UNIVERSITI PUTRA MALAYSIA

AWARENESS OF GLYCOSYLATED HAEMOGLOBIN (HbAIc) AMONG TYPE 2 DIABETIC PATIENTS IN HOSPITAL PUTRAJAYA

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By

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ABSTRACT

AWARENESS OF GLYCOSYLATED HAEMOGLOBIN (HbA1c) AMONG TYPE 2 DIABETIC PATIENTS IN HOSPITAL PUTRAJAYA

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Background: Diabetes mellitus (DM) is a group of metabolic disorders of carbohydrate metabolism characterised mainly by hyperglycaemia leading to micro and macrovascular complications. Improved glycaemic control decreases development of diabetic complications. The glycosylated haemoglobin (HbA1c) test has been the most widely accepted laboratory test for evaluating long term glycaemic control. The aim of this research is to determine the level of HbA1c awareness and understanding among type 2 DM patients and the effect on their glycaemic control.

Methods: This was a cross-sectional descriptive study among Type 2 DM patients undergoing routine follow up in endocrine clinic of Hospital Putrajaya. Patients were invited to answer validated questionnaire which assess their awareness and knowledge of HbA1c. Their last HbA1c results are checked through the laboratory information system.

Result: A total of 92 participants were recruited. 39.1% (36/92) have not heard of HbA1c. However, those who have heard of HbA1c, 82.1% (46/56) had good understanding of HbA1c. Factors which significantly affect understanding are the higher income group and levels of education. 55% of those who had good understanding of HbA1c had achieved their glycaemic control compared to 45% who had poor understanding. This was however not statistically significant.

Conclusion: The level of awareness of HbA1c among Type 2 diabetic patients is still low as some patients have not heard of HbA1c. However for those who have heard of HbA1c, they had good understanding of HbA1c.

Keywords: Type 2 diabetes mellitus, HbA1c, HbA1c awareness, glycaemic control,

ABSTRAK

KESEDARAN MENGENAI HEMOGLOBIN GLIKOSILAT (HbA1c) DALAM KALANGAN PESAKIT TYPE 2 DIABETES MELLITUS DI HOSPITAL PUTRAJAYA.

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Latar belakang: Diabetes Mellitus (DM) atau kencing manis adalah penyakit metabolik metabolisme karbohidrat yang menyebabkan kandungan glukosa (gula) berlebihan dalam dalam darah meyebabkan komplikasi mikro dan makrovaskular. Kawalan kandungan glukosa yang baik akan mengelakkan komplikasi-komplikasi tersebut. Ujian hemoglobin glikosilat (HbA1c) telah digunakan secara meluas untuk menilai kawalan glukosa pada jangka masa panjang. Tujuan kajian ini adalah untuk menentukan tahap kesedaran dan pengetahuan HbA1c dalam kalangan pesakit kencing manis type 2 dan kesan keatas kawalan glikamik.

Kaedah: Ini merupakan kajian keratan rentas deskriptif dalam kalangan pesakit kencing manis type 2 yang menjalani pemeriksaan kesihatan susulan di klinik endokrin Hospital Putrajaya. Pesakit kencing manis diminta untuk menjawab kaji selidik untuk menilai kesedaran dan pengetahuan mengenai HbA1c. Keputusan HbA1c pesakit telah disemak melalui sistem maklumat makmal.

Keputusan: Seramai 92 pesakit telah menyertai kajian ini. 39.1% (36/92) daripada mereka tidak pernah mendengar mengenai HbA1c. Walaubagaimanapun, dalam kalangan mereka yang pernah mendengar mengenai HbA1c, 82.1% (46/56) mempunyai pengetahuan yang baik. Faktor signifikan yang mempengaruhi pengetahuan adalah tahap pendidikan dan pendapatan sebulan yang tinggi. 55% dari kalangan mereka yang mempunyai pengetahuan yang baik mencapai tahap kawalan glisemik yang baik berbanding 45% yang mempunyai tahap pengeathuan yang lemah. Walaubagaimanapun, ianya tidak signifikan secara statistik.

Kesimpulan: Tahap kesedaran HbA1c dalam kalangan pesakit type 2 diabetes mellitus masih rendah kerana beberapa pesakit tidak pernah mendengar tentang HbA1c. Walaubagaimanapun di kalangan meraka yang pernah mendengar mengenai HbA1c , tahap pengetahuan adalah baik.

Kata kunci: Kencing manis type 2, HbA1c, kesedaran HbA1c, Kawalan glikemik

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CHAPTER 1: INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic disorders of carbohydrate metabolism characterised mainly by hyperglycaemia (Sacks 2006). The hyperglycaemia results from defects in insulin secretion, insulin action or both (Kumar V et al, 2007). Chronic hyperglycaemia results in the appearance of micro and macrovascular complications involving the heart, eyes, kidneys and the nervous system. Several studies have reported that improved glycaemic control decreases the development or progression of diabetic complications (Viswanathan et al., 2010; Diana et al.,2003). The glycosylated haemoglobin (HbA1c) test has been the most widely accepted, reliable outcome measure for evaluating long term glycaemic control.

HbA1c is formed during the non-enzymatic reaction of glucose with amino-acid residues of haemoglobin. HbA1c rate of composition is mainly dependent on the glucose concentrations that the plasma red blood cells are exposed to. HbA1c is a reliable index of glycaemia for the last 3 months, which is dependent on the duration of life of red blood cells (Katsilambro N,2006). The Malaysian Clinical Practice Guideline states that achieving a HbA1c level of <6.5% reduces the risk of vascular complications. Maintaining HbA1c levels to near normal range results in considerable reduction in long-term diabetes complications (Manoharan D et al., 2010). The American Diabetes Association (ADA), 2003 recommends diabetic patients to be aware of their target and the actual HbA1c value.

1.1 Problem Statement

Patients' awareness of HbA1c will help to improve the glycaemic control among diabetic patients. Manoharan D et al. (2010) showed that even though there are increasing efforts by various health organizations such as Health Maintenance Organization (HMO) and Place of Service (POS) to increase public awareness regarding HbA1c, some patients are still not aware of the importance of HbA1c and their HbA1c target goals.

Heisler et al.(2005) found that diabetic patients who knew their HbA1c values had better glycaemic control than those who did not. However, the study showed only 25% out of 686 diabetic patients were able to remember their last HbA1c values. Factors which may affect HbA1c awareness include age, gender, race, income, level of education and duration since diagnosis of diabetes.

There are limited studies looking on patients' awareness of HbA1c in Malaysia. Thus, the aim of this research was to determine the level of HbA1c awareness among type 2 DM patients.

1.2 Objectives

1.2.1 General Objective

To determine the level of HbA1c awareness among Type 2 DM patients in Hospital Putrajaya.

1.2.2 Specific Objective

1. To determine the factors (sociodemographics, clinical exposure) associated with HbA1c awareness among Type 2 DM patients.
2. To determine whether awareness of HbA1c was associated with better glycaemic control.

1.3 Research Hypothesis

Null hypothesis:

There was no association between awareness of HbA1c and glycaemic control in Type 2 diabetic patients.

Alternative hypothesis:

There was an association between awareness of HbA1c and glycaemic control in Type 2 diabetic patients.

Chapter 2: Literature Review

2.1 Prevalence of DM

Based on the Third National Health and Morbidity Survey 2006 (NHMS III), it is estimated that 1 out of every 8 Malaysians age 30 years and above have diabetes, which accounts for nearly 1.7 million adults. The increased in the prevalence may be due to an increase in the number of elderly people, urbanization lifestyles such as unhealthy diets, less physical activities and access to healthcare facilities both in urban and rural areas (Ismail et al., 2011) However, the latest NHMS IV showed that the prevalence of diabetes has increased to 15.2% in 2011 among people of age 18 years old and above.

2.2 Pathophysiology of Type 2 DM

DM is a group of metabolic disease associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels (Mahato RV, 2011), (Triplitt CL, 2012). Type 2 DM is characterised by insulin resistance and/or insulin deficiency. In most cases, insulin resistance occurs prior to insulin deficiency. Insulin resistance is the inability of insulin to inhibit hepatic glucose production and to stimulate uptake of glucose by skeletal muscle and adipose tissue . This causes decreased glucose uptake in Type 2 DM, in the presence of physiologically possible levels of insulin in humans. Initially, insulin resistance is compensated by enhanced insulin secretion. As time progress, however, the early phase insulin secretion is impaired due to progressive deterioration of β-cell mass and function, leads to transition from normal glucose tolerance to impaired glucose tolerance and DM (Triplitt CL, 2012)

2.3 Complications of Type 2 DM

The long-term effects of diabetes include development of retinopathy, nephropathy and neuropathy. People with diabetes are also at increased risk of cardiac, peripheral arterial and cerebrovascular disease. The most common complications were neuropathy (30.1%) followed by background retinopathy (23.5%), albuminuria (22.9%) and microalbuminuria (20.4%) (Mafauzy, 2005). Patients with uncontrolled diabetes tend to develop these micro ad macrovascular complications.

