



PHARMACEUTICAL SERVICES DIVISION
MINISTRY OF HEALTH MALAYSIA

THE COST OF DIABETES CARE FOR AMBULATORY PATIENTS IN MALAYSIAN MINISTRY OF HEALTH FACILITIES



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Preface

In the name of Allah, The Most Gracious The Most Merciful.

The Phase II study of “Drug utilisation in the treatment of diabetes mellitus in the Ministry of Health (MOH) facilities” focuses on the cost of diabetes care for ambulatory patients based on diabetes cost diary. The survey complements the investigation on the drug utilisation, drug usage pattern and adherence to anti-diabetic drugs in Phase I, on other factors that influence the management of patients with Type 2 Diabetes Mellitus (T2DM). The factors studied were the three main activities, namely going for doctor’s appointment/consultation, seeking treatment from the medical doctor, the traditional/complementary practitioner, performing blood tests or dialysis, and activities such as purchase of medical devices, drugs, herbal remedies and consumables.

For each of the above activities, the patient recorded their means of transportation, time taken to attend those activities, and the cost incurred. The diary for the 6-month duration was analysed and presented in this report. It revealed pertinent insight into the patient’s journey in getting treatment for T2DM which will be of practical relevance to doctors, pharmacists, and other healthcare professionals in managing such patients.

It is hoped that this report will generate new interest in reviewing our model of care for managing T2DM by the MOH, create new approaches involving all sectors, and enhance new approaches by pharmacists in delivering pharmaceutical care.

Thank you to the DUS investigators, the R&D unit of the Pharmaceutical Services Division, MOH and all other parties involved in making this report a success.

Pharmaceutical Services Division
Ministry of Health Malaysia

Executive Summary

THE COST OF DIABETES CARE FOR AMBULATORY PATIENTS IN MALAYSIAN MINISTRY OF HEALTH FACILITIES

The project of Drug Utilisation in the Treatment of Diabetes Mellitus in the Ministry of Health facilities was conducted by the Drug Utilisation Study (DUS) project team whose members include policy makers and pharmacists-practitioners from the Ministry of Health Malaysia and academicians from two local universities, namely Universiti Teknologi MARA and University of Malaya. A phase I cross-sectional study was conducted from November 2010 to December 2011 to determine the drug utilisation in the treatment of diabetes mellitus (DM) in the Ministry of Health facilities. A full report of the Phase I study has been published and can be obtained from <http://www.pharmacy.gov.my>. Subsequently, a phase II prospective study to estimate the total cost of treatment of diabetes care for ambulatory patients was conducted to calculate the direct (direct healthcare and direct non-healthcare costs) and indirect costs. This report is written to present the findings of the phase II prospective study that was conducted in 2011 and 2012.

Diabetes mellitus is a costly disease whose treatment incurs high costs to both healthcare providers and the patients including their family members. In order to estimate the total costs of diabetes mellitus treatment for the Ministry of Health and the patients involved, the direct healthcare costs and indirect costs were calculated. The direct healthcare costs include costs incurred by the Ministry of Health Malaysia such as ambulatory care services (out-patient) and hospitalisation whilst the non-healthcare costs include expenses incurred by the patients and their family. The indirect costs refer to absenteeism or productivity loss due to diabetic-related activities.

A cost diary for patients with diabetes mellitus was developed and presented in a booklet forms which suitable for self-administered by the patient or their family. The diary was used to obtain information, for a period of 6-month, on diabetes mellitus-specific resource use by the patients and their family for the management of diabetes mellitus. A total of 986 diaries were completed and returned from the targeted number of 323 patients (89.5% response rate). The findings showed that the mean age is 53 years, 59% are female and 64% of the respondents are Malays. The income bracket of RM1,000-3,000 constitutes almost half of the respondents (49%). Mean number of years diagnosed with diabetes mellitus is 9.5 years, with majority of them (74%) on insulin for five years or less and 12.5% suffers from three or more co-morbidities.

This is the first comprehensive cost study for diabetes mellitus in Malaysia. Findings showed that the total direct healthcare cost, i.e. expenses incurred by the Ministry of Health Malaysia for management of diabetes mellitus calculated for the 6-month period

is RM386,531.21. For the component of direct healthcare cost for ambulatory care (out-patient) which include costs of drugs, laboratory and investigations, consultation fee and other procedures (e.g. wound dressing), the cost for 6-month period is RM125,003.28. This constitutes 32.3% of the direct healthcare costs. Whereas, the components for hospitalisation which include costs of drugs, laboratory and investigation and admission fee gave the total cost of RM38,432.87, that is 9.9% of the direct healthcare costs. For the components of the direct non-healthcare cost (i.e. expenses incurred by patients to purchase products and services related to diabetes mellitus) which include costs of consumables, transportation, lodging, home-help, complementary treatment and miscellaneous is RM223,095.06. This component constitutes 58% of the direct cost.

Indirect costs refer to the number of days absent from work and other daily activities. The total indirect cost calculated for the 6-month period is RM150,929.60.

We also found that the estimated total cost of treatment of diabetes care for ambulatory patients in the Malaysian Ministry of Health facilities is RM537,460.81 (for the 6-month duration) and it was similar across all facilities. The total direct cost amounts to 72% of the total cost while the indirect costs constitute 28%.

As an overall calculation, the estimated direct cost per patient per year is RM2,684.24, meanwhile for indirect cost is RM1,062.88. Thus, from this survey we summarised that the estimation expenditure in treating diabetes care for ambulatory patients per year was RM3,747.12.

These findings provide initial cost estimates that can be further analysed to provide evidence for policy decision-making and resource allocation for Type 2 diabetes mellitus in the future.

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Abbreviations

CPG	Clinical Practice Guidelines
COI	Cost of Illness
DM	Diabetes Mellitus
DMTAC	Diabetes Medication Therapy Adherence Clinic
DUS	Drug Utilisation Survey
ECG	Electrocardiogram
ICF	Informed Consent Form
GBD	Global Burden of Disease
GDP	Gross Domestic Product
HbA1c	Glycosylated Haemoglobin
HKL	Hospital Kuala Lumpur
MOH	Ministry of Health
MREC	Medical Research and Ethics Committee
N/A	Not applicable
NHMS	National Health & Morbidity Survey
NMRR	National Medical Research Register
OOP	Out-of-pocket
OTC	Over-the-counter
PIS	Patient Information Sheet
RM	Ringgit Malaysia
SD	Standard Deviation
T2DM	Type 2 Diabetes Mellitus
USA	United States of America
USD	US Dollar
WHO	World Health Organisation
YLD	Years Lived with Disability

1.0 INTRODUCTION

Estimation of direct healthcare and non-healthcare cost of diabetes care in Malaysian government health facilities

Diabetes mellitus (DM) is a disease that is affecting millions worldwide. In Malaysia, the National Health & Morbidity Survey (NHMS)¹ latest report showed the prevalence of DM is 15.2% where 7.2% were individuals with known disease while 8% have yet to be diagnosed. Therefore, it is not surprising that diabetes was reported by the Global Burden of Disease (GBD) 2000 as the 20th leading cause for total years lived with disability (YLD)².

Treatment of diabetes is complex where patients also suffered other complications, such as hypertension and cardiovascular related diseases. Due to this reasons, the patients usually had multiple physician visits and repeated hospitalisation. This is proven by the study by Gram J and Damsgaard EM³, in which they found that patients with diabetes use primary health care services two to three times more often as controls, have a hospital bed-day occupancy rate two to three times greater than the general population of the same age, and have an estimated cost of drug therapy more than 2.5 times higher than controls.

The high cost of treating diabetes is evaluated by Barcelo et al 2003⁴ in the Latin America and the Caribbean. Their findings highlighted that diabetes imposes a high economic burden for the individual and society. However, the high cost did not equate to better control. This is because Costa B, Arroyo J and Sabate⁵ reported that there is no effective drug treatment for specific long-term complications of diabetes, such as retinopathy, neuropathy and vascular diseases.

The recent report on the prevalence of diabetes in the Malaysian NHMS III⁶ and the above observations clearly outline the seriousness of the underlying problems equated to DM. Since most of the patients used government health facilities for their diabetic care, the questions of cost would be the ensuing dilemma. In the United States, it was reported that the annual economic cost of diabetes in 2007 was USD174 billion⁷. These costs include the direct healthcare expenditures, such as diabetes care, chronic diabetes-related complications and general healthcare cost. Indirect costs resulting from absenteeism, reduced productivity, disease-related unemployment disability and loss of productive capacity are estimated at USD58 billion. World Health Organisation (WHO) further reiterated that DM takes an ever-increasing proportion of the national health care budget in most countries.

