increased from 19,629 cases in 1991 to 30,661 cases in 2001. The diabetes mortality has increased from 254 deaths in 1991 to 380 deaths in 2001 (MOH, 2003, Shafie O. *et al.*, 2004). Similar trend was observed in Kelantan. The admission to government hospitals due to DM has increased from 954 cases in 1996 to 1828 cases in 2002, with 90% increment within six years. The number of new diabetes cases in health centres (HC) in Kelantan increased from 4,787 cases in 1998 to 6,904 cases in 2002 which constitutes about 44% increment in four years (JKNK, 2003b).

The first burden of disease results produced for Malaysia by Institute for Public Health reported DM as the sixth DALYs in male and fifth in female in 2000. In 2000, there were 47,060 DALYs for DM or 2.9% of the total DALYs in male and 56,390 DALYs for DM or 4.6% of the total DALYs in female in Malaysia. DM is the third cause of years lived with disability (YLD) in Malaysia in 2000, in both male and female. DM constituted about 34,750 YLD or 6.0% of the total YLD in male and 37.631 YLD or 7.2% of the total YLD in female (Ahmad Faudzi *et al.*, 2005).

Glycaemic control in Malaysia and Kelantan

Majority of diabetic patients in Malaysia, or Kelantan had poor glycaemic control. Diabetes Care Data Collection Project (DCDCP), a survey-study done in 1997 on diabetes management and complication status in Asian countries reported the mean HbA_{1c} in Malaysia was 9.1%. Only 12% of the patients had good glycaemic control with HbA_{1c} of less than 6.5%, meaning majority or 88% of Malaysian diabetic patients had poor glycaemic control. The mean FBG also showed similar trend with the mean of 10.4 mmol/L with 86% of them had FBG levels of above 6.1% (DCDCP, 1997).

In Kelantan, a study done in Hospital Universiti Sains Malaysia (HUSM) showed 73% of type 2 diabetic patients had HbA_{1c} levels of more than 7%, and 60% had FBG levels of above 7.2 mmol/L. The worst glycaemic control were seen in Malays with HbA_{1c} levels of 8.7% (Eid *et al.*, 2003). Another study done in Kelantan also showed poor glycaemic control in diabetic patients where 85.7% had HbA_{1c} levels of more than 7.5% and mean HbA_{1c} levels of 9.9% (Suhaiza *et al.*, 2004). The study however was done in one district in Kelantan only and may not be representative of the whole Kelantan. Kelantan State Department of Health (Jabatan Kesihatan Negeri Kelantan or JKNK) reported 61.1% of diabetic patients from HC in Kelantan had HbA_{1c} levels of more than 8% in the year 2003 and 86% had HbA_{1c} levels of above 6.5% in 2004 (JKNK, 2003a, JKNK, 2004). The figure may not be truly representative of Kelantan due to purposive selection of patients to whom the HbA_{1c} measurements were done in clinical setting.

1.1.3 Management and complications of type 2 diabetes

The management of type 2 DM must not only address the glycaemic control, but also other CVD risk factors such as dyslipidaemia, hypertension and obesity (Asian-Pacific Type 2 Diabetes Policy Group, 2002). Holistic approach of management by treating the whole person is important in diabetic patients because DM is a life-long disease and can cause a lot of complications if not managed properly (Mohamad Taha *et al.*, 2004). Currently there are four available classes of oral hypoglycaemic agents (OHA), namely biguanides, insulin secretagogues, alpha-glucosidase inhibitors and thiazolidinediones. Insulin is indicated in type 2 diabetic patients whose hyperglycaemia was not well controlled on maximum doses of combinations OHA or as initial therapy in those who have significant hyperglycaemia (Dailey, 2004). Just recently, on the 17th October 2006, the USA Food and Drug Administration (FDA) approved a new class of OHA, sitagliptin phosphate (Januvia^{TM}). It is a dipeptidyl peptidase IV inhibitors which can enhance the body's own ability to lower elevated blood sugar (FDA, 2006, Januvia, 2006).

DM is the leading cause of blindness, renal failure and non-traumatic lower limb amputation. Chronic hyperglycaemia, even without symptoms, will lead to tissue damage in many organ systems such which can cause serious complications and can be fatal (IDF, 2003). Complications of type 2 DM can be classified into acute and chronic complications and the latter can be further divided into macrovascular and microvascular complications.