2.4 HbA1c

2.4.1 Historical background

The relation of glycated haemoglobin to blood glucose level was first discovered about 40 years ago (Gough S, 2010). Over the next decade assays were developed to allow its routine use. It was a massive breakthrough for people with diabetes and health professionals, as for the first time there was an independent way of assessing average blood glucose level over a period of several weeks. The test was first used for assessing diabetic control in 1976, and later a wide range of different test method was developed. In Malaysia, the HbA1c test is used as part of diabetes patients' management. The Malaysian Ministry of Health CPG,(2009)recommends that HbA1c should be measured approximately every 3 to 6 months to ensure that glycaemic targets are being met.

2.4.2 Definition

HbA1c is defined by the International Federation of Clinical Chemistry (IFCC) as HbA with glucose attached to its N-terminal valine residue of β-chain. It is the major fraction (80%) of total glycated haemoglobin. HbA1c level is expressed as the percentage of total blood haemoglobin concentration. The HbA1c values

represent the average glucose values over the preceding 6 to 8 weeks. HbA1c is considered to be the gold standard for the evaluation of glycaemic control in diabetic patients.

2.4.3 Clinical utility of HbA1c in DM

HbA1c has been established as a maker of long-term glucose concentration and is used as a measure of risk for development of diabetic complications. The United Kingdom Prospective Diabetes Study has demonstrated that HbA1c had a direct relation with development of diabetic complications. Decreasing HbA1c level can reduce 54% risk of progression of retinopathy and 25% risk reduction for micro vascular complication in DM. Epic-Norflok (1999) had showed that an increasing HbA1c concentration will cause 40% increase in cardiovascular or ischaemic heart disease mortality. HbA1c is now used for monitoring treatment and management of diabetes and is use to guide adjustment therapy. ADA 2003 states that an adult with diabetes should have a HbA1c level less than 7% whilst the American College of Endocrinology and the International Diabetes Federation recommended a HbA1c target of 6.5%. The Malaysian Clinical Practice Guidelines for Type 2 diabetes (2009) recommended that the target for HbA1c is < 6.5%.

2.5 HbA1c measurement in the clinical laboratory

There are more than 30 methods available for HbA1c measurement (Sack 2005). These methods identify HbA1c either based on i) charge difference example ion exchange chromatography and high performance liquid chromatography (HPLC) and ii) structural difference example boronate affinity and immunoassay (WHO 2011). The vast majority of clinical laboratories use cation-exchange HPLC or immunoassay (Sacks 2003). The principle use in ion exchange chromatography is that HbA1c has a lower isoelectric point

and migrate faster than other Hb components. The technique used in immunoassay uses specific antibodies to measure HbA1c (IFCC 2010).

2.6 Awareness of HbA1c among diabetic patients

Studies have shown contradictory reports on the level of HbA1c awareness depending on the place or setting of the study and its population.

2.6.1 Research which found low level of HbA1c awareness

Mehrotra R et al (2000) showed that only 7.6% out of 793 patients seen in diabetic clinic in India knew about HbA1c. Iqbal et al. (2008) noted that only 40.5% (45/111 patients; 31 type 1 DM, 14 type 2 DM) were aware of HbA1c. Patients were from a hospital diabetic clinic in England. They found that patient's knowledge of HbA1c was poor, especially in type 2 diabetes patient. Beard et al (2010) reported that the majority of participants from outpatient clinics in UK had poor understanding of HbA1c. Only 26.5% out of 83 participants had good understanding of HbA1c. Good understanding was defined as patients who knew what HbA1c meant, were able to give correct definition and correctly provided their last HbA1c test result (within 0.5%).

2.6.2 Research which found high level of HbA1c awareness

Svien Skeie et al. (2001) reported that 80% out of 201 patients were aware and knew their last HbA1c value. Participants were recruited from a diabetic clinic of a hospital in Norway. They however, only looked at type 1 DM patients, with at least 14 years history of DM. Good awareness was defined as patients who can give correct definition and correctly provide their last HbA1c test result (within 1%).

Diana V et al. (2005) reported that 51% out of 150 diabetic patients seen in an ophthalmic clinic in United States understood HbA1c, 17% not sure and 33% did not understand.

Viswanathan V et al. (2010) noted that 74% of 480 participants had knowledge of HbA1c. Participants were from an outpatient dept of tertiary centre in India. In their centre, it is the clinical practice guideline to measure HbA1c every 3 months and to educate patients about HbA1c.

2.7 Factors associated with awareness of HbA1c

2.7.1 Age

Age was found to be an important factor in determining HbA1c awareness. Beard et al. (2010) found that those of an older age, with type 2 DM generally had a poor understanding of their HbA1c test result. Poor understanding will decrease the awareness of HbA1c test.

2.7.2 Gender

There were no significant difference of HbA1c awareness among male and females (Viswanathan , 2010).

2.7.3 Race

There were no significant difference between awareness and race (Sanjay et al, 2013)

2.7.4 Education level

Viswanathan V et al. (2010) found that patients with higher education level are significantly more aware of HbA1c. Higher education level results in more understanding of the importance of the HbA1c goal.

2.7.5 Location

Majority of the study subjects who were aware of HbA1c belong to the urban area and middle income category. However, the result showed there was no significant difference between the location and income among study subjects (Viswanathan V et al, 2010).