In this era of scarce resources and rising cost of healthcare services, understanding of the economic aspect of diabetes is critical in order to develop and implement sound public health and prevention policies. Globally, the direct healthcare cost of diabetes for people in the 20 to 79 age group is estimated to be at least USD153 billion annually⁸. On the average, diabetes alone claims around 8% of total health care budgets in developed countries⁹.

The differences in the quality of care between countries has led to the healthcare cost of one diabetic patient varies hugely between countries, from USD13 in Bangladesh to USD11,157 in the USA per year¹⁰. The economic aspects of diabetes and its care continue to attract

attention as the world diabetes epidemic progresses and health care systems remain under pressure to accomplish more and more within constrained resources⁸. Healthcare cost is two to three fold higher⁴ and the economic cost is two to five folds higher in people who have diabetes compared to those without diabetes⁷. These factors provide valid and strong reasons for which a study to estimate direct healthcare and non-healthcare cost of diabetes in government health facilities need to be undertaken.

Malaysian patient's patroning the health facilities are heavily subsidised and drugs are provided free. Treatment of DM follows current clinical practice guidelines (CPG) and patients are being reviewed routinely¹¹. Interventions covered both healthcare and non-healthcare care and across all sectors of the populations. However, health status control among diabetic patients is still poor as the NHMS III showed that only 26% had HbA1c controlled at below 6.5%⁶. On the provider perspective, these findings are unjustifiable and needs urgent answers.

Measurement of cost for healthcare is gaining utmost importance. Cost-effectiveness of interventions had been investigated through pharmacoeconomic evaluation in many acute and chronic diseases. However, DM is a very different disease where treatment can be just for the treatment of DM or can be for a multitude of disease co-morbidities. This showed that cost of treatment is not on DM alone but also other related diseases and a thorough pharmacoeconomic evaluation would be exhaustive and expensive to undertake.

In the perspective of the healthcare provider, evaluation on the cost of

illness (COI) would give an estimate of the budgetary needs to treat DM. These COI studies however lack information on the patient's perspective in terms of healthcare and non-healthcare costs. These costs can be detrimental on the patient's own health budget which may affect the outcome of therapy. The complexity of DM has led to patients seeking other therapies (modern and traditional) that they might think can help to improve recovery. Thus, an evaluation of these DM non-conventional treatments may be useful for healthcare providers on its added value in term of DM outcome.

The success of treatment is however dependent not only on the services provided by the provider but also on patient attitude and acceptance. This is especially true for chronic diseases such as DM where the aim is to control the disease. Patient's contribution to either direct healthcare or non-healthcare cost for their disease seems insignificant and at most times neglected. This is further heighten by studies on the direct healthcare and non-healthcare cost of diabetes is rather limited and local cost data is rather sketchy. Little is known of cost per diabetic patient and whether this cost includes both direct healthcare and non-healthcare and indirect healthcare cost. Direct healthcare, non-healthcare and indirect healthcare cost has been defined by Goossens et al¹² and data on patient's related cost were extracted by the use of cost diary. Their findings showed the cost diary method can be useful to estimate direct healthcare and non-healthcare cost.

Based on the above reasons, the current study is initiated to inquire on the direct healthcare and non-healthcare cost of Malaysian diabetic patients at the

government health facilities. Direct cost will commensurate to the Ministry of Health (MOH) commitment towards diabetic healthcare cost while the indirect cost will demonstrate the patients willingness to pay in attaining diabetes control. Thus, this study will be examining the total cost of treatment of both the provider and patient's perspective. This is relevant since the estimated overall cost obtained would better portray the true cost and might be indicative on the true outcome of treatment.

2.0 OBJECTIVES

2.1 Aim

To determine the direct and indirect cost in treatment of DM.

2.2 Specific Objectives

- i. To calculate the direct healthcare costs of activities in treatment of DM.
- ii. To calculate the indirect healthcare cost due to absenteeism of ambulatory and hospitalisation activities.
- iii. To determine the total cost in the treatment of DM.

3.0 METHODS

3.1 Overview of Research Design

This is a prospective study conducted in 2011-2012, in all four different types of facilities in MOH. The data on direct and indirect costs were collected prospectively for a period of 6-month using a self-administered cost diary. A cost diary was developed to capture data on patients and family resource use in management of DM. The research framework is as shown as in Figure 1.

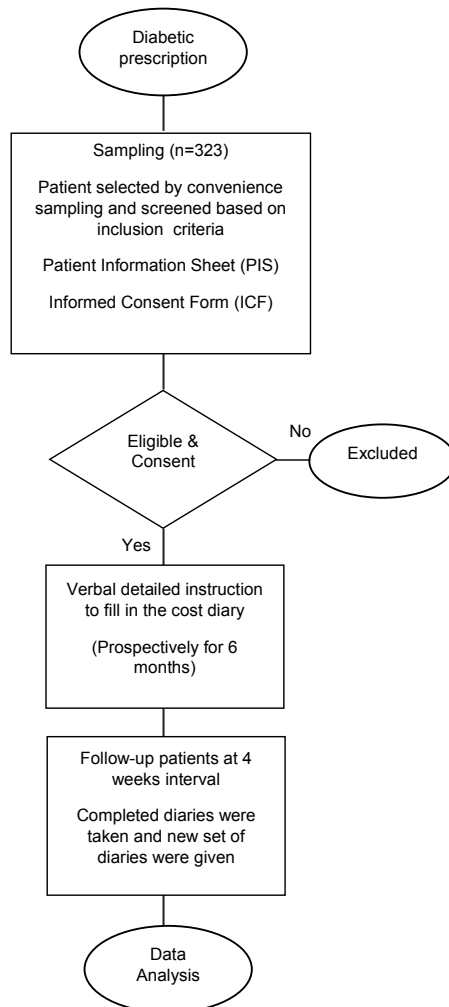


Figure 1: Algorithm of research framework for DUS Phase II

3.2 Sampling

3.2.1 Study Population

We performed a further 6-month study after the completion of 1-year period of Phase I study which was conducted in 94 Malaysia MOH facilities. The Phase II study included 84 facilities. These facilities were the subset of the facilities in Phase I study, included 14 state hospitals, 19 hospitals with specialist, 27 hospitals without specialist and 24 health clinics.

3.2.2 Sample Size

The sample size for this study was estimated based on 10% of the participants in the Phase I study ($n=2,509$). The 10% figure was then further inflated by 30% to accommodate for dropout and withdrawal. The sample size calculated was then divided to 84 facilities (each recruiting a minimum of four subjects). However, taking account of limited human resources in thirteen health clinics without Diabetes Medication Adherence Clinic (DMTAC) services, they were required to recruit only a minimum of three subjects. Hence, the final sample size was 323 subjects. The target number of patients assigned to each facility was tabulated in Table 1.

Table 1: Recruited patients and facilities

Type of Facilities*	Number of Facilities	Target Number of Patients
State Hospitals	14	56
Hospitals with Specialist	19	76
Hospitals without Specialist	27	108
Health Clinics	24	83
Total	84	323

*Facilities are listed under **Appendix 1**

3.2.3 Sampling Method

Patients were screened and selected at the outpatient pharmacies based on following inclusion criteria:

- Type 2 Diabetes Mellitus
- Age 18 to 65 years old
- Malaysian citizen
- Treated for T2DM for at least 1 year

Convenience sampling was performed and included all groups representative of patient's gender, age and patient's disease status. The patient information sheet (Appendix 2) was given together with the informed consent form (ICF) (Appendix 3). Patients who consented and signed the ICF were given the cost diary. Research officers who are also pharmacists in each facility were given the responsibility to liaise with the patients. Detailed

instructions were given verbally to the patients by the research officers who were trained prior to the studies. Each hospital and health clinic was required to recruit four and three patients consecutively for a duration of 6-month. Each facility recruited two or more research officers to conduct this study and monitoring of these officers were done regularly either at their facility or via phone. Patients were given the cost diaries during their first visit of the study and subsequently at 4 weeks interval up to at least 16 weeks or maximum 24 weeks.