Acute complications of DM are hypo and hyperglycaemia. Hypoglycemia can be life-threatening if not corrected. It may occur in diabetic patients if food intake is insufficient, delayed or omitted, insulin or sulphonylurea overdose, or if there is increase in physical exercise. Diabetic ketoacidosis is caused by insulin deficiency, characterized by hyperglycaemia, hyperketonaemia and metabolic acidosis. Typically affecting young type 1 DM, it can be precipitated in type 2 diabetic patients during severe infections and other illnesses. Hyperosmolar non-ketotic hyperglycaemia is characterized by gradual development of marked hyperglycaemia with dehydration and prerenal uraemia, without significant ketosis and acidosis. It usually occurs in middle-aged or elderly type 2 diabetic patients and relatively uncommon but carries high mortality, particularly in the elderly (Williams and Pickup, 2004).

DM can cause increase in atherosclerotic disease of large vessels, including cardiac, cerebral and peripheral vascular disease, or CVD, which are its macrovascular complications (Nathan, 1993, Ekoe *et al.*, 2001). CVD is the most common cause of mortality and morbidity and accounts for up to 65% of deaths in people with type 2 DM (WHO, 1994, Diabetes NSF Team, 2002). The UKPDS has shown that for each 1% increment in HbA_{1c} levels, there was an increased risk of 11% in the occurrence of CHD (Turner *et al.*, 1998).

The chronic complications that are specific to diabetes include retinopathy, nephropathy and neuropathy, which are the microvascular complications. Diabetic retinopathy is characterized by varying degree of microaneurysms, haemorrhages, exudates, venous changes, new vessels formation and retinal thickening. It can involve the peripheral retina, the macula or both. It can lead to blindness, the most feared but preventable

microvascular complications of DM (Harding, 2003, Watkins, 2003a). Diabetic nephropathy occurs in 25-40% of diabetic patients within 20-25 years of the onset of DM (Strippoli *et al.*, 2004). Peripheral neuropathy is commonest in diabetic patients, causing painful neuropathy, disabling foot ulcers, and death from autonomic neuropathy (Hughes, 2002). It occurs in approximately 60-70% of diabetic patients (Dailey, 2004). Neuropathy and ischaemia are the main underlying disorders of diabetic foot problems. Ulcers can be secondarily infected by bacteria and if confounded by ischaemic foot, the risk for gangrene is high and could lead to amputation (Watkins, 2003b).

1.1.4 Diabetes program in Malaysia

Diabetes program has long been in the health care service in Malaysia but it was not very well coordinated. A National Diabetes Prevention and Control Program was initiated by the Ministry of Health Malaysia (MOH) in 1996 to improve the DM program in Malaysia. Later in 1998, the National Diabetes Care Seminar, organized by MOH, Malaysian Endocrine and Metabolic Society (MEMS) and Malaysian Diabetes Association or Persatuan Diabetes Malaysia (PDM) has highlighted several issues which had then been incorporated into the national program. Structured diabetes clinics and diabetes resource centre has been established in all public hospitals. Green diabetes card has been introduced to be used by all diabetic patients to improve record keeping. Besides record keeping, the card can be used as a guideline to educate diabetic patients. It has essential information in diabetes care, e.g. the treatment given, target for diabetic control, presence of complications etc. Paramedics has been given greater role and responsibility in managing diabetic patients. They were trained in preventive and diabetes care, also to work as diabetes care team (DCT), together with medical officers

(MOH, 2003, Shafie O. *et al.*, 2004). Training of DCT members was usually done regularly by the local health authority about once or twice each year. The training was not concentrated on diabetic CPG alone but incorporated into a one or two days general course on non-communicable diseases or CVD.