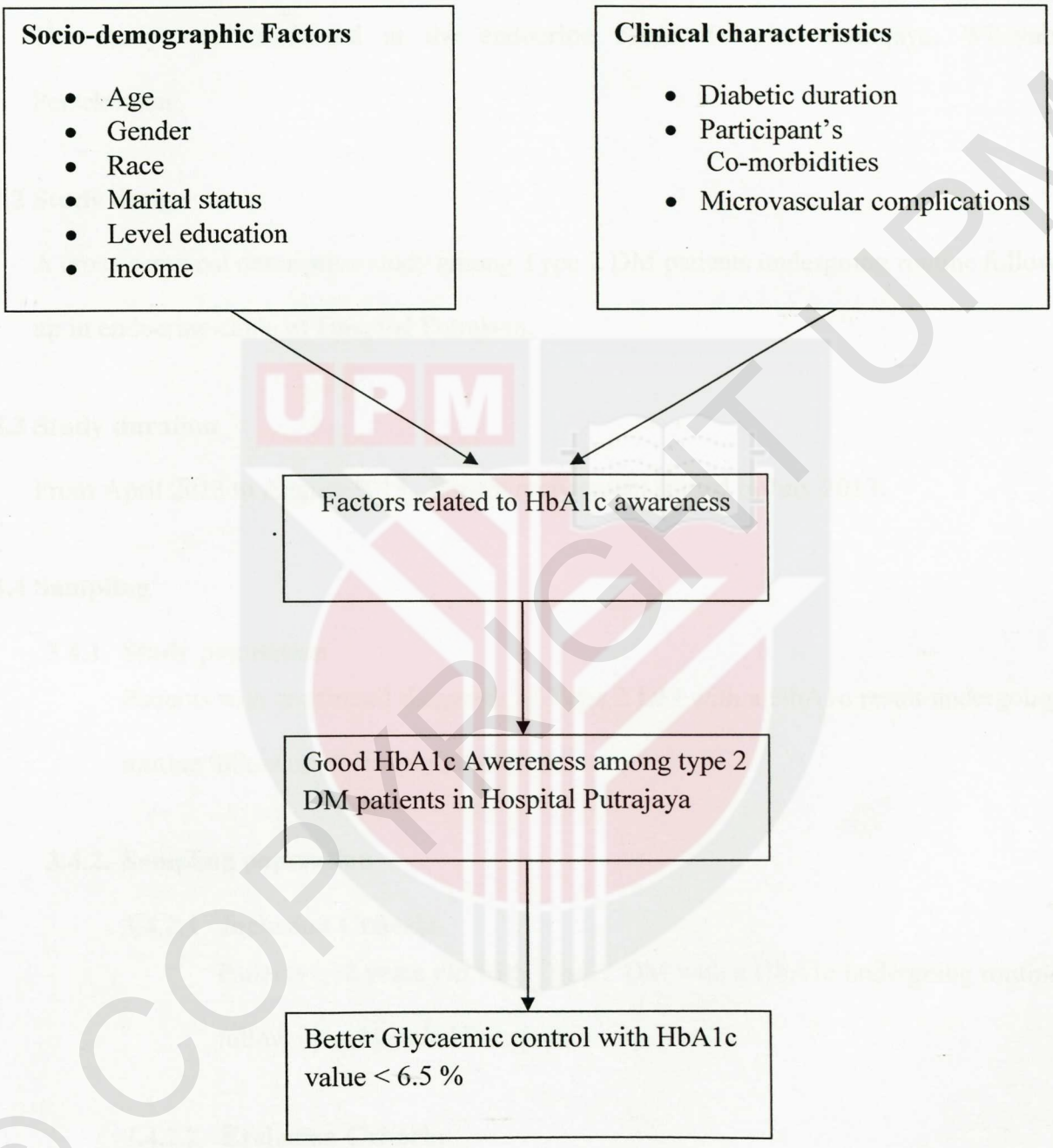
2.7.6 Diabetic duration

Emma Beard et al. (2010) reported a good understanding of HbA1c in patients with longer diabetic duration. Viswanathan V et al. (2010) found that majority of the subjects had knowledge about HbA1c test and this might be because of longer duration of diabetes.

2.8 Benefits of awareness of HbA1c test

Viswanathan V et al. (2010) reported that patients who were aware of HbA1c test and their goal had better glycemic control compared to patients who were not aware of HbA1c test. The study also showed that 35% of those who knew their goal were able to maintain their HbA1c percentage less than 7. They concluded that knowledge and awareness about HbA1c test and its target goal contributed to better glycaemic control. This is important as better glycaemic control reduces diabetic complications.

2.9 Conceptual Framework



CHAPTER 3: METHODOLOGY

3.1 Study location

The study was conducted at the endocrine clinic, Hospital Putrajaya, Wilayah Persekutuan.

3.2 Study design

A cross-sectional descriptive study among Type 2 DM patients undergoing routine follow up in endocrine clinic of Hospital Putrajaya.

3.3 Study duration

From April 2013 to August 2013. Patient recruitment started in July 2013.

3.4 Sampling

3.4.1. Study population

Patients with confirmed diagnosis of Type 2 DM with a HbA1c result undergoing routine follow up at Hospital Putrajaya.

3.4.2. Sampling population

3.4.2.1 Inclusion Criteria

Patients ≥18 years old with Type 2 DM with a HbA1c undergoing routine follow up at Hospital Putrajaya.

3.4.2.2 Exclusion Criteria

Type 2 diabetes mellitus with:

- End stage renal disease
- Haemoglobinopathies
- Recent blood transfusion within the past 30 days
- Malignant disease

3.4.3. Sampling unit

Type 2 DM patients undergoing follow up at Hospital Putrajaya.

3.4.4. Sampling method

This study did not involve any sampling method as all patients who meet the inclusion criteria were included in this study.

3.4.5. Sample size

In order to obtain the minimum sample size, we use the following formula:

$$n = \frac{Z^2\,(1-\alpha/2)\,P(1-P)}{d^2}$$

$$= \frac{1.96^2 \times 0.076(1-0.076)}{0.05^2}$$

$$= 107.908$$

z = confidence level at 95% (standard value of 1.96)

α =level of significance

P = prevalence of awareness of HbA1c among diabetic patients (Mehrotra, 2000) 7.6%= 0.076

d = margin of error at 5% (standard value of 0.05)

Total number of patients = 108 patients

As such, at least 108 patients are needed for this research. However, to overcome non-response bias, approximately 10% more of sample will be collected where minimum sample size is 119 patients.

3.5 Instrument and data collection

3.5.1 Instruments

Instruments used in this study were questionnaire and IBM SPSS 21.0 statistic program.

3.5.2 Data collection techniques

A cross-sectional study in the endocrine clinic of Hospital Putrajaya. Information sheet was given and informed consent were taken from the participants. A validated questionnaire was then given to the participants to answer. The questionnaire consists of a combination of closed and open-ended questions assessing patients' knowledge on HbA1c. Patients' HbA1c results are checked through the laboratory information system.

3.5.3 Quality control

Data collection and analyses was monitored by supervisors and statisticians.

3.6 Data Analysis

Statistical calculations was performed using the standard statistical software package, IBM SPSS 21.0 for Windows (LEADTOOLS ©, LEAD technologies, Inc, US). Median and range was be calculated for all non-normally distributed continuous variables. In all statistical analyses, a 'p' value of < 0.05 (95% confidence interval) was considered to be statistically significant. The tests we used are descriptive statistic and chi-square test. Chi-square test was used to compare two variables which are patients' awareness of HbA1C and factors affect it.

3.7 Study Ethics

1. Ethical approval was obtained from
   - Jawatankuasa Etika Universiti Penyelidikan UPM.
   - National Institutes of Health (NIH), Ministry of Health Malaysia
2. Approval letter was also obtained from the director of Hospital Putrajaya.

3.8 Variables

3.8.1 Dependent variable: The awareness of HbA1c test and its target goal in type 2 diabetic patients.

3.8.2 Independent variable: Gender, ethnicity, age, education level, income, and clinical characteristics.

Variable	**Definition**	**Scale**
Gender	As stated in the identification card.	Male or female
Ethnicity	As stated in the identification card	1. Malay 2. Chinese 3. Indian 4. Others
Age	The length of time that the person live	Years
Education level	As reported by respondent.	1. No formal education 2. Primary 3. Secondary 4. Tertiary
Income	As reported by respondent.	

3.9 Definition of terms

Term	Definition
HbA1c	HbA with glucose attached to its N-terminal valine residue of β-chain
Type 2 Diabetes	insulin-resistant diabetes, non-insulin dependent diabetes, and adult-onset diabetes.
Immunoassay	A biochemical test that measures the presence or concentration of a substance in solutions that frequently contain a complex mixture of substances.
Glycated Hemoglobin	A form of hemoglobin used primarily to identify the average plasma glucose concentration over prolonged periods of time. Also known as HbA1c.
HPLC	High Performance Liquid Chromatography
Boronate affinity	A method of separating biochemical mixtures and based on a highly specific biological interaction such as that between antigen and antibody, enzyme and substrate, or receptor and ligand.

Chapter 4: Results

4.1 Sociodemographic characteristics of participants

A total of 92 participants were recruited. Majority were male (n=53, 57.6%), Malays (n=60, 65.2%) and married (n=79, 85.9%). The median age was 53 (IQR: 16) years old. Most of the participants had attained a tertiary level of education (n=56, 60.9%) and earned more than RM5000 per month (n=27, 29.3%). Table 1 describes the sociodemographic characteristics of the participant.

Table 1 Sociodemographic characteristics of participants

Characteristic	n (%)
Age (years)	
< 40	15 (16.3)
40 to 49	19 (20.7)
50 to 59	31 (33.7)
≥ 60	27 (29.3)
Race	
Malay	60 (65.2)
Chinese	14 (15.2)
Indian	15 (16.3)
Others	3 (3.3)
Gender	
Male	53 (57.6)
Female	39 (42.4)
Marital status	
Married	79 (85.9)
Not married	13 (14.1)
Education level	
Below secondary education	36 (39.1)
Tertiary education	56 (60.9)
Monthly income (RM)	
<1000	12 (13.0)
1000-3000	22 (23.9)
3001-5000	16 (17.4)
>5000	27 (29.3)
Retired	15 (16.3)

4.2 Clinical characteristics of participants

The participants' clinical characteristics are shown in Table 2. The median duration of diabetes was 10 years (IQR: 11) and majority were on insulin (n=59, 64.1%). Almost all of the respondents had seen a diabetic nurse or physician (98.9%). Most participants claimed to have hypertension (62%) and hypercholesterolemia (53.3%). However only 33.7% claimed to have diabetic nephropathy, 52.2% retinopathy and 47% neuropathy.