3.3 Instrument and Method for Data Collection

3.3.1 Structure of the Cost Diary

The cost diary was developed via consultations among investigators and extensive literature reviews¹². The diary (Appendix 4, 5) was designed in the booklet format which contains instructions, guidelines, illustration and telephone number to dial in the event of enquiries. An accompanying manual (Appendix 6) is attached to explain the overall procedure involved so as to guide both instructors and patients on use of the cost diary. The content of the cost diary is based on the predetermined patient variables such as demography, disease history, types of interventions at health facilities, medications and treatment cost. Each diary has four different sections which consist of patient details, activities, ward admission and additional help. They were meant to be fully filled by four weeks. A patient may need more than one diary if the activities precede the allocated sections.

Components of the cost diary

The cost diary has several important components:

- Instruction on how to use the cost diary
- Information on direct healthcare cost
- Information on direct non-healthcare cost

Under the cost components, patients will record all resources used in each activity and will then be converted into unit prices. The information on cost related with activities in treating DM by patients are as follows:

a) Direct healthcare costs

The costs shall include any activity that involved on the use of any healthcare services, such as visits to the general practice, specialist care, alternative medicine and physiotherapy, days of hospitalisation and the respective units that prescribed the medication.

b) Direct non-healthcare costs

Costs incurred by the patient and family to seek treatment, such as costs of over-the-counter (OTC) medication, costs of health activities, hours of paid and unpaid household help, transportation and the value of other out-of-pocket (OOP) expenses.

c) Indirect costs

These costs refer to the value of production lost due to illness-related absence, such as the number of days absent from work (paid and unpaid) and days lost from housekeeping and other daily activities. The patient was directed to indicate when, where and how often the activities, consultations and other related

information that took place within the time period of interest. He or she was also directed to document the accompanying person(s), the job status and salary to calculate indirect costs.

The cost diary was written in *Bahasa Melayu* (Malay). Pilot studies were conducted on the cost diary.

3.3.2 Pilot Study

Clarity and completeness of the cost diary was pre-tested over a period of four weeks at two different health centres, Hospital Putrajaya and Klinik Kesihatan Tanglin. Seventeen patients met the criteria but only five patients were consented to pursue in the pilot study. However, only two diaries were returned. The pre-test findings were then used to make changes and modification so as to ensure the cost diary is comprehensible.

3.3.3 Method for Data Collection

The six months follow-up records of patient's data at the clinic were collected. Each of the cost diaries is able to document for four weeks of activities, thus every patient will be receiving at least six booklets of the cost diary. During patients' first collection of the cost diary, they were reminded verbally to fill in the diary for each related activities involving treatment and consequences of DM in the diary. The instruction was reminded repeatedly during patients' follow-up treatment at the clinic visit. This is to encourage prospective reporting of the information. The patient was also asked

to bring their receipts for related payment, the packaging of any medication purchased and bills of other expenses for counter checking purpose. Patients were encouraged to fill the diaries upon receiving every set of diaries. The data in completed diaries were discussed with the patient during these visits so as to minimize partial responses and missing information.

Patients were given the options to return the booklet after the fourth week at the pharmacy on the next visit or by mail to the address given on the booklet with postage prepaid envelope. The site investigator will contact the patient via telephone call and arrangement to collect the cost diary will be made whenever there were cases of unreturned booklets. The subsequent copy of cost diary booklet will be given to the patient's during the next visit to the clinic or pharmacy. The cost diary could be sent by post to the patient's preferred address if requested. Any missing or lost cost diary will be replaced.

The cost diary was self-administered by the patient. The documented information will be checked for accuracy and the patient could be contacted for verification. The patient was advised to call the site investigator whenever any difficulties encountered in the event of filling the cost diary. The site investigators were also provided with the cost diary procedure manual as a guide.

Figure 2 shows process and action given by the site investigator to all patients recruited for the cost diary.

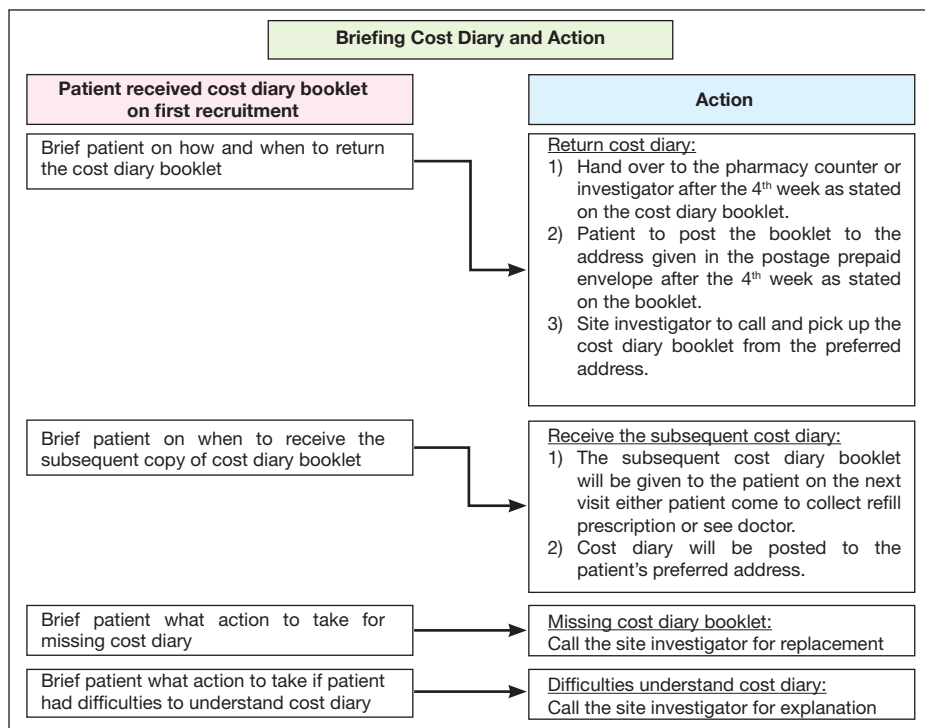


Figure 2: Instruction on how to use the cost diary

3.3.4 Training of Research Pharmacist

Pharmacists from 84 selected facilities were appointed as research pharmacists. Research pharmacists were given adequate training and retraining before embarking into this study (Appendix 7). The training module covers aspect on patient selection, important aspects of the cost diary and filling up the cost diary to the patients. The important aspects of the cost diary were as follows:

i. What to capture in the cost diary

- All visits to any facility to seek treatment or purchase items related to DM.
- All items paid for from OOP related

to DM and co-morbid treatment.

- Any hospitalisation during the period and amount paid.
- All travelling cost to and from the facilities.
- Any payment made to care givers or accompanying person.

ii. Duration of the cost diary

The important to capture the activities by weekly and follow up for 6-month duration.

iii. Completeness of cost diary

It is important to complete the cost diary without any unanswered space. For space which is not applicable, use

dash or write N/A instead of leaving it blank.

iv. Return and supply of new booklet

It is important to return cost diary after each cycle of four weeks and to supply the new booklet.

3.3.5 Monitoring by Investigators

Reinforcing and monitoring state level performances by the investigators were by clustering the facilities to specific zones and conducting meetings based on the zones (Appendix 8). The zones involved are North, South, East and Middle Peninsular and East Cost (Sabah & Sarawak). All research pharmacists were also contacted occasionally by phone to monitor their progress. Any technical problems were solved with a consensus by the main project team.

3.3.6 Quality Check

All cost diaries returned to the research pharmacist were reviewed for completeness and accuracy. The data was subsequently reviewed at the Pharmaceutical Services Division for quality check. Quality was monitored by:

1. Number of booklet issued and returned by courier services
2. Checked for completeness by trained research officers
3. Discrepancies were cross-checked with the respective research pharmacist

3.4 Data Entry and Statistical Analysis

3.4.1 Data Entry and Cleaning Process

All completed cost diaries were sent to Pharmaceutical Services Division, MOH for data entry and analysis. Data were entered in the DUS Data Entry Module (eDrugUseDM2) database. The database server used was Windows 2003 R2 Server. Cross-checks were conducted every month prior to and post data entry to ensure accuracy. All entries were reviewed for missing data and subjected to further cleaning for post data analysis.

3.4.2 Data Analysis

The sample was divided into four groups and analysed according to State Hospitals, Hospitals with Specialist, Hospitals without Specialist and Health Clinics. Data analysis was conducted using Statistical Packages for Social Sciences (SPSS) version 20. Distributions and frequencies of the independent variables were explored and analysed by using Fisher's Exact, Chi-square and one-way ANOVA test. Demographic characteristics and cost on respondents' activities on treatment of diabetics were analysed descriptively.

The medication and laboratory costs were cross-checked using the price list from Hospital Kuala Lumpur. Admission fee for hospitalisation in MOH facilities was calculated based on single bedded room per day according to the Medical Fees (Full Paying Patient) Order 2007¹³.