Reorganization of the National Diabetes Program in 2000 has given emphasis on health promotion and education, diabetes screening, diabetes care management and monitoring, screening for complications, training, recording, monitoring and involvement of non-governmental organisations (NGOs). NGOs involved with diabetes care in Malaysia are MEMS, PDM, Nutrition Society of Malaysia, Dietician Society of Malaysia and National Diabetes Institute (NADI). Health promotion and education is important as primary prevention. Therefore, emphasis has been given on the importance of promoting healthy lifestyle and behaviour through the use of media publicity campaigns and production and distribution of educational materials. Opportunistic screening, especially for the high risk group has been conducted since 1996 and found to be useful. In 2002, 18% of cases had been found to have definite abnormal readings (MOH, 2003, Shafie O. *et al.*, 2004). Diabetes care management and monitoring is important in view of findings from DCCT and UKPDS which had shown delay in the onset of the diabetic complications with intensive glycaemic control (DCCT Research Group, 1993, Stratton *et al.*, 2000). To facilitate the early detection for complications, MOH has introduced the microalbumin testing kit and fundus camera in government hospitals and HC. Training of health personnel, especially DCT members was seen as a crucial component in the National Diabetes Program because successful disease prevention needs not only motivated but also knowledgeable health personnel (MOH, 2003, Shafie O. *et al.*, 2004).

1.2 Clinical Practice Guideline (CPG)

1.2.1 Definition and purposes

Oxford Advanced Learner's Dictionary of Current English and The New Oxford American Dictionary defined the word "guideline" as "a general rule, instruction or piece of advice" (Hornby, 1995, Jewel and Abate F. (eds), 2001). Oxford Reference English Dictionary defined it as "a principle or criterion guiding or directing action" (Pearsal and Trumble B. (eds), 2002). Similarly, Merriam-Webster's Collegiate Dictionary defines guideline as "an indication or outline of policy or conduct" (Mish F. C. *et al* (eds), 1996).

Clinical practice guideline (CPG) was defined by WHO as "systematically developed statements to assist providers and users of health services to make decisions about appropriate health care for specific circumstances" (WHO, 2001). An online encyclopedia defines CPG as a document with the aim of guiding decisions and criteria in specific areas of healthcare using evidence-based medicine. It could include summarized consensus statements and also address practical issues in the health care (Wikipedia Encyclopedia, 2006).

There are many CPG circulating worldwide on many topics, including CPG on the management of DM. Many countries has their own CPG on topics which were important or relevant to their countries. In the United States of America (USA) alone, there are a few CPG on the management of DM, produced or published by the American Diabetes Association (ADA, 2002), the American Association of Clinical

Endocrinologists (AACE, 2002), the Veterans Health Administration (Clark *et al.*, 2000) and the American Geriatric Society (Olson and Norris, 2004).

The use and value of CPG goes back even to the time of Plato (360 BC). The CPG then were more of consensus-based until about thirty years ago when it becoming more evidence-based and put most weight on evidences produced by RCT. A comparative analysis of diabetes CPG from 13 countries (Australia, Canada, Denmark, England, Finland, France, Italy, The Netherlands, New Zealand, Scotland, Spain, Switzerland and USA) showed that the CPG were in agreement about the general management of type 2 DM and there was overlapped in the evidence cited with 18% of citations shared with any other CPG. Research originating from the USA predominated (40% of citations) but nearly all the CPG were more likely to cite evidence from their own countries (Burgers *et al.*, 2002).

The aims of CPG are to promote the best practices and raise quality of care. This can assist in achieving better health outcomes or outcomes of treatment by improving the practice of health care providers. It is also hoped to increase patients' awareness of the options available for the management of specific conditions (Haycox *et al.*, 1999, MOH, 2003, Wikipedia Encyclopedia, 2006). Some of the other purposes of CPG are to standardize the medical care and reduce the inappropriate variation in practice, to provide a more rational basis for referral and a focus for continuing education, to promote efficient use of resources and to achieve the best balance between cost and clinical practice. CPG can also act as focus for quality control, including audit (Zaleski *et al.*, 1997, MOH, 2003, Open Clinical, 2006, Wikipedia Encyclopedia, 2006).

Mandatory practice guidelines has also been introduced as a way of cost containment, as being done in France (Zaleski *et al.*, 1997).

The objectives of CPG can only become reality if the outcomes identified in RCT are reproducible in normal practice and there is rapid and universal adoption of the CPG which leads to optimal treatment for the whole population. Local evidence therefore is a priority to be used in CPG (Burgers *et al.*, 2002). However, in clinical practice in the community, resources are more restricted, patients are less compliance and treatment cannot be limited to a small group of patients. Due to that, the anticipated benefits are rarely fully realised (Haycox *et al.*, 1999).