Table 2 Clinical characteristics of participants

Clinical Characteristics	n (%)
Diabetic Duration (Years)	
< 5	29 (31.5)
5 to 10	26 (28.3)
11 to 15	20 (21.7)
≥ 16	17 (18.5)
Seen a diabetic nurse or doctor	
Yes	91 (98.9)
No	1 (1.1)
On Insulin	
Yes	59 (64.1)
No	33 (35.9)
Co-morbidities	
Hypertension on hypertensive medication	57 (62.0)
Hypercholesterolaemia	49 (53.3)
On lipid lowering agent	64 (69.6)
Microvascular complications	
Diabetic nephropathy	2(2.2)
Diabetic retinopathy	8(8.7)
Diabetic neuropathy	7(7.6)
Diabetic nephropathy with retinopathy	3(3.3)
Diabetic nephropathy with neuropathy	0(0)
Diabetic retinopathy with neuropathy	11(12)
Diabetic nephropathy with retinopathy and neuropathy	26(28.3)
Normal	35(38)

4.3 Awareness and Understanding of HbA1c

Table 3 shows participants' awareness of HbA1c. Out of 92 participants, 56 (60.9%) participants claimed to have heard of HbA1c (Table 3). Table 4 shows that out of those who have heard of HbA1c, 66.1% (n=37) of the participants knew what HbA1c indicates. 35 (62.5%) of them knew their HbA1c target goal out of which 18 (51.4%) had achieved this target. Most were also able to correctly report their last HbA1c result (n=46, 82.1%). Of those who reported their last HbA1c results incorrectly, 1 over-estimated their HbA1c, while 9 underestimated their HbA1c levels. The median HbA1c result was 7.6% (SD ± 1.8). The main source from where they have heard of HbA1c are mainly from physician (n=47, 83.9%), nurses (n=8, 14.2%), own self (n=17, 30.3 %) and others (n=2, 3.5%).

Table 5 shows that out of the total 92 participants, 46 (50%) were found to have good knowledge. Participants were categorized as having good knowledge if they could answer 3 out of 4 questions correctly. The 4 questions are whether they have heard about HbA1c, knew the indication for HbA1c, could report their last HbA1c result within 0.5% and knew their HbA1c target goals.

Table 3: Patients Awareness of HbA1c (N = 92)

Question	Yes n (%)	No n (%)
Reported they have heard of HbA1c test	56 (60.9)	36 (39.1)

| Question | Yes n (%) | No n (%) |

Knew the correct indication or use of HbA1c test	37 (66.1)	19 (33.9)
Knew their correct HbA1c target goal	35(62.5)	21 (37.5)
Reported their last HbA1c correctly (within 0.5%)	46 (82.1)	10 (17.9)

Table 4: Patient's knowledge on HbA1c (N = 56)

Table 5 : Participant's Understanding of HbA1c (N = 92)

Question	Yes n (%)	No n (%)
Good understanding of HbA1c test result	46 (50%)	46 (50%)

*Criteria of good understanding:

1. Aware of HbA1c
2. Knew the indication of HbA1c
3. Knew their HbA1c target goal
4. Correctly report their last HbA1c result $\leq 0.5\%$

(Beard et al. (2010)

4.4 Factors associated with awareness and understanding of HbA1c

4.4.1 Sociodemographic factors

Table 6 shows the association between socio-demographic factors and awareness of HbA1c among type 2 diabetics patients in Hospital Putrajaya. There was a significant relationship between HbA1c awareness with respondents' age, level of education and monthly income. There was however, no significant association between race (p=0.264), gender (p=0.208) and marital status (p=0.765).

Table 6: Association between sociodemographic factors with HbA1c understanding

Characteristic	Understanding of HbA1c		Total	X^2	p-value
	Good	Poor / No knowledge	n(%)		
	n(%)	n(%)			
Age (median)	(49)	(56)			
Less than 40	10(66.7)	5(33.3)	15	7.601	0.025*
40 to 49	14(73.7)	5(26.3)	19		
50 to 59	12(38.7)	19(61.3)	31		
60 and above	10(37.0)	17(63.0)	27		
Total	46(50.0)	46(50.0)	92		
Race					
Malay	30(50.0)	30(50.0)	60	1.219 14	0.748
Chinese	6(42.9)	8(57.1)	15		
Indian	9(60.0)	6(40.0)	3		
Others	1(33.3)	2(66.7)	92		
Total	46(50.0)	46(50.0)			
Gender					
Male	30(56.6)	23(43.4)	53	2.181	0.140
Female	16(41.0)	23(59.0)	39		
Total	46(50.0)	46(50.0)	92		
Marital Status					
Married	40(50.6)	39(49.4)	13	0.090	0.765
Not Married	6(46.2)	7(53.8)	79		
Total	46(50.0)	46(50.0)	92		
Level of Education					
Below Secondary education	9(25.0)	27(75.0)	36	13.534	0.001*
Tertiary education	37(66.1)	19(33.9)	56		
Total	46(50.0)	46(50.0)	92		
Monthly Income (RM)					
< 1000	4(33.3)	8(66.7)	12	11.177	0.025*
1000-RM3000	11(50.0)	11(50.0)	22		
3000-RM5000	8(50.0)	8(50.0)	16		
> 5000	20(74.1)	7(25.9)	27		
Retired	3(20.0)	12(80.0)	15		
Total	46(50.0)	46(50.0)	92		

4.4.2 Diabetes duration

Table 7 shows the association between participants' diabetes duration with awareness and understanding of HbA1c. There was no significant association between diabetic duration and HbA1c awareness and understanding (p=0.869) as their p value was >0.05. Accepted null hypothesis, there was no relationship between diabetic duration and HbA1c awareness.

Table 7: Association between diabetes duration and HbA1c understanding

Diabetic Duration (years)	Understanding of HbA1c		Total n(%)	X^2	*P*
	Good n(%)	Poor / No knowledge n(%)			
< 5	15(51.7)	14(48.3)	29	0.718	0.869
5 to10	14(53.8)	12(46.2)	26		
11 to 15	10(50.0)	10(50.0)	20		
≥ 16	7(41.2)	10(58.8)	17		
Median	10	10			
Total	46(50.0)	46(50.0)	92		

4.4.3 Associations between Participants' Co-morbidities and HbA1c understanding

Table 8 shows the relationship between co-morbidities and participants understanding of HbA1c. There was no significant association between either hypertension or hypercholesterolemia with awareness and understanding of HbA1c.

Table 8: Participants' Co-morbidities and Understanding of HbA1c

Variable		Understanding of HbA1c		Total	X^2	*P*
		Good n(%)	Poor / No knowledge n(%)			
Hypertension	Yes	26(46.4)	30(53.6)	56	0.730	0.393
	No	20(55.6)	16(44.4)	30		
Total		46(50.0)	46(50.0)	92		
Hypercholesterolaemia	Yes	24(49.0)	25(51.0)	46	0.044	0.834
	No	22(51.2)	21(48.8)	43		
Total		46(50.0)	46(50.0)	92		

4.4.4 Association between Microvascular Complications and HbA1c understanding

Table 9 shows the relationship between microvascular complications (nephropathy, neuropathy and retinopathy) and participants understanding of HbA1c. There was no significant association found.

4.5 Effect of participants' understanding of HbA1c on their glycaemic control

Table 10 shows the association between glycaemic control and understanding of HbA1c. There was no statistically significant association between participants HbA1c awareness and their last HbA1c test result (p=0.613).

Table 9: Association between microvascular complications and HbA1c understanding

Microvascular complication	Understanding of HbA1c		Total n(%)	X^2	*P*
	Good n(%)	Poor / No knowledge n(%)			
Nephropathy	0(0)	2(100)	2	7.765	0.256
Retinopathy	3(37.5)	5(62.5)	8		
Neuropathy	5(71.4)	2(28.6)	7		
Nephropathy with retinopathy	1(33.3)	2(66.7)	3		
Nephropathy with neuropathy	0(0)	0(0)	0		
Retinopathy with neuropathy	3(27.3)	8(72.7)	11		
Nephropathy, retinopathy and neuropathy	17(65.4)	9(34.6)	26		
No nephropathy, retinopathy or neuropathy	17(48.6)	18(51.4)	35		
TOTAL	46(50.0)	46(50.0)	92		

Table 10: Glycaemic control and understanding of HbA1c

Variable		Understanding of HbA1c		Total	X^2	*P*
		Good n(%)	Poor / No knowledge n(%)			
Glycaemic Control	<6.5	11(55.0)	9(45.0)	20	0.256	0.613
	>6.6	35(48.6)	37(51.4)	72		
	Total	46	46	92		

Chapter 5: Discussion

5.1 Awareness and Understanding of HbA1c

HbA1c measurement is widely used for assessment of glycaemic control and risks of microvascular complications. Given its significance, diabetes patients should be knowledgeable on HbA1c and its relation to glycaemic control to improve their clinical outcome.

outcome.