Direct healthcare cost was those borne by the government while those which are not government subsidised are categorised as OOP.

Treatment cost of DM over the entire 6-month period was assessed according to Figure 3. The direct cost of DM was analysed from provider perspective and societal perspective. The OOP expenses was calculated from the drugs purchased, private laboratory, clinic visit charge, complementary treatments and medicines which were purchased by the patients and not reimbursed by the government. The indirect cost was calculated using the time away from work in relation with patient's income. Costs were measured in Ringgit Malaysia (RM).

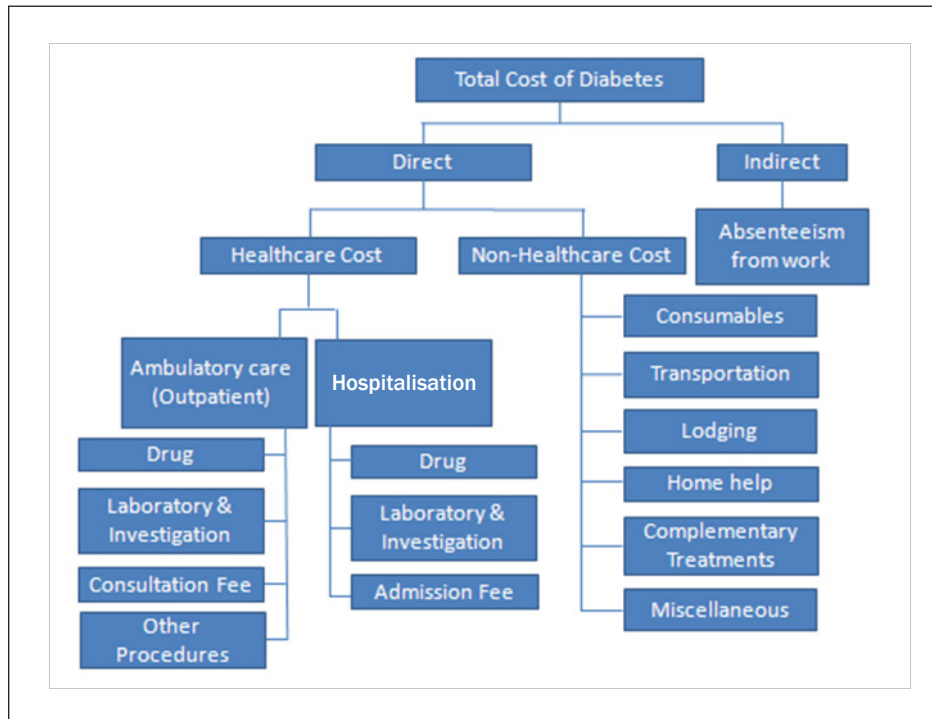


Figure 3: Outline of the cost components measured in the cost diary

Association for COI with demographic and patient characteristics were carried out. Mean costs and standard deviations (SD) were compared between the categories of independent variables.

The cost was calculated based on 6-month period according to the study and divided by six to determine the monthly cost. Subsequently, the annual estimation

was calculated using the 6-month cost multiplied by two.

3.4.3 Costing of Costs/Valuation of the Cost Diary Items

In order to determine the direct and indirect costs of treating DM, the following components were measured and calculated:

Direct healthcare cost

1. Consultation fee

Consultation fee was defined as the expenses incurred by the patient for physician visit, either in public or private facilities. In the MOH (public) facilities, the fee for an ambulatory consultation with a doctor and specialist is RM1.00 and RM5.00 respectively. There was no fee for consultation with pharmacists or dietitian in the MOH facilities. In the event of missing cost, the information was cross-checked with the type of consultation (either with a doctor or specialist) and fees were assigned according to the Fee Act¹³.

The costs of consultation did not include the salaries of health professionals and procedure costs (e.g. dressing, ECG, etc), consumables costs (e.g. syringes, glucometer strips, etc) and infrastructure costs (such as use emergency room, medical equipment, etc).

2. Cost of drug

Drug costs were defined as the sum of the cost of all drugs prescribed by healthcare professionals (public or private facilities). The drug costs prescribed in the public facilities was calculated by multiplying the quantity of drug prescribed with unit cost according to 2011 Hospital Kuala Lumpur (HKL) price list. In the event of missing data on quantity of drug prescribed, the quantity was estimated by using the average dose of the drug prescribed for one month (30 days). The drug costs prescribed or purchased in private healthcare facilities were considered OOP expenses.

3. Cost of laboratory tests and investigations

Laboratory and investigations costs were defined as the sum of cost of all tests and procedures (e.g. blood tests) conducted in public or private healthcare facilities. The laboratory and investigations costs in the public facilities were calculated by multiplying the number of consumption with the unit cost according to 2011 HKL price list. If a service of laboratory is used then it is considered as OOP expenses.

4. Cost of hospitalisation

Cost of hospitalisation admission was defined as the sum for admission fee, laboratory and investigation and drug costs. The calculation of drug cost and laboratory cost were described as above. The cost of hospitalisation in this study did not include the salaries of health professionals, infrastructure cost (bed charges, hospital meals, emergency room), and consumables cost (syringes, drips, bandages, etc) and administrative cost. Hospitalisation cost for private hospital admission is considered as OOP expenses.

Direct non-healthcare cost

5. Cost of consumables

The cost of consumables was defined as the sum of all expenditure on medical items (e.g. needles, alcohol swabs, lancets, etc), complementary medicines, supplements (e.g. multivitamins, fish oils, glucosamine, etc), food (oats, diabetic milk) and others such as exercise equipment and diabetic shoes. All expenditure

except complementary medicines is categorised under direct non-healthcare cost.

6. Cost of transportation

Transportation costs were defined as the sum of all return journeys to healthcare facilities, parking fee and toll charges (if any). In the event of missing cost for those travelling by car and motorcycle, the cost were calculated by multiplying the distance travelled (in kilometer) by mileage rate. The mileage rate for car and motorcycle were defined as RM0.70 and RM0.50 per kilometer respectively. The missing costs for those travelling by public transports (e.g. taxi, train, bus, etc) were not calculated.

7. Cost of lodging

Costs of lodging were defined as the sum of expenditure on all lodging for patient who had to seek treatment away from his home vicinity. All expenditure on lodging is categorised under direct non-healthcare cost.

8. Cost of home help

Costs of home help were defined as the sum of expenditure of hiring maid (hourly or monthly), nursing care, laundry services, physiotherapist or massagers. All expenditure on home help is categorised under direct non-healthcare cost.

Indirect cost

The indirect costs were defined as the sum of cost due to absenteeism from work for the enrolled patients and their accompanying family, relatives or friends,

if there were any based on length of hospital admissions, medical leave and/or time-off from work.

Cost due to absenteeism from work

Cost of absenteeism from work due to DM was estimated by calculating the total time spent in the healthcare facilities multiplied by the income per day or hour. Daily income was calculated by using the upper limit of the monthly household income range multiplied by twelve and divided by 52 and five; with the assumption that workers are employed five days per week and 52 weeks per year. This study assumed that one working day is equivalent to eight working hours. Hence, the income per hour was estimated by using income per day divided by eight¹⁴.

Cost per day due to days away from

$$\text{work} = \frac{\text{monthly wage} \times 12}{52 \text{ weeks} \times 5}$$

The indirect cost due to hospitalisation was calculated by multiplying the number of days of admission and number of medical leave in days by income per day. The cost of absenteeism in ambulatory activities was calculated by multiplying the sum of hours spent in facilities by income per hour. The same calculations were applied to determine cost of absenteeism for accompanying family, relatives and friends.

3.5 Ethical Approval

This study was registered with National Medical Research Register (NMRR) and ethical approval was obtained from Medical Research and Ethics Committee (MREC) with ID number NMRR-09-298-3538 and Protocol No. 3538 (Appendix 9).

4.0 RESULTS

4.1 Response Rate

Table 2 summarised facilities involved in this study. The response rate was 96.4%. Two hospitals with specialist and one hospital without specialist were not included due to no submission of cost diary. The state hospitals and health clinics achieved 100.0%. The lowest rate was from hospitals with specialists (89.5%). The list of facilities involved is in Appendix 1.

A total of 289 (89.5%) patients out of 323 patients were enrolled. The number of respondents in health clinics had exceeded by three more patients (103.6%). The lowest respondent rate was from hospitals with specialist (76.3%).