1.2.2 CPG on type 2 DM in Malaysia

In Malaysia, CPG have been produced since 1992 under the responsibility of the Health Care Quality Unit of the Medical Development Division under MOH. In 2001, with reorganization in the MOH, it came under the purview of the Health Technology Assessment Unit (MOH, 2003). Many CPG developed in Malaysia are available on various topics, examples are on management of chronic obstructive pulmonary disease (Zainudin *et al.*, 1998), management of heart failure (Rajadurai *et al.*, 2000), management of obesity (Ikram Shah *et al.*, 2004) and others.

The specific CPG for management of type 2 DM was published in 1997 under the Diabetes Info Series by MOH and PDM (MOH and PDM, 1997). It has been revised and the newest revised edition is only recently become available for use (CPG Task

Force, 2004). It focused on screening and diagnosis, management of type 2 DM and its chronic complications, and prevention of type 2 DM. It is meant to be a guide for clinical practice, based on the best available evidence at the time of its development (CPG Task Force, 2004). Targets for control in the management of type 2 DM according to the CPG is as listed in table 1 below.

Table 1 : Targets for type 2 DM

	Levels
Glycaemic control	
Fasting	4.4 – 6.1 mmol/L
Non-fasting	4.4 – 8.0 mmol/L
HbA_{1c}	< 6.5%
Lipids	
Triglycerides (TG)	≤ 1.7 mmol/L
HDL-cholesterol (HDL)	≥ 1.1 mmol/L
LDL-cholesterol (LDL)	≤ 2.6 mmol/L
Body mass index (BMI)	< 23 kg/m^2
Blood Pressure (BP)	
Normal renal function	≤ 130/80 mm/Hg
Renal impairment / gross proteinuria	≤ 120/75 mm/Hg

Adapted (CPG Task Force, 2004)

1.2.3 Effect of CPG-based intervention

(a) Effect on diabetic care processes

A before and after study done to assess the impact of the publication of the ADA CPG on diabetes showed no significant improvement in the diabetic patient care as anticipated, except in the areas of foot care, eye examination and lipid screening (Stolar, 1995). Later the ADA CPG on diabetes has been implemented through a series of lectures for all the primary care providers and the distribution of "tool-kits" to all points of care. CPG adherence was also encouraged at regular departmental meetings. The before and after study done to assess the effectiveness of the implementation showed significant increase only in the percentages of patients receiving yearly microalbumin screens and recommended education, however no significant improvement in the other processes of care evaluated (Lesho *et al.*, 2005).

An RCT done in general practices in east London where the locally developed diabetic CPG disseminated through practice based education and multidisciplinary educational outreach or academic detailing showed significant improvements in recording of all the key variables in patient records (Feder *et al.*, 1995).

(b) Effect on diabetic outcome

The sudy by Lesho *et al.* (2005) mentioned above also measure the HbA_{1c} levels in the diabetic patients as an outcome, but found no significant change in the mean HbA_{1c} levels before and after the implementation of the diabetic CPG. Benjamin *et al.* (1999) however noted significant improvement in HbA_{1c} levels after CPG training of their staffs based on Staged Diabetes Management in a problem-based learning program.