60.9 % of our participants were aware of HbA1c. Unfortunately, the remainder (36/92) had never heard of HbA1c despite this being written in their diabetes diary. Iqbal et al (2008) even reported a higher percentage, (59.4% (66/111) of their patients (both type 1and 2) attending the diabetic clinic in a hospital in UK were unfamiliar with the term HbA1c. They also reported that out of those 'familiar' with HbA1c, only 13.3% (6/45) were aware of the correct interpretation of a given HbA1c value in terms of its association with mean plasma glucose over the preceding 3 months. In contrast, nearly two thirds of our participants who were aware or have heard of HbA1c knew its correct interpretation.

Our study reported an equivocal number of participants who had good (46/92) and poor understanding of HbA1c. However, if specifically looking at those who were aware of HbA1c, 82.1% (46/56) had good understanding. Viswanathan et al (2010) reported that that 74% of their 480 type 2 diabetes patients visiting a tertiary care centre in India were knowledgeable on HbA1c. Skiei (2001) also found that majority of their participants had good knowledge on HbA1c, although their participants were limited to type 1 diabetes patients only. In contrast, Beard et al (2010), found a low percentage i.e. 26.5% of their 83 patients were knowledgeable on HbA1c. They had recruited patients form seven

diabetes outpatients clinic in UK. We had used similar criteria to Beard to define those who had good awareness and understanding of HbA1c i.e they have heard of HbA1c, knew the indication for HbA1c, could report their last HbA1c result within 0.5% and knew their HbA1c target goals. 0.5% was chosen on the basis that a 1% reduction in HbA1c levels can significantly reduce the likelihood of developing diabetes complications. Few other studies had also reported poor knowledge and awareness on HbA1c among their participants (Do et. Al, 2006; Harwell et. al., 2002 Hessler et. al; 2005).

5.2 Factors affecting awareness and understanding of HbA1c

In our study, only age (p=0.025), education level (p=0.001) and monthly income (p=0.025) were found to be significant contributors to the participants understanding of HbA1c. Similar to Viswanathan (2010), those with higher level of education had better understanding of HbA1c. However, there are studies which found no significant association between level of education and HbA1c understanding (Heisler et al (2005). We also found those with higher income to have better understanding of HbA1c. This however is in contrast to Beard (2010) which found income was not a significant contributor to patients understanding of HbA1c. Beard et al also reported that older diabetic patients had poor awareness and hence poorer glycaemic control. In their study, those who had good understanding had a mean age of 39.3 compared to those with poor understanding (52.28 years old) (Beard el at (2010). Similarly in our study, those with good understanding were slightly younger (49 years old) compared to those with poor understanding (56 years old).

We did not find gender or race to be significant factors which influenced understanding of HbA1c.

Duration of diabetes was thought to be an important factor determining the level of understanding of HbA1c. However, this was not demonstrated in our study. Similarly, although Beard et al noted that that those who had good understanding had longer diabetes mean duration (18 years) compared to those with poor understanding (14.4 years), their findings was not statistically significant. Our median duration of diagnosis for our participants was even shorter (10 years).

Diabetes type was also a factor which affects knowledge on HbA1c. Type 1 diabetes patients had significantly good understanding compared to type 2 (Beard et al, Iqbal et al). This finding is contributed mainly by the longer duration of diabetes and more intensive education programme in type 1 (Iqbal 2008). We only recruited type 2 diabetes patients thus unable to determine whether type of diabetes contributes to the understanding of HbA1c.

5.3 Effect of participants' awareness and understanding of HbA1c on their glycaemic control

There were no significant association between good HbA1c knowledge and better glycaemic control, although there were a higher percentage of those with good understanding that achieved the target glycaemia control compared to those with poor understanding. This was in concordance with Iqbal et al (2008). However, when followed up 7 months later, they found that those who were unfamiliar with the term HbA1c had significantly improved their HbA1c results and thus glycaemic control when these patients were educated by providing patients with written information on the association between HbA1c and mean blood glucose levels in the preceding three months.

Beard et al (2010) also reported that those with good understanding of HbA1c were significantly more likely to report better levels of self care in relation to their dietary regimes, self-efficacy for exercise, self monitoring of blood glucose and had better glycemic control, as indicated by their HbA1c levels. Thus, strategies to engage patients to know and interpret their HbA1c values should be encouraged in routine clinical practice.

5.4 Limitation

Since this study was carried out only in one hospital, the data obtained may not be representative of the whole diabetic patient population in Malaysia. Due to time constraint, we only manage to recruit 92 participants out of 119 that were required.

5.5 Conclusion

From our study, we concluded that the level of awareness of HbA1c among Type 2 diabetic patients is still low as some particpants have not even heard of HbA1c. We found overall equivocal number of participants with good and poor understanding of HbA1c. However for those who have heard of HbA1c, they had good understanding of HbA1c, although this unfortunately did not lead to better glycaemic control. Only age, education level and monthly income were significantly associated with better understanding of HbA1c.

5.6 Recommendation

More health campaigns are required to be given to patients to be aware and knowledgeable on HbA1c, diabetic complications and lifestyle change especially to those in the older age group, lower education and income. In future, we hope to assess whether giving further information on HbA1c to the participants especially to those who were not aware of it could result in improvement of their glycaemic control.

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APPENDIX

FAKULTI PERUBATAN DAN SAINS KESIHATAN
FACULTY OF MEDICINE AND HEALTH SCIENCES
UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG,
SELANGOR, MALAYSIA

RESPONDENT'S INFORMATION SHEET

Please read the following information carefully, do not hesitate to discuss any questions you may have with your researcher.

STUDY TITLE
AWARENESS OF GLYCOSYLATED HAEMOGLOBIN (HbA1c) AMONG TYPE 2 DIABETIC PATIENTS IN HOSPITAL PUTRAJAYA

INTRODUCTION
Diabetes mellitus (DM) is a group of metabolic disorders of carbohydrate metabolism characterized mainly by hyperglycemia. The hyperglycemia results from defects in insulin secretion, insulin action or both. Chronic hyperglycemia results in diabetic complications involving the heart, eyes, kidneys and the nervous system. Improved glycaemic control decreases the development or progression of these complications. The glycosylated haemoglobin (HbA1c) test has been widely used for evaluating long term glycaemic control.

WHAT WILL YOU HAVE TO DO?
Please read this respondent's information sheet for further information on the study. If you agree to participate in this study, you will need to sign the informed consent as evidence of approval. The researcher will then give you a written questionnaire for you to answer.

WHO SHOULD NOT ENTER THE STUDY?
Patients with end stage renal disease, haemoglobinopathies, recent blood transfusion within the past 30 days and malignant disease

WHAT WILL BE THE BENEFITS OF THE STUDY:

(a) TO YOU AS THE SUBJECT?
You will know your level of HbA1c awareness.

b) TO THE INVESTIGATOR?
We will be able to assess patients awareness of HbA1c among type 2 diabetic patients. The result of this study will determine whether the HbA1c awareness can help patients have a better glycaemic control.

ARE THERE ANY RISKS?
There are no additional risks as the research only involves answering the questionnaire.

DO I HAVE TO TAKE PART IN THIS STUDY?
The participation in this study is voluntary. If you prefer not to participate, you do not need to give reasons. You may also withdraw from the study at any point in time during the study without giving any reasons. Your treatment will not be affected if you wish not to participate or withdraw from this study.

You will not need to pay nor is payment given to you for participating in this study.

WILL THE INFORMATION AND MY IDENTITY REMAIN CONFIDENTIAL?

The results of the data obtained will be reported in a collected manner with no reference to a specific individual. Hence, data from each individual will remain confidential.

WHO SHOULD I CONTACT IF I HAVE ADDITIONAL QUESTIONS DURING THE COURSE OF THE RESEARCH?

You may contact us at:
Dr Intan Nureslyna Samsudin
Pathology Department, Faculty of Medicine and Health Sciences
University Putra Malaysia
Tel:0389472374

FAKULTI PERUBATAN DAN SAINS KESIHATAN
FACULTY OF MEDICINE AND HEALTH SCIENCES
UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG,
SELANGOR, MALAYSIA

HELAIAN PENERANGAN RESPONDEN

Sila baca maklumat berikut dengan teliti dan kemukakan sebarang pertanyaan sekiranya ada.

TAJUK KAJIAN:
KESEDARAN MENGENAI HEMOGLOBIN GLIKOSILAT (HbA1c) DI KALANGAN PESAKIT KENCING MANIS TYPE 2 DI HOSPITAL PUTRAJAYA.