Details on the cost diaries as in Appendix 5.

Table 2: Response rate based on number of facilities, sample size and cost diary (Appendix 10)

Item		All	State Hospitals ^a	Hospitals with Specialist	Hospitals without Specialist	Health Clinics
Response according to number of facilities	Target	84	14	19	27	24
	Number of facilities participated	81	14	17 ^b	26 ^b	24
	Response rate (%)	96.4	100.0	89.5	96.3	100.0
Response according to number of samples (Target sample size: 10% from DUS Phase I samples)	Target	323	56	76	108	83
	Number of patients enrolled	289	53	58	92	86
	Response rate (%)	89.5	94.6	76.3	85.2	103.6
Response according to number of cost diary returned	Number of diary returned to facilities	1,002	183	244	293	282
	Number of diary completed by patients	986	182	237	293	274
	Response rate (%)	98.4	99.5	97.1	100.0	97.2
Average number of cost diary returned	Number of diary completed by patients divided by number of patients enrolled	3.4	3.4	4.1	3.2	3.2

^a State hospitals consists of HKL and thirteen state hospitals.

^b Two hospitals with specialist and one hospital without specialist were not included due to no submission of cost diary.

PART 1: DEMOGRAPHIC CHARACTERISTICS

4.2 Profile of Participants

4.2.1 Social Demographic Profile

Table 3 showed the demographic characteristics of the patients enrolled from the four types of health facilities. The patient's characteristics are gender, age, race, occupation, marital status and household income. No significant differences were observed between patients from all facilities.

Table 3: Demographic characteristics of patients (n=289)

Patient characteristics	All (n=289) n %	State Hospitals (n=53) n %	Hospitals with Specialist (n=58) n %	Hospitals without Specialist (n=92) n %	Health Clinics (n=86) n %	p-value
Gender (n=289)						
Male	118 (40.8)	30 (56.6)	26 (44.8)	30 (32.6)	32 (37.2)	>0.05 ^a
Female	171 (59.2)	23 (43.4)	32 (55.2)	62 (67.4)	54 (62.8)	
Age, years (n=289)						
Mean Age (SD)	52.7 (9.5)	49.7 (11.8)	52.4 (8.7)	54.5 (8.7)	53.0 (8.9)	>0.05 ^b
< 45	48 (16.6)	12 (22.6)	9 (15.5)	8 (8.7)	19 (22.1)	
45 – 49	30 (10.4)	9 (17.0)	6 (10.3)	12 (13.0)	3 (3.5)	
50 – 54	73 (25.2)	10 (18.9)	15 (25.9)	28 (30.4)	20 (23.3)	
55 – 59	77 (26.6)	9 (17.0)	18 (31.0)	23 (25.0)	27 (31.4)	
60 – 64	49 (17.0)	12 (22.6)	9 (15.5)	14 (15.2)	14 (16.3)	
≥ 65	12 (4.2)	1 (1.9)	1 (1.7)	7 (7.6)	3 (3.5)	
Race (n=289)						
Malay	186 (64.4)	32 (60.4)	41 (70.7)	62 (67.4)	51 (59.3)	>0.05 ^a
Chinese	40 (13.8)	5 (9.4)	10 (17.2)	6 (6.5)	19 (22.1)	
Indian/Punjabi	33 (11.4)	12 (22.6)	3 (5.2)	4 (4.4)	14 (16.3)	
Others ^c	30 (10.4)	4 (7.5)	4 (6.9)	20 (21.7)	2 (2.3)	
Occupation (n=264)						
Government Employee	89 (33.7)	16 (32.0)	13 (26.5)	40 (48.2)	20 (24.4)	>0.05 ^a
Private Employee	32 (12.1)	6 (12.0)	6 (12.2)	4 (4.8)	16 (19.5)	
Self Employed	28 (10.6)	5 (10.0)	5 (10.2)	10 (12.0)	8 (9.8)	
Retiree	48 (18.2)	9 (18.0)	14 (28.6)	11 (13.3)	14 (17.1)	
Housewife	37 (14.0)	7 (14.0)	9 (18.4)	7 (8.4)	14 (17.1)	
Unemployed	30 (11.4)	7 (14.0)	2 (4.1)	11 (13.3)	10 (12.2)	
Marital Status (n=267)						
Not Married	15 (5.6)	8 (16.0)	2 (4.0)	3 (3.9)	2 (2.5)	>0.05 ^a
Married	232 (86.9)	41 (82.0)	46 (92.0)	75 (97.4)	70 (86.4)	
Widowed	16 (6.0)	0 (0.0)	1 (2.0)	6 (7.8)	9 (11.1)	
Divorced/Separated	4 (1.5)	1 (2.0)	1 (2.0)	2 (2.6)	0 (0.0)	
Household Income, RM (n=273)						
< 1,000	54 (19.8)	7 (13.7)	11 (19.6)	16 (18.4)	20 (25.3)	>0.05 ^d
1,000 – 3,000	134 (49.1)	23 (45.1)	26 (46.4)	49 (56.3)	36 (45.6)	
3,001 – 5,000	49 (17.9)	11 (21.6)	11 (19.6)	15 (17.2)	12 (15.2)	
> 5,000	36 (13.2)	10 (19.6)	8 (14.3)	7 (8.0)	11 (13.9)	

^a Fisher's Exact Test

^b One-way ANOVA

^c Other races include Kadazan, Iban, Bajau, Dusun, Other Sabahan Bumiputera, Other Sarawakian Bumiputera and others.

^d Chi-square Test

4.2.2 Patients Diabetes Characteristics

Table 4 showed that the mean disease duration was 9.5 years (SD 7.2) while more than fifty percent were diagnosed of having DM for more than five years.

The number of patients on insulin, duration on insulin, number of co-morbidities and number of hospitalisation showed no significant difference.

Table 4: Patients' disease status (n=289)

Diabetes Characteristics	All (n=289)		State Hospitals (n=53)		Hospitals with Specialist (n=58)		Hospitals without Specialist (n=92)		Health Clinics (n=86)		p-value
	n	%	n	%	n	%	n	%	n	%	
Duration Diagnosed with DM, years (n=258)											
Mean (SD)	9.5	(7.2)	11.0	(6.9)	8.8	(7.3)	8.8	(6.9)	9.7	(7.5)	>0.05 ^a
≤ 5	97	(37.6)	11	(23.4)	22	(44.0)	33	(40.2)	31	(39.2)	
> 5 and < 10	48	(18.6)	9	(19.1)	11	(22.0)	16	(19.5)	12	(15.2)	
≥ 10	113	(43.8)	27	(57.4)	17	(34.0)	33	(40.2)	36	(45.6)	
Insulin (n=289)											
Yes	138	(47.8)	38	(71.7)	21	(36.2)	36	(39.1)	43	(50.0)	>0.05 ^b
No ^c	151	(52.2)	15	(28.3)	37	(63.8)	56	(60.9)	43	(50.0)	
Duration on Insulin, years (n=121)											
Mean (SD)	3.7	(3.7)	3.9	(3.8)	3.9	(2.6)	4.0	(3.7)	3.4	(4.3)	>0.05 ^a
≤ 5	90	(74.4)	21	(77.8)	15	(71.4)	21	(65.6)	33	(80.5)	
> 5 and < 10	19	(15.7)	2	(7.4)	5	(23.8)	7	(21.9)	5	(12.2)	
≥ 10	12	(9.9)	4	(14.8)	1	(4.8)	4	(12.5)	3	(7.3)	
Number of Co-morbidities (n=289)											
Nil ^c	67	(23.2)	11	(20.8)	14	(24.1)	23	(25.0)	19	(22.1)	>0.05 ^a
1	123	(42.5)	21	(39.6)	22	(37.9)	40	(43.5)	40	(46.5)	
2	63	(21.8)	9	(17.0)	16	(27.6)	19	(20.7)	19	(22.1)	
≥ 3	36	(12.5)	12	(22.6)	6	(10.3)	10	(10.9)	8	(9.3)	
Number of Hospitalisation (n=289)											
Nil ^c	268	(92.7)	47	(88.7)	53	(91.4)	85	(92.4)	83	(96.5)	>0.05 ^a
1	15	(5.2)	3	(5.7)	4	(6.9)	5	(5.4)	3	(3.5)	
2	4	(1.4)	3	(5.7)	0	(0.0)	1	(1.1)	0	(0.0)	
3	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
4	2	(0.7)	0	(0.0)	1	(1.7)	1	(1.1)	0	(0.0)	

^a One-way ANOVA

^b Fisher's Exact Test

^c Non-respondents to each item were assumed to be not on insulin, had no co-morbidity and no hospitalisation respectively.