1.3 Conceptual framework

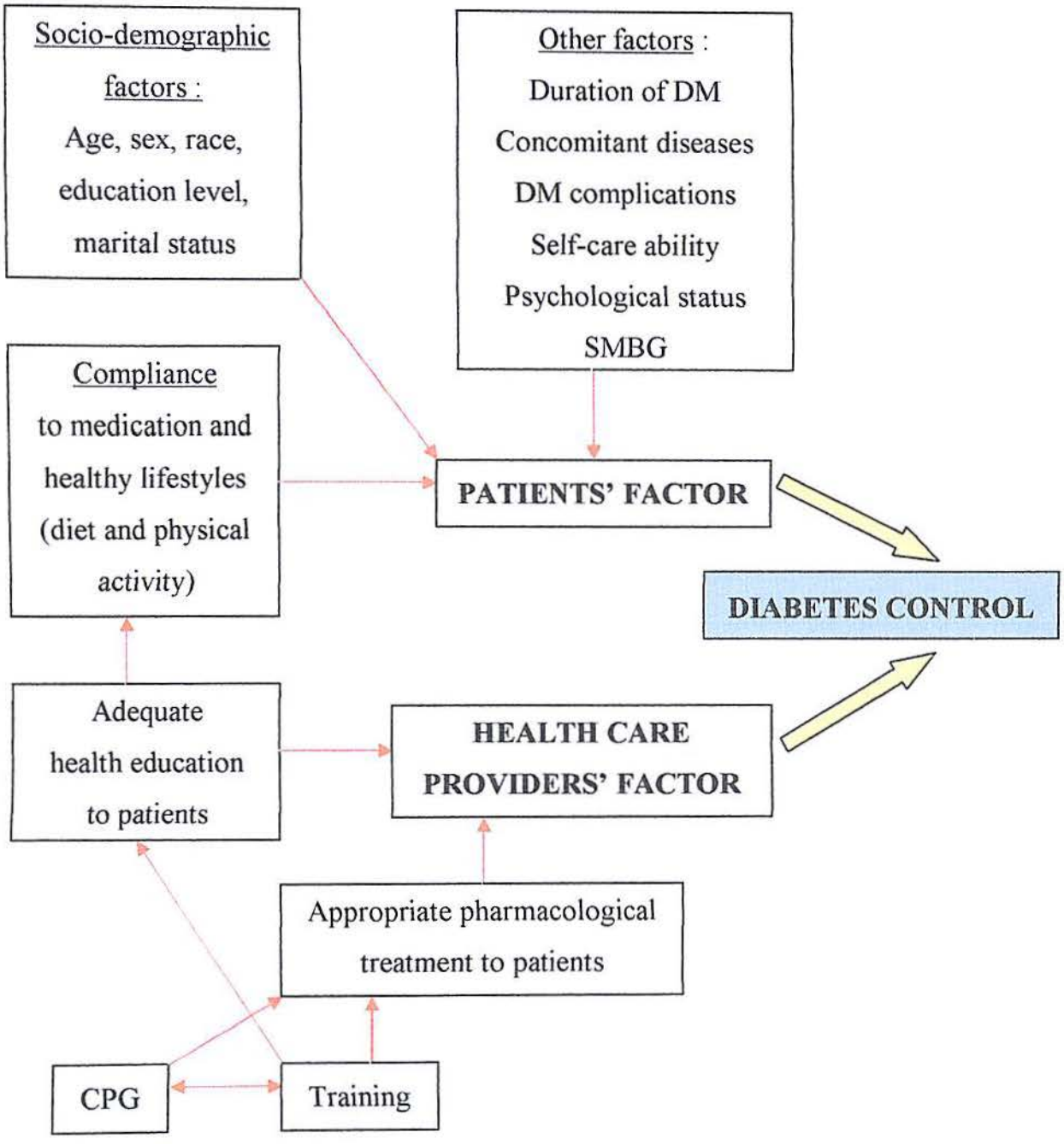

Figure 1: Conceptual framework of factors associated with diabetic control

From the above conceptual framework, this study is expected to ascertain the sociodemographic and compliance factors associated with glycaemic control in diabetic patients with poor control. Intensive course on diabetic CPG given to DCT is expected

Glycaemic control in diabetic patients is a complex and multifactorial function of the patients' factors and health care providers' factors (figure 1). Patients' factor associated with glycaemic control can be divided into socio-demographic and other factors and adherence to medication and healthy lifestyle. Many previous studies done on factors associated with glycaemic control reported conflicting results. This could be due to the difference in the source population and methodology used, categorisation of the patients' characteristics, and the difference in the classification of poor and good glycaemic control.

a) Socio-demographic factors

Studies done in Indiana and HUSM showed that younger age group was associated with poorer glycaemic control type 2 diabetic patients (Nichols *et al.*, 2000, Eid *et al.*, 2003), but reverse association was found in another study (Ferrannini *et al.*, 1992). However, no significant association was found in a few other studies (Blaum *et al.*, 1997, Suhaiza *et al.*, 2004).