PENGENALAN

Kencing manis (DM)adalah penyakit metabolik metabolisme karbohidrat yang menyebabkan kandungan glukosa (gula) berlebihan di dalam darah.Kandungan glukosa yang berlebihan adalah disebabkan oleh kekurangan penghasilan insulin, tindakan insulin atau kedua-duanya sekali. Kandungan glukosa yang berlebihan dalam jangka masa panjang akan menyebabkan komplikasi jantung, mata, buah pinggang dan sistem saraf. Kawalan kandungan glukosa yang baik akan mengelakkan komplikasi-komplikasi tersebut. Ujian hemoglobin glikosilat (HbA1c) telah digunakan secara meluas untuk menilai kawalan glukosa pada jangka masa panjang.

APAKAH YANG PERLU ANDA LAKUKAN?

Sila baca helaian penerangan responden ini untuk mengetahui maklumat lanjut tentang kajian ini. Seterusnya, anda dikehendaki menandatangani borang persetujuan responden sebagai tanda persetujuan. Penyelidik akan memberikan anda soal selidik bertulis kepada anda untuk dijawab.

SIAPAKAH YANG TIDAK BOLEH MENYERTAI KAJIAN INI?

Pesakit yang mempunyai penyakit buah pinggang peringkat akhir, *haemoglobinopathies*, transfusi darah dalam tempoh 30 hari yang lepas dan penyakit kanser.

APAKAH FAEDAH MENYERTAI KAJIAN INI?

(a) KEPADA ANDA SEBAGAI PESERTA?

Andaakantahutahapkesedaran HbA1c bagidirianda.

(b) KEPADA PENYELIDIK

Kami dapatmenilaitahapkesedaranmengenaiHbA1c dikalanganpesakitkencingmanis.Hasilkajianiniakanmenentukansamaadakesedaranmengenai HbA1c bolehmembantupesakitmengawalkandunganglukosadenganlebihbaik.

FAKULTI PERUBATAN DAN SAINS KESIHATAN
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UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG,
SELANGOR, MALAYSIA

ADAKAH IA BERISIKO?

Tiada risiko tambahan oleh kerana penyelidikan ini tidak melibatkan prosedur tambahan dan prosedur yang dilakukan adalah sebahagian daripada rawatan piawai.

ADAKAH PERLU UNTUK SAYA MENYERTAI PENYELIDIKAN INI?

Penglibatan dalam penyelidikan ini adalah secara sukarela. Sekiranya anda tidak bersetuju, anda tidak perlu memberikan sebab dan ini tidak menjejaskan rawatan yang akan diberikan. Anda juga boleh menarik diri pada bila-bila masa sahaja tanpa memberikan sebab.

Anda tidak akan dikenakan sebarang bayaran dan anda juga tidak akan dibayar bagi penglibatan dalam penyelidikan ini.

ADAKAH MAKLUMAT DAN IDENTITI SAYA KEKAL RAHSIA?

Maklumat dan identiti diri anda akan dirahsiakan. Selain itu, sebarang data yang digunakan daripada kajian ini untuk tujuan penerbitan adalah berpandukan data terkumpul semua responden. Keputusan yang diperolehi akan dimaklumkan secara keseluruhan (kolektif) dan tidak akan merujuk pada nama individu pesakit. Maklumat dan keputusan dari setiap pesakit adalah sulit. Sabagai responden, anda hanya berhak mengetahui keputusan ujian anda sahaja.

SIAPA YANG PERLU DIHUBUNGI SEKIRANYA SAYA MEMPUNYAI SOALAN TAMBAHAN SEMASA MENGIKUTI PENYELIDIKAN INI?

Anda boleh menghubungi kami di:
Dr IntanNureslynaSamsudin
Pathology Department, Faculty of Medicine and Health Sciences
University Putra Malaysia
Tel:0389472374

Code :

JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)
UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG, SELANGOR, MALAYSIA

CONSENT FORM (RESPONDENT)

RESEARCH: **AWARENESS OF GLYCOSYLATED HAEMOGLOBIN (HbA1c) AMONG TYPE 2 DIABETIC PATIENT IN HOSPITAL PUTRAJAYA**

RESEARCHER : **Faculty of Medicine and Health Sciences, UPM**
Dr Intan Nureslyna Samsudin
Dr Subashini C. Thambiah
Professor Dr. Elizabeth George
Ng Wan Cheng
Wan Mohamad Asyraf b Wan Mohammed Ayub

Hospital Putrajaya, KKM
Dr Zanariah Hussein
Dr. Nurain Mohd Noor
Dr. Masni Mohamad

I ..... Identity Card No. .....
address.....
....here by voluntarily agree to take part in the clinical research *(clinical study, questionnaire study/ drug trial) specified above.

I have been informed about the nature of the clinical research in terms of methodology, possible adverse effects and complications (as written in the Respondent Information Sheet). I understand that I have the right to withdraw from this clinical research at any time without assigning any reason whatsoever. I also understand that this study is confidential and all information provided with regards to my identity will remain private and confidential.

I* wish / do not wish to know the results of the tests performed on any samples taken from me.

* delete where necessary

Signature ..... Signature .....
(*Respondent*) (*Witness*)

Date :..... Name :.....

IC No :.....

I confirm that I have explained to the respondent the nature and purpose of the above – mentioned clinical research.

Date ..... Signature .....
(Researcher)

Code :

JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)
UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG, SELANGOR, MALAYSIA

BORANG PERSETUJUAN RESPONDEN

TAJUK PENYELIDIKAN : KESEDARAN HEMOGLOBIN GLIKOSILAT (HbA1c) DI KALANGAN PESAKIT KENCING MANIS TYPE 2 DI HOSPITAL PUTRAJAYA.

PENYELIDIK : Fakulti Perubatan dan Sains Kesihatan, UPM

Dr Intan Nureslyna Samsudin
Dr Subashini C. Thambiah
Professor Dr. Elizabeth George
Ng Wan Cheng
Wan Mohamad Asyraf b Wan Mohammed Ayub

Hospital Putrajaya, KKM
Dr Zanariah Hussein
Dr. Nurain Mohd Noor
Dr. Masni Mohamad

Saya..... No Kad Pengenalan. .....
beralamat.....
.....dengan ini bersetuju untuk mengambil bahagian secara sukarela dalam menyertai penyelidikan klinikal *(pengajian klinikal/ pengajian soal selidik/ percubaan ubat-ubatan) seperti yang disebut di atas.

Saya telah diberi penjelasan secara menyeluruh mengenai dasar penyelidikan klinikal dari segi metodologi, risiko dan komplikasi (seperti tertulis pada Helaian Penerangan Responden). Saya memahami bahawa saya berhak menarik diri dari penyelidikan ini pada bila-bila masa tanpa memberi sebarang alasan.Saya juga memahami bahawa sebarang maklumat yang berkaitan identiti saya akan dirahsiakan.

Saya* berminat / tidak berminat untuk mengetahui keputusan kajian yang dijalankan ke atas sampel yang diambil dari saya.
*potong yang tidak berkenaan

Tandatangan ..... Tandatangan .....
(*Responden*) (*Saksi*)

Tarikh :..... Nama :.....

No. K/P: .....

Saya mengesahkan bahawa saya telah menerangkan kepada responden sifat dan tujuan penyelidikan klinikal tersebut di atas.

Tarikh ..... Tandatangan .....
(*Penyelidik*)

Questionnaire **Code:_____**

(This questioner contain section A and section B. Please answer both section and tick [√] the answer you feel most suitable in the empty box)

Section A – Sociodemographics and clinical exposure

1. Age :_____

2. Race: Malay ☐
   Chinese ☐
   Indian ☐
   Others: _____

3. Gender : Male ☐ Female ☐

4. Marital Status :

   Single ☐ Married ☐ Divorced ☐ Widowed ☐

5. Level of education:

   a. No formal education ☐
   b. Primary education ☐
   c. Secondary education ☐
   d. Tertiary education ☐

6. Income (monthly):

   a. <RM1000 ☐
   b. -RM1000-RM3000 ☐
   c. >RM3000 - RM5000 ☐
   d. >RM 5000 ☐

7. How long have you been diagnosed as having diabetes mellitus?

_____

8. Have you been referred to the diabetic doctor or nurse?

a. Yes ☐

(If Yes, specify the number of times you have seen the doctor or nurse).