^d Chi-square Test

4.2.3 Number of Ambulatory Visits and Types of Activities

Details of activity on ambulatory visit during the 6-month period were summarized as in Table 5. The activities include appointment/consultation, laboratory tests and investigations and purchase of consumables. Most patient had only one activity per visit across all facilities. Among those patients who attended the facility and performing a single activity, attending appointments/consultation were the most frequent activity followed by purchasing of consumables and appointment for laboratory tests and investigations. The highest number of visits was 5.2 for purchase of consumables, followed by doctor's appointment/consultation (4.7) and lastly, laboratory and investigations (3.9).

The highest reason for two activities per visit was for appointment/consultation and laboratory test and investigation. This was followed by appointment/consultation and purchase of consumables. A total of 21 patients performed three activities per visit. Patients from health clinics had the highest number of visits (24).

The mean number of visits for patients in the three categories was 12.3. However, comparing the facility types, hospitals with specialist recorded highest mean number of visits among all four facilities.

Table 5: Details of activities on ambulatory visits

Type of Ambulatory Visits	All Patients			State Hospitals Patients			Hospitals with Specialist Patients			Hospitals without Specialist Patients			Health Clinics Patients		
	n	No. of visits	Mean no. of visits	n	No. of visits	Mean no. of visits	n	No. of visits	Mean no. of visits	n	No. of visits	Mean no. of visits	n	No. of visits	Mean no. of visits
Single Activity Per Visit															
Appointments & Consultations	253	1,194	4.7	46	228	5.0	50	251	5.0	82	351	4.3	75	364	4.9
Laboratory & Investigation	155	603	3.9	30	67	2.2	39	165	4.3	50	231	4.6	36	140	3.9
Purchase of Consumables	193	1,006	5.2	37	158	4.3	43	245	5.7	51	274	5.4	62	329	5.3
Others ^a	17	144	8.5	4	49	12.3	6	71	11.8	4	18	4.5	3	6	2.0
Two activities per visit															
Appointment & Consultations + Laboratory & Investigation	62	140	2.3	10	33	3.3	11	20	1.8	13	27	2.1	28	60	2.1
Appointment & Consultations + Purchase of Consumables	40	91	2.3	3	8	2.7	9	15	1.7	17	50	2.9	11	18	1.6
Laboratory & Investigation + Purchase of Consumables	17	36	2.1	0	0	0.0	6	13	2.2	8	18	2.3	3	5	1.7
Three activities per visit															
Appointment & Consultations + Laboratory & Investigation + Purchase of Consumables	21	45	2.1	2	2	1.0	6	8	1.3	6	11	1.7	7	24	3.4
Total number of ambulatory visits	268	3,259	12.3	47	545	11.6	53	788	14.9	85	980	11.5	83	946	11.4

^a Others refer to exercise, tai chi, sport activities and massage.

4.2.4 Association of Disease Status to Duration Diagnosed with DM and Number of Co-morbidities

The association of duration diagnosed with DM and the frequency of ambulatory visits within the 6-month period is shown in Table 6. Less than five years DM diagnosed patients had the highest visits (49.5%) in the 6 - 10 times category. However, there is no significant difference in years of duration diagnosed towards frequency of ambulatory visit. Significant differences were found between the number of co-morbidities and frequency of ambulatory visit.

Table 6: Association between number of ambulatory visit with duration of DM and number of co-morbidities per 6-month (n=289)

Disease status	Frequency of Ambulatory Visit ^b within 6-month, n (%)					p-value
	1 – 5	6 – 10	11 – 15	16 – 20	> 20	
Duration diagnosed with DM, years (n=258)						
≤ 5	11 (11.3)	48 (49.5)	21 (21.6)	8 (8.2)	9 (9.3)	0.692 ^a
> 5 and < 10	7 (14.6)	17 (35.4)	13 (27.1)	6 (12.5)	5 (10.4)	
≥ 10	15 (13.3)	42 (37.1)	25 (22.1)	15 (13.3)	16 (14.2)	
Number of co-morbidities (n=289)						
0	10 (14.9)	26 (38.8)	14 (20.9)	11 (16.4)	6 (9.0)	0.004 ^a
1	25 (20.3)	47 (38.2)	32 (26.0)	6 (4.9)	13 (10.6)	
≥ 2	5 (5.1)	45 (45.5)	17 (17.2)	15 (15.1)	17 (17.2)	

^a Chi-square Test

^b Ambulatory visits include appointments and consultations (doctor, pharmacist, dietitian, etc), laboratory and investigation (blood tests, urine tests, traditional treatment, dialysis, etc.), purchase of consumables (healthcare devices, healthcare equipments, drugs, herbal or nutritional products, healthcare consumables, etc.).

PART 2: DIRECT AND INDIRECT COST ON TREATMENT OF DIABETES MELLITUS

4.3 Cost of Treatment for Diabetes Mellitus

4.3.1 Direct Healthcare Cost

Direct cost was estimated by direct healthcare cost on ambulatory care (Figure 4) and hospitalisation (Figure 5).

Figure 4 showed the components for healthcare cost. This cost on drugs is similar for all facilities except health clinics. Other procedures such as physiotherapy, wound dressing and minor surgery constitute less than 2% among all facilities. The drug component contributed the highest healthcare cost (Appendix 11, 12).

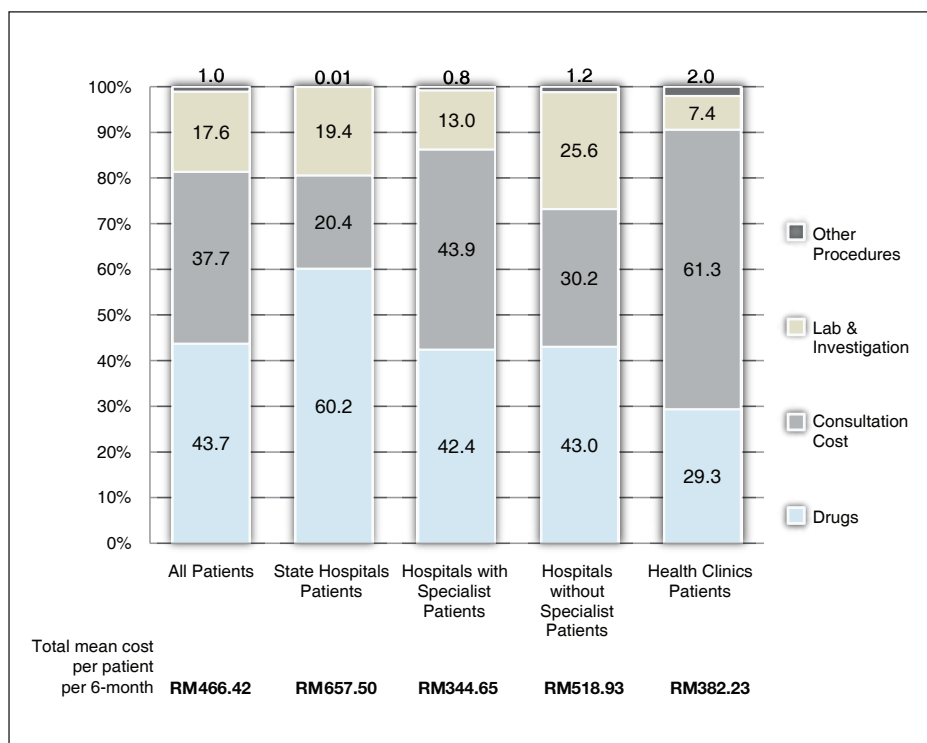


Figure 4: Distribution of mean direct healthcare cost on ambulatory care per patient per 6-month (n=268). Other procedures refer to physiotherapy, wound dressing, minor surgery and etc.

From the findings, only 21 out of 289 enrolled patients reported being hospitalised within 6-month period. One patient was admitted to a private hospital but the cost was omitted from direct healthcare estimation. The lowest mean for direct healthcare cost was observed from health clinics where 93.8% of the total cost was for admission fees. The findings were similar among all facilities. The mean costs for hospitalisation of the three types of hospital were found to be higher than the overall total mean cost (Figure 5) (Appendix 13).