Many studies done found no significant association between sex and glycaemic control (Ferrannini *et al.*, 1992, Blaum *et al.*, 1997, Eid *et al.*, 2003, Suhaiza *et al.*, 2004). However, Nichols *et al.* (2000) found that male sex predicted worse glycaemic control. Studies done in the USA found significantly higher HbA_{1c} concentrations in blacks as compared to whites (Schectman *et al.*, 2002, Rekeneire *et al.*, 2003). Eid *et al.* (2003) observed worst glycaemic control in Malay type 2 diabetic patients compared to non-Malay subjects. No significant association between poor glycaemic control and educational level was found in a secondary analysis of data by Blaum *et al.* (1997).

Suhaiza *et al.* (2004) found no association between marital status and glycaemic control. Better marital satisfaction or good quality of marriage was found to be related to higher levels of diabetes-related satisfaction and better general quality of life. The same study found non-significant but strong trend relating good glycaemic control to good marriages, but no relationship was found between intimacy and glycaemic control (Trief *et al.*, 2001). It might be difficult to demonstrate an effect for any specific psychosocial variable in view of numerous factors affecting glycaemic control.

b) Other factors

Studies by Blaum *et al.* (1997) and Eid *et al.* (2003) showed that longer duration of DM was significantly associated with poorer glycaemic control, however no significant association was found in study by Suhaiza *et al.* (2004). No significant association between BMI and glycaemic control was found in studies done by Ferrannini *et al.* (1992), Blaum *et al.* (1997), Eid *et al.* (2003) and Suhaiza *et al.* (2004), though obesity was deemed as one of the important risk factor for the development of type 2 DM.

A meta-analysis of 24 studies reported association between depression and hyperglycaemia in patients with type 1 and type 2 DM (Lustman *et al.*, 2000). Study done by Blaum *et al.* (1997) showed significant independent association between poor self-care ability and perceived absence of dietary recommendations with poor glycaemic control. The self care ability scale was based on questions to evaluate patients' ability to comply with diet, exercise and medication and their ability to cope with the demands of DM. Poorer HbA_{1c} levels was also found to be associated with higher SF-36 Bodily Pain subscale score and low physical functioning subscale score (Sinnott *et al.*, 2005).

c) Adherence to medication and healthy lifestyle

A retrospective study done by Rhee *et al.* (2005) showed that there was a significant improvement in the glycaemic control in patients with high adherence level to keeping appointments and taking medications as directed. Study by Schectman *et al.* (2002) also found better metabolic control with greater medication adherence.

High dietary fiber intake has been shown to improve blood glucose and HbA_{1c} levels, decrease hyperinsulinaemia, lower plasma lipid concentrations and the number of hypoglycaemic events in type 1 and type 2 diabetic patients (Chandalia *et al.*, 2000, Giacco *et al.*, 2000). Low glycaemic index diet has a therapeutic potential in type 2 DM and has been shown to lower the glucose and insulin responses throughout the day while improving the glucose utilization by the body, lipid profile and fibrinolytic activity, as measured by the PAI-1 activity (Jarvi *et al.*, 1999, Rizkalla *et al.*, 2004).

Low levels of physical activity were found to be associated with poor glycaemic control in type 1 diabetic women (Waden *et al.*, 2005). On the other hand, high-intensity resistance training, in combination of moderate weight loss was found to be effective in improving glycaemic control in older patients with type 2 DM (Dunstan *et al.*, 2002).

SMBG has been associated with better glycaemic control among type 2 diabetic patients on insulin therapy (Franciosi et al., 2001, Murata et al., 2003). A systematic review of randomised controlled trial also reported an overall significant improvement in the HbA1c levels in type 2 diabetic patients not on insulin using SMBG compared to control, with the decrease of 0.39% in HbA1c (Welschen et al., 2005).

2 OBJECTIVES AND RESEARCH QUESTIONS

2.1 General objective

To determine the use of diabetic CPG among DCT in managing type 2 diabetic patients in Kelantan

2.2 Specific objectives

1. To determine the use of CPG on management of type 2 DM among DCT members in Kelantan and their KAP on the CPG.

2. To determine the characteristics of type 2 diabetic patients with poor control in Kelantan and factors associated with their HbA_{1c} levels.