_____

b. No ☐

9. Are you on insulin?

a. Yes ☐

b. No ☐

10. Do you have hypertension?

a. Yes ☐

b. No ☐

11. Are you on anti-hypertensive drugs?

a. Yes ☐

b. No ☐

12. Do you have high cholesterol level?

a. Yes ☐

b. No ☐

13. Are you on lipid lowering medications?

a. Yes ☐

b. No ☐

14. Do you know whether you have kidney disease?

a. Yes ☐
b. No ☐

15. Do you know whether you have eye disease as a result of diabetes?

a. Yes ☐
b. No ☐

16. Do you know whether you have peripheral nerve disease as a result of diabetes?

a. Yes ☐
b. No ☐

Section B- Knowledge of HbA1c

17. Do you know about HbA1c?

a. Yes (If YES, proceed to question 18) ☐
b. Yes, a little bit (If YES, proceed to question 18) ☐
c. No, never heard about it (If NO, go straight to question 22) ☐

18. Where did you find out about HbA1c?

a. Doctors ☐
b. Nurse ☐
c. Own self (interned/books/magazine) ☐
d. Others (specific) : _____

19. What does HbA1c indicate?

a. The percentage of total blood haemoglobin concentration. ☐

b. The average plasma glucose concentration over the preceding 6 to 8 weeks. ☐

c. The average plasma glucose concentration in short term period. ☐

d. Don't know. ☐

e. Other:_____

20. What is your target HbA1c goal?

_____

Don't know : ☐

21. Have you achieved your HbA1c goal?

a. Yes ☐

b. No ☐

22. Do you know your last HbA1c test result?

a. Yes ☐

(please write down:_____)

b. No ☐

Soalan kaji selidik **Code:_____**

(Soalan kaji selidik ini mengandungi bahagian A dan bahagian B. Sila jawab kedua-dua bahagian dan tandakan [√] pada jawapan yang sesuai di dalam kotak kosong)

Bahagian A- Sociodemographics dan pendedahan klinikal

1. Umur :_____

2. Bangsa : Melayu ☐
   Cina ☐
   India ☐
   Lain-lain: _____

3. Jantina : Lelaki ☐ Perempuan ☐

4. Status Perkahwinan :

   Bujang ☐ Berkahwin ☐ Bercerai ☐ Lain:_____

5. Tahap Pembelajaran :

   a. Pembelajaran tidak formal ☐
   b. Sekolah Kebangsaan ☐
   c. Sekolah Menengah ☐
   d. Universiti ☐

6. Pendapatan Sebulan:
   a. <RM1000 ☐
   b. RM1000-RM3000 ☐
   c. >RM3000- 5000 ☐
   d. >RM5000 ☐

7. Berapa lamakah anda menghadapi penyakit kencing manis?

_____(tahun)

8. Adakah anda pernah dirujuk kepada doktor atau jururawat ?

a. Ya ☐

(Jika Ya , sila nyatakan berapa kali anda berjumpa dengan doktor atau jururawat)

_____(sebulan)

b. Tidak ☐

9. Adakah anda mengambil insulin?

a. Ya ☐

b. Tidak ☐

10. Adakah anda mengalami tekanan darah tinggi ?

a. Ya ☐

b. Tidak ☐

11. Adakah anda mengambil ubat darah tinggi?

a. Ya ☐

b. Tidak ☐

12. Adakah anda menghadapi tahap kolestrol yang tinggi?

a. Ya ☐

b. Tidak ☐

13. Adakah anda mengambil rawatan penurunan tahap kolestrol dalam darah?

a. Ya ☐

b. Tidak ☐

14. Adakah anda tahu anda kemungkinan menghadapi penyakit buah pinggang disebabkan penyakit kencing manis?

a. Ya ☐

b. Tidak ☐

15. Adakah anda tahu anda kemungkinan menghadapi penyakit mata disebabkan penyakit kencing manis?

a. Ya ☐

b. Tidak ☐

16. Adakah anda tahu anda menghadapi penyakit urat saraf disebabkan penyakit kencing manis?

a. Ya ☐

b. Tidak ☐

Bahagian B – Pengetahuan tentang HbA1c.

17. Adakah anda tahu tentang HbA1c?

a. Ya (Jika Ya, sila menjawab soalan 18) ☐

b. Ya, sedikit sahaja (Jika Ya, sila menjawab soalan 18) ☐

c. Tidak, dan tidak pernah mendengar(Jika Tidak, sila terus memjawab soalan 22) ☐

18. Dimanakah anda mendapat maklumat tentang HbA1c?

a. Doktor ☐

b. Jururawat ☐

c. Sendiri (laman sesawang/buku/majalah) ☐

d. Lain-lain (Nyatakan) _____

19. HbA1c menandakan apa?

a. Jumlah peratusan kepekatan sel darah merah. ☐

b. Purata kepekatan gula dalam plasma dalam tempoh jangka panjang. ☐

c. Purata kepekatan gula dalam plasma dalam tempoh jangka pendek. ☐

d. Tidak tahu. ☐

e. Lain-lain : _____ .

20. Apakah tahap HbA1c yang perlu anda capai?

_____

Tidak tahu : ☐

21. Adakah anda pernah mencapai tahap HbA1c yang di kehendaki?

a. Ya ☐

b. Tidak ☐

22. Adakah anda tahu keputusan terahkir HbA1c anda?

a. Ya ☐

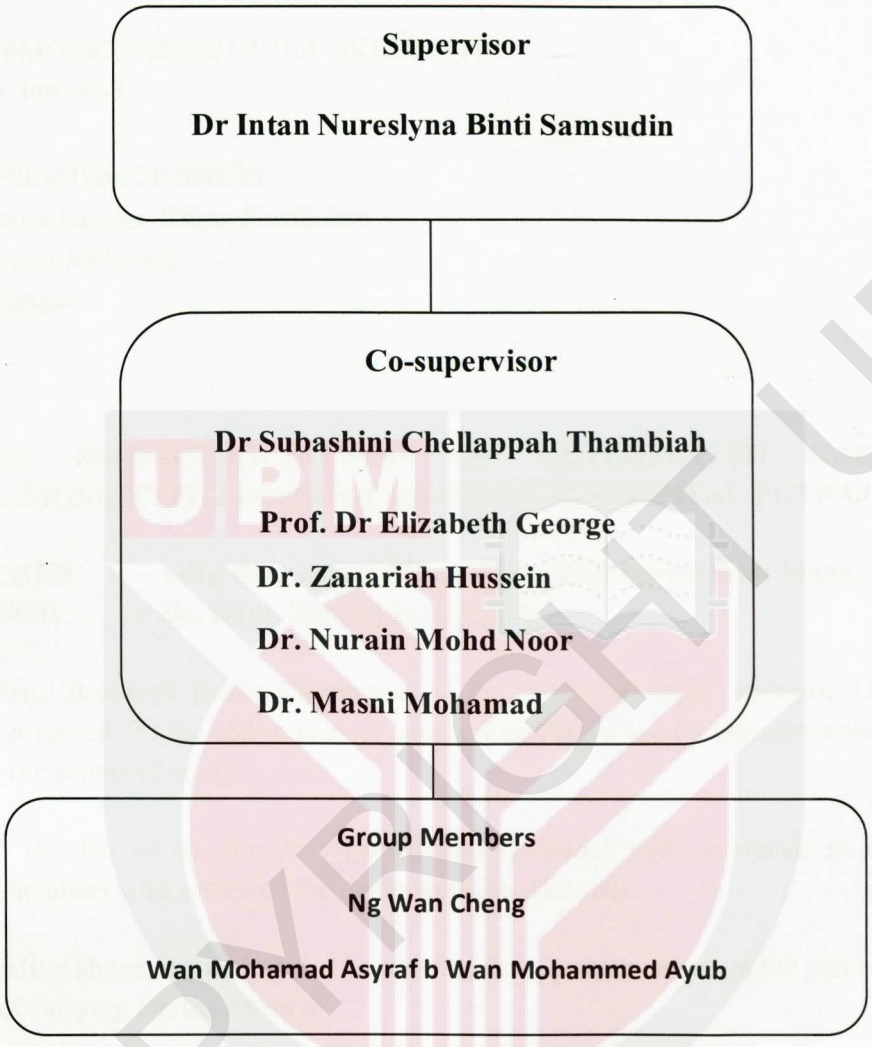
(sila nyatakan :_____)

b. Tidak ☐

Gantt Chart

Month / Activities	Mar	Apr	May	June	July	Aug
Proposal preparation						
Submission of proposal						
Proposal presentation						
Preparation of ethical approval to organization						
Data collection and analysis						
Presentation of analysed data						
Report writing						
Final presentation						