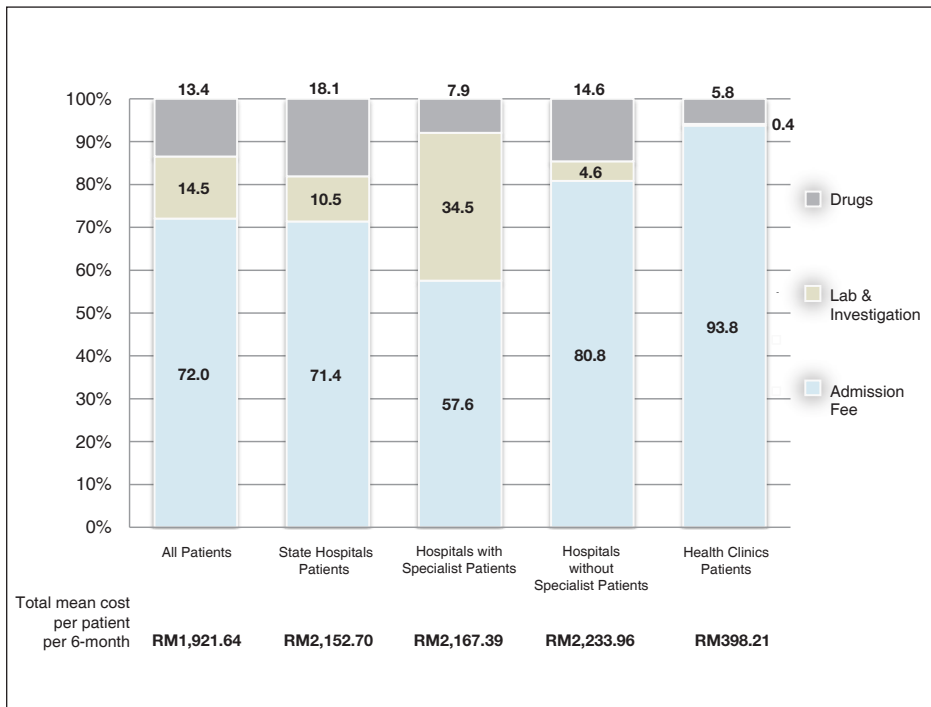


Figure 5: Distribution of mean direct healthcare cost on hospitalisation in public hospitals, per patient per 6-month (n=20)

4.3.2 Direct Non-healthcare Cost

a. Direct non-healthcare cost for ambulatory care and hospitalisation

The direct non-healthcare cost for ambulatory care and hospitalisation is summarised in Figure 6 (Appendix 14, 15). The mean total cost per patient per 6-month for state hospitals and health clinics was higher than the total mean. Home help contributes the main cost spent for state hospital (72.9%) and complementary treatment (41.7%) in health clinic. For hospitals with specialist and hospital without specialist, the main cost spent was for the purchase of consumables.

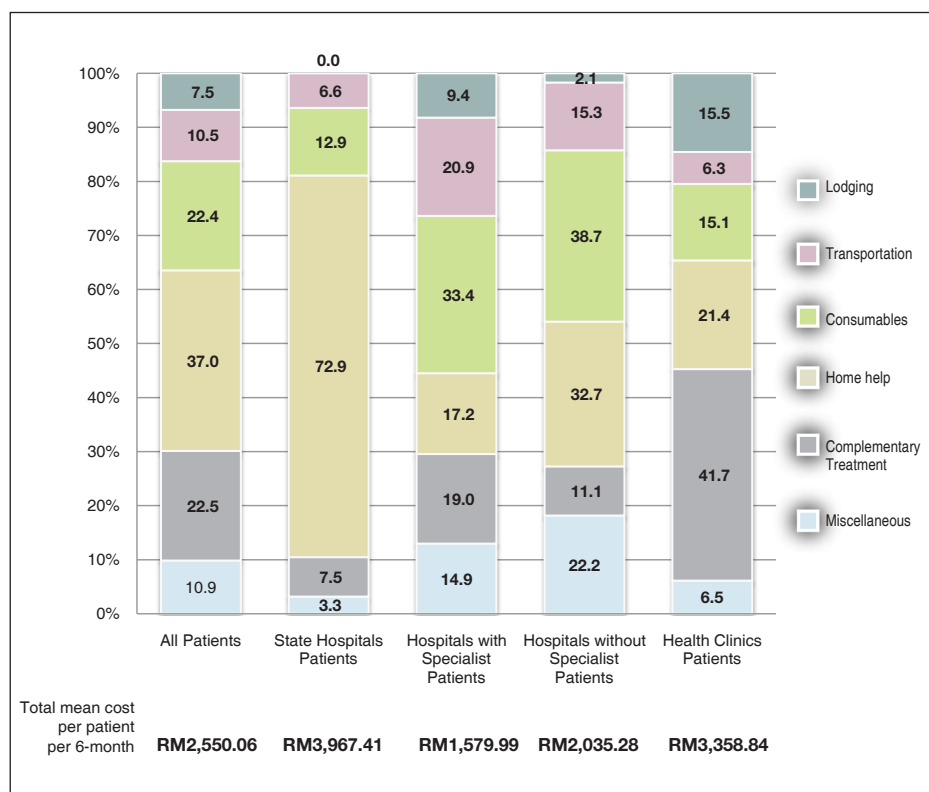


Figure 6: Distribution of direct non-healthcare cost per patient per 6-month, for ambulatory care and hospitalisation (n=289)

b. Direct non-healthcare cost on miscellaneous expenses

The cost of patients paying for clinic visits charges, seeking private laboratory testing and drugs was summarised in Figure 7 (Appendix 15, 16). Hospitals without specialist showed highest total mean cost (RM451.81) than the overall total mean (RM278.73). The main cost spent was for the drug purchased except for health clinics where payment for private laboratory constitute the most spent direct non-healthcare cost.

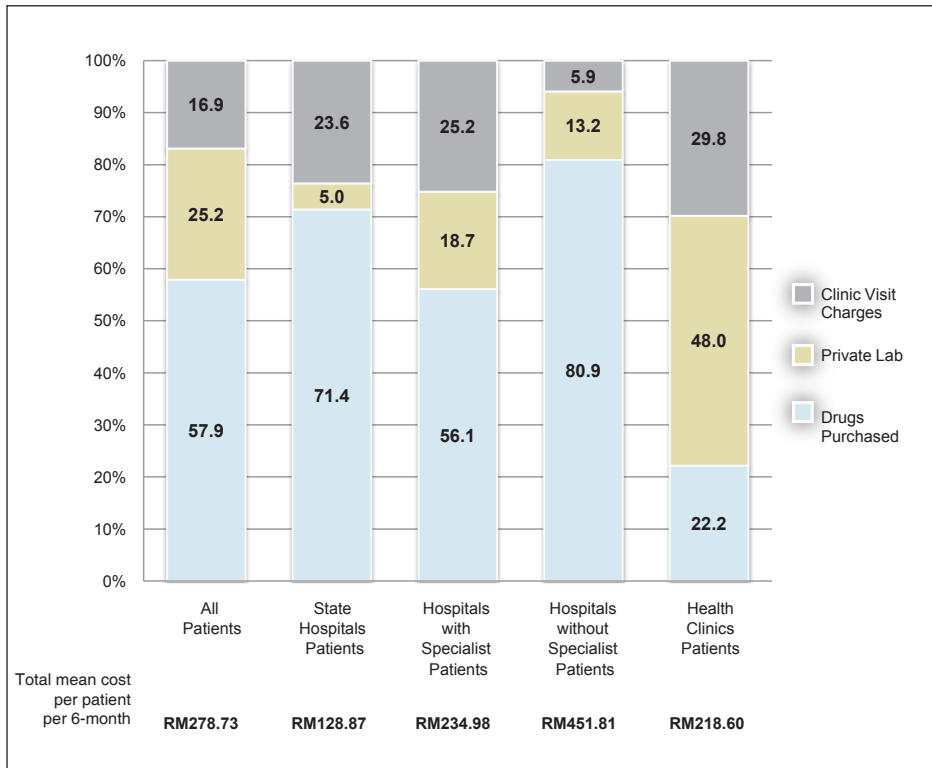
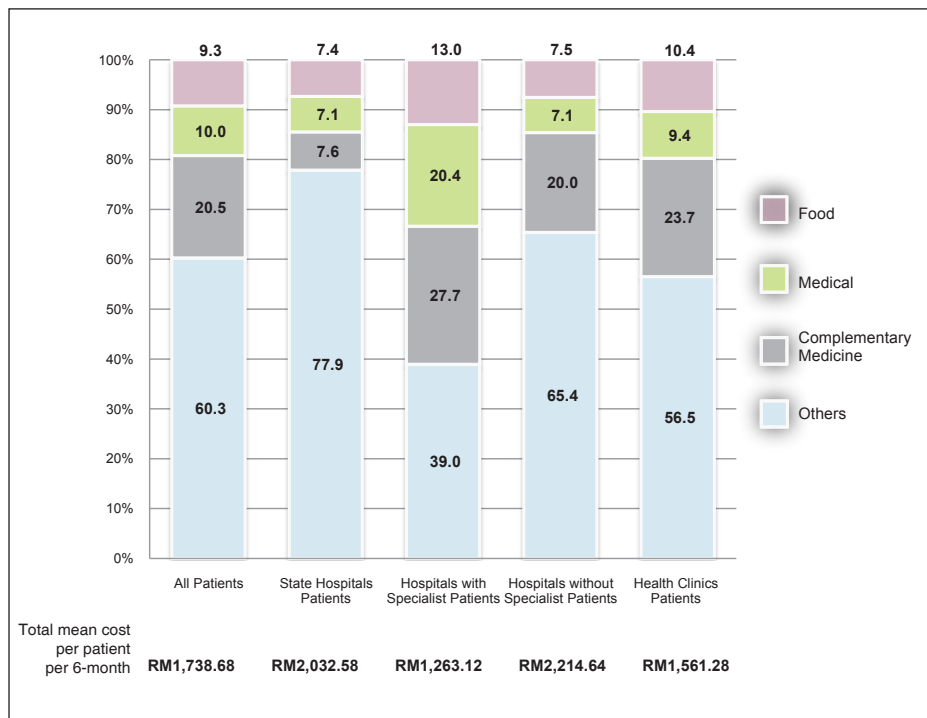