3. To evaluate the effectiveness of intensive refresher course on CPG on DM given to DCT members in Kelantan on their KAP on the CPG, compared to those without the intensive course.

4. To evaluate the effect of the above intensive revision course given to DCT on patients' KAP about diabetes and its management and their diabetic control compared to patients with the usual care.

2.3 Research hypothesis

1. The use of diabetic CPG among DCT in Kelantan and their KAP is high.

2. There is improvement in KAP of DCT in Kelantan after being given intensive refresher course on diabetic CPG compared to control group.

3. There is improvement in KAP and diabetic control of diabetic patients' under the DCT's care who were being given intensive refresher course on diabetic CPG as compared to usual care.

4. There is association between socio-demographic and clinical factors and KAP of diabetic patients with poor control in Kelantan with their HbA_{1c} levels.

2.4 Rationale of the study

1. CPG were developed to decrease the practice variation among the health care providers and hoped to assist in achieving better health outcomes of the patients by improving the practice of the health care providers. However, many experts acknowledge the uncertainty of the effectiveness of CPG but still encourage their implementation (Lesho *et al.*, 2005).

2. JKNK acknowledged that use of CPG among DCT was not satisfactory (JKNK, 2003b), but no formal study was done before to determine that fact.

3. Not many studies were done to determine the effect of training of diabetic CPG on DCT's KAP and diabetic control of patients with type 2 DM.

4. To comply to the Western Pacific Declaration on Diabetes who encourage research to advance and apply knowledge about the effective management of diabetes (Asian-Pacific Type 2 Diabetes Policy Group, 2002).

5. To comply to WHO recommendation about the need to do intervention research on different models of care for diabetes in different societies (WHO, 1994).

6. Finding the factors associated with poorly controlled diabetic patients can give insight in the management of the patients to give better care for better diabetic control.

7. Study on patients' KAP is still important because current approach in management of DM is towards self-management. To be able to do that, the patients must have good knowledge and attitude about DM and its management. This can contribute to good practice among the patients towards their disease and its management.

8. Study on DCT KAP is also important because health care providers involved in the management of diabetic patients must have good knowledge and attitude about DM and its management, which can then improve their practice towards the disease and its management in order to give appropriate care and management for the patients.

2.5 Definition of terms

Term		Definition
CPG	:	A systematically developed statements to assist providers and users of health services to make decisions about appropriate health care for specific circumstances (WHO, 2001)
Diabetic control	:	Metabolic control which was needed to be monitored in a diabetic patient as an appropriate management of DM to prevent or delay the development of diabetic complications, which is HbA_{1c} and / or FBG. Other related control are fasting lipid profile (FLP), BP and BMI
DCT	:	Interdisciplinary group of care providers, including Family Medicine Specialist (FMS), Medical and Health Officer (M&HO), medical assistants (MA), nurses and medical laboratory technician (MLT), responsible in taking care of diabetic patients, counseling them in all aspect of their disease management and empowering them for self-management (King *et al.*, 1995)
Effectiveness	:	The effects of the activity and the end-results, outcomes or benefits for the population achieved in relation to the stated objectives (King *et al.*, 1995)
FBG	:	Blood glucose level which is measured from the serum. The blood is taken after the patient has fasted overnight or for about 8-16 hours, during which plain water may be drunk
FLP	:	Used to measure the levels of cholesterol components, including TC, TG, HDL and LDL in the blood. The blood is taken after the patient has fasted overnight or for about 8-16 hours because the level is affected by the meal taken before the blood taking

Term		Definition
Glycaemic control	:	The measure of blood glucose level in diabetic patients, measured by HbA_{1c} levels
HbA_{1c}	:	Also known as glycaeted haemoglobin or glycohaemoglobin, HbA_{1c} measures the amount of glucose that has bonded with the haemoglobin in red blood cells which is formed slowly and non-enzymatically. It gives the average blood glucose levels over the past two or three months because the average survival of the red blood cells was 120 days(Goldstein *et al.*, 2004, Roberts, 2004)
Health intervention	:	A program, procedure, service or activity which is carried out to improve or maintain health, health behaviours or other factors associated with health (WHO, 2001)
Intensive course	:	A revision course during which all the related knowledge and practicalities were given in a short period of time, which was one day only instead of a longer, extensive course
KAP	:	Knowledge, attitude and practice about a certain matter which was measured using a specially constructed questionnaire which was validated prior to its usage
Poorly controlled type 2 diabetic patients	:	Type 2 diabetic patients who had poor glycaemic control with the HbA_{1c} levels of more than 6.5% (Asian-Pacific Type 2 Diabetes Policy Group, 2002, CPG Task Force, 2004)