Research team



Budget Planning

No	Items	Estimated cost
1.	Printing	RM 50.00
2.	Hard cover	RM 50.00
3.	Photocopy	RM 150.00
4.	Binding	RM 10.00
5.	Transportation	RM 100.00
	Total	**RM 360.00**

Reff. : UPM/TNCPI/RMC/1.4.18.1 (JKEUPM)/F1
Date : 18 Jun 2013

Dr. Intan Nureslyna Samsudin
Fakulti Perubatan dan Sains Kesihatan
Universiti Putra Malaysia
Serdang Selangor

Dear Sir,

RESEARCH PROJECT:AWARENESS OF GLYCOSLATED HAEMOGLOBIN 9HBA1C) AMONG TYPE 2 DIABETIC PATIENTS IN HOSPITAL PUTRAJAYA

RESEARCHER : Ng Wan cheng &Wan Mohamad Asyraf Wan Mohammed Ayub
SUPERVISOR : Dr. Intan Nureslyna Samsudin

The University Research Ethics Committee of the Universiti Putra Malaysia (JKEUPM) has studied the proposal for the above project and find that there are no objectionable ethical issues involved in the proposed study.

Please find the list of documents received and reviewed with reference to the study and committee members who reviewed the documents (as attached).

Notwithstanding above, we will not be responsible for any misconduct on the part of researcher in the course of carrying out the research.

Thank you.

"WITH KNOWLEDGE WE SERVE"

Sincerely yours,

PROFESSOR DR. NORLIJAH OTHMAN
Chairman
University Research Ethics Committee (JKEUPM)
Universiti Putra Malaysia

Attachment 1

JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN YANG MELIBATKAN MANUSIA (JKEUPM)
UNIVERSITI PUTRA MALAYSIA

Research title	:	**Awareness of Glycoslated haemoglobin 9hBa1c) among type 2 diabetic patients in Hospital putrajaya**
Study Site	:	**Hospital putrajaya**
JKEUPM Ref No.	:	**FPSK_Mei(13)14 (undergraduate)**
Principal Investigator	:	**Ng Wan cheng & Wan Mohamad Asyraf Wan Mohammed Ayub**
Supervisor	:	**Dr. Intan Nureslyna Samsudin**

Documents received and reviewed with reference to the above study:

1. Ethics Application Form, received on 8/5/2013.
2. Respondent Information Sheet, Version English
3. Consent form, Version English
4. Proposal, Version English
5. Questionnaire, Version English

The University Research Ethics Committee, Universiti Putra Malaysia (JKEUPM) operates in accordance to the ICH-GCP Guidelines.

Decision by JKEUPM:

[X] Approved

[ ] Conditionally Approved

[ ] Disapproved

Please be informed that you are required to submit annual reports, completion reports and "all adverse events, both serious and unexpected" to the committee.

Date of Decision:7/6/2013

PROFESSOR DR. NORLIJAH OTHMAN
Chairman
University Research Ethics Committee
(JKEUPM)
Universiti Putra Malaysia

Attachment 2

JKEUPM Ref No. : FPSK_Mei(13)14 (undergraduate)

Members of the JKEUPM who reviewed the documents:

Prof. Dato' Dr. Lye Munn Sann

Date of approval: 28/5/2013

Endorsed at JKEUPM Meeting on **7/6/2013**, attended by:

NAME	DESIGNATION	GENDER	TICK IF PRESENT
Prof. Dr. Norlijah Othman	Paediatrics& Dean, Faculty of Medicine and Health Sciences	Female	√
Prof. DrZamberiSekawi	Medical Microbiologist & Deputy Dean of Research and Internationalization, Faculty of Medicine and Health Sciences	Male	
Prof. Dato' Dr. Lye Munn Sann	Medical Statistician, Dept of Community Health, Faculty of Medicine and Health Sciences	Male	√
Prof. Dr. TengkuAizanAbd Hamid	Gerontologist & Director, Institute of Gerontology	Female	
Prof. Dr. LekhrajRampal	Medical Statistician, Dept of Community Health, Faculty of Medicine and Health Sciences	Male	√
Prof. Dr. Elizabeth George	Pathologist, Dept of Pathology, Faculty of Medicine and Health Sciences	Female	
Prof. Dr. Lim ThiamAun	Anesthesiologist, Dept of Surgery, Faculty of Medicine and Health Sciences	Male	
Prof. Dr. Wan Omar Abdullah	Medical Parasitologist, Dept of Medical Microbiology and Parasitology, Faculty of Medicine and Health Sciences	Male	√
Prof. Dr. Patimah Ismail	Professor of Biomedicine, Dept of Biomedical Sciences, Faculty of Medicine and Health Sciences	Female	√
Prof. Dr. Azali Mohamed	Professor of Macroeconomics, Dept of Economics, Faculty of Economics and Management	Female	
Assoc. Prof. Dr. Johnson Stanslas	Pharmacologist, Dept of Medicine, Faculty of Medicine and Health Sciences	Male	√
Assoc. Prof Dr. Mansor Abu Talib	Assoc. Professor of Guidance and Counselling, Dept of Human Development and Family Studies, Faculty of Human Ecology	Male	
Assoc. Prof. Dr. Noritah Omar (Lay Person)	Assoc. Professor of English Language, Dept of English Language, Faculty of Communication and Modern Languages	Female	√
Dr. RojanahKahar (Lay Person)	Lecturer of Dept of Human Development and Family Studies, Faculty of Human Ecology	Female	√
Tan Sri Dato' Napsiah Omar (Lay Person)	Chairman, National Population and Family Development Board	Female	√

NATIONAL INSTITUTES OF HEALTH (NIH) RECOMMENDATION FOR THE CONDUCT OF RESEARCH IN THE MINISTRY OF HEALTH MALAYSIA
PENGESAHAN INSTITUSI KEBANGSAAN NEGARA UNTUK MENJALANKAN PENYELIDIKAN DI KEMENTERIAN KESIHATAN

This is an auto-generated document. It is issued by one of the research institute under the National Institutes of Health (NIH). The institutes as follows: Institute for Medical Research (IMR), Institute for Public Health (IPH), Clinical research centre (CRC), Institute for health Management (IHM), Institute for Health System Research (IHSR) and Institute for Health Behavioural Research (IHBR).

Dokumen ini adalah cetakan berkomputer. Borang ini dikeluarkan oleh salah satu institusi dibawah National Institutes of Health (NIH) iaitu Institut Penyelidikan Perubatan (IMR), Institut Kesihatan Umum (IKU), Pusat Penyelidikan Klinikal (CRC), Institut Pengurusan Kesihatan (IPK), Institut Pengurusan Sistem Kesihatan (IPSK) dan Institut Penyelidikan Tingkahlaku Kesihatan (IPTK).

Unique NMRR *[Nombor Pendaftaran]*	NMRR-13-392-15934
Research Title *[Tajuk]*	AWARENESS OF GLYCOSYLATED HAEMOGLOBIN (HbA1c) AMONG TYPE 2 DIABETIC PATIENTS IN HOSPITAL PUTRAJAYA
Protocol Number if *[Nombor Protokol jika ada]*	

#	**Investigator Name** ***[Nama Penyelidikan]***	**Institution Name** ***[Nama Institusi]***
1	Elizabeth George	Putrajaya Hospital
2	Intan Nureslyna Samsudin	Putrajaya Hospital
3	MASNI BINTI MOHAMAD	Putrajaya Hospital
4	NG WAN CHENG	Putrajaya Hospital
5	Nurain binti Mohd Noor	Putrajaya Hospital
6	Subashini C. Thambiah	Putrajaya Hospital
7	WAN MOHAMAD ASYRAF B WAN MOHAMMED AYUB	Putrajaya Hospital
8	Zanariah Hussein	Putrajaya Hospital

I have reviewed the above titled research, and has recommended to MREC* for its decision.

Saya telah menyemak penyelidikan yang bertajuk diatas, dan telah disyorkan untuk MREC bagi keputusannya.

Name of Director *[Nama pengarah]*	Dr. Goh Pik Pin
NIH Institute (IMR, IPH, CRC, IHM, IHSR, IHBR) *[Nama institusi di bawah NIH]*	Clinical Research Centre (CRC)
Signature & Official Stamp *[Tandatangan dan Cop Rasmi]*	
Date *[Tarikh]*	03-06-2013

*Final approval is pending MREC decision.