3 MATERIALS AND METHODS

3.1 Study area

This study was done in Kelantan, one of the states in Malaysia. It is situated at the east coast of Peninsular Malaysia (figure 2) with the total population of 1,479,800 people (MOH, 2004). It consists of ten 'Jajahan' or administrative districts, namely Kota Bharu, Bachok, Pasir Puteh, Machang, Tanah Merah, Jeli, Kuala Krai, Tumpat, Pasir Mas and Gua Musang (figure 3). Every district has its own District Health Office, under the administration of a Medical Officer of Health. Some District Health Office has a second Medical Officer of Health or Epidemiology Officer to assist the principal Medical Officer of Health. To cater for the population, every district has a few health centres (HC) depending on the wide area covered and the population density in the respective districts.

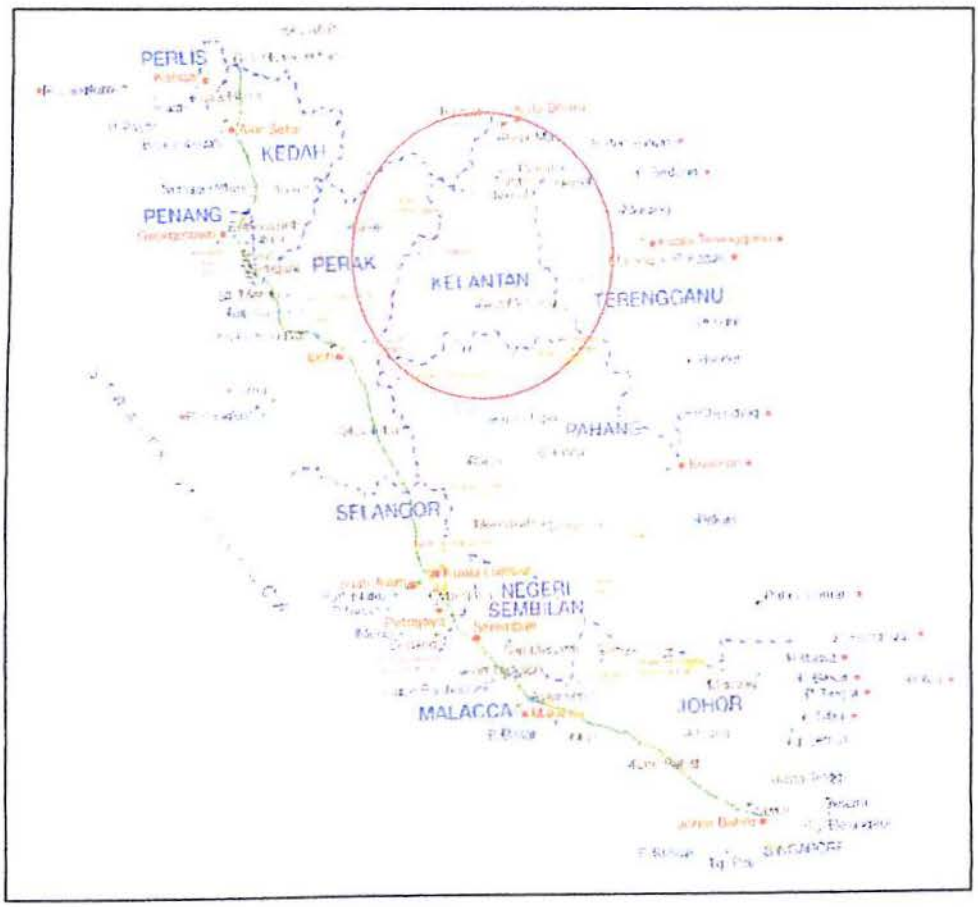

Figure 2 : The map of Malaysia