Figure 7: Distribution of expenses on miscellaneous for ambulatory care per patient per 6-month (n=268)

c. Direct non-healthcare cost for consumables

Figure 8 showed the direct non-healthcare cost for purchases of consumables in the four facility types (Appendix 17, 18). The main cost spent was for purchase of DM related accessories such as exercise equipment and shoes. Facilities that showed high total mean cost than the average overall mean were state hospitals and hospitals without specialist.



Food: oats, rice (multigrain), diabetic milk.

Medical: insulin needles, lancets, strips, alcohol swabs, medical devices, bandages and cottons.

Complementary medicine: multivitamins, supplements, glucosamine, fish oils, spirulina and herbal.

Others: exercise equipment, diabetic shoes and others.

Figure 8: Distribution of direct non-healthcare cost on types of consumables, per patient per 6-month (n=289)

4.3.3 Indirect Cost in the Treatment of Diabetes Mellitus

a. Cost of absenteeism in ambulatory activities

The table below described the cost of absenteeism by DM patients seeking treatment. From the total number of visits, the total time away from work was 3,874.7 hours amounting to a total cost of RM70,616.44. Patients from hospitals with specialist showed the highest cost of absenteeism and highest mean cost per patient per 6-month.

Table 7: Cost of absenteeism from work due to ambulatory activities by patients (n=252)

	All Patients	State Hospitals Patients	Hospitals with Specialist Patients	Hospitals without Specialist Patients	Health Clinics Patients
	(n=252)	(n=45)	(n=50)	(n=81)	(n=76)
Number of visit	3,049	511	734	914	890
Total time away from work, hours	3,874.7	620.9	1,064.7	1,089.6	1,099.5
Average time per visit, hours	1.3	1.2	1.5	1.2	1.2
Total cost, RM	70,616.44	12,494.72	19,892.68	19,011.68	19,217.36
Mean cost per 6-month, RM (SD)	280.22 (348.76)	277.66 (218.35)	397.85 (635.97)	234.71 (220.61)	252.86 (225.21)

Table 8 described the cost of absenteeism by DM patient's accompanying person seeking treatment. The total cost of absenteeism was RM40,906.42 where the main contributor being health clinics. The highest mean cost per month per accompanying person was by patients from hospitals with specialist.

Table 8: Cost of absenteeism from work due to ambulatory activities by accompanying persons (n=138)

	All Patients	State Hospitals Patients	Hospitals with Specialist Patients	Hospitals without Specialist Patients	Health Clinics Patients
	(n=138)	(n=21)	(n=27)	(n=44)	(n=46)
Number of visit	1,356	181	379	436	360
Total time away from work, hours	3,123.6	361.7	914.1	981.1	866.7
Average time per visit, hours	2.3	2.0	2.4	2.3	2.4
Total cost, RM	40,906.42	4,927.98	10,946.14	11,617.07	13,415.23
Mean cost per 6-month, RM (SD)	296.42 (376.36)	234.67 (260.97)	405.41 (455.08)	264.02 (395.19)	291.64 (365.09)

b. Cost of absenteeism in hospitalisation activities

The cost of absenteeism by patients who were hospitalised during the study period is shown in Table 9. The total cost of absenteeism by patients was RM37, 799.98 of which the main contributor was from hospitals without specialist. The mean cost per patient per 6-month was RM1,890.00

Table 9: Cost of absenteeism from work due to hospitalisation activities by patients (n=20)

	All patients	State Hospitals Patients	Hospitals with Specialist Patients	Hospitals without Specialist ^a Patients	Health Clinics Patients
	(n=20)	(n=6)	(n=5)	(n=6)	(n=3)
Total days of admission	177	52	39	76	7
Total days of healthcare leave	91	15	4	69	3
Total time away from work, days	268	67	43	145	10
Total cost, RM	37,799.98	10,107.61	5,584.62	20,446.22	1,661.54
Mean cost per 6-month, RM (SD)	1,890.00 (3,700.71)	1,684.60 (1,908.73)	1,116.92 (1,085.55)	3,407.70 (6,539.51)	553.85 (719.47)

^aOne patient did not report the monthly household income.

The mean cost of accompanying person being absent from work was RM267.79 with a total cost of RM1, 606.76. Patients from hospitals without specialist had the highest mean cost per 6-month per accompanying person.

Table 10: Cost of absenteeism from work due to hospitalisation activities by accompanying persons (n=6)

	All patients	State Hospitals Patients	Hospitals with Specialist Patients	Hospitals without Specialist Patients	Health Clinics Patients
	(n=6)	(n=1)	(n=2)	(n=2)	(n=1)
Total time away from work, days	13.3	1.0	1.3	8.0	3.0
Total cost, RM	1,606.76	46.15	175.97	969.25	415.39
Mean cost per 6-month, RM (SD)	267.79 (221.04)	46.15	87.99 (71.39)	484.62 (97.91)	415.39

c. Total cost of absenteeism (ambulatory and hospitalisation)

Table 11 showed the indirect costs (absenteeism) associated with ambulatory care and hospitalisation for patients and accompanying person. The mean cost of absenteeism from work for a period of 6-month for patients and the accompanying person was RM398.59 and RM295.23 respectively.

The cost of absenteeism for ambulatory visit was higher for both patients and accompanying persons compared to the absenteeism due to hospitalisation across all facilities. The cost of absenteeism due to ambulatory visit by the patients accounted for 65.1% of the total cost while for hospitalisation only 34.9%. As for the accompanying person, the cost for absenteeism due to ambulatory visits was 96.2% of the total cost compared to 3.8% for hospitalisation.

The mean cost of absenteeism was highest for patients from hospitals with specialist as compared to other facilities.

Table 11: Total cost of absenteeism from work due to ambulatory care and hospitalisation activities by patients and accompanying persons

Patients						Accompanying Person				
	All	State Hospitals	Hospitals with Specialist	Hospitals without Specialist	Health Clinics	All	State Hospitals	Hospitals with Specialist	Hospitals without Specialist	Health Clinics
	(n=272)	(n=51)	(n=55)	(n=87)	(n=79)	(n=144)	(n=22)	(n=29)	(n=46)	(n=47)
Ambulatory visits, RM (%)	70,616.44 (65.1)	12,494.72 (55.3)	19,892.68 (78.1)	19,011.68 (48.2)	19,217.36 (92.0)	40,906.42 (96.2)	4,927.98 (99.1)	10,946.14 (98.4)	11,617.07 (92.3)	13,415.23 (97.0)
Hospitalisation, RM (%)	37,799.99 (34.9)	10,107.61 (44.7)	5,584.62 (21.9)	20,446.22 (51.8)	1,661.54 (8.0)	1,606.76 (3.8)	46.15 (3.8)	175.97 (1.6)	969.25 (7.7)	415.39 (3.0)
Total cost, RM	108,416.43	22,602.33	25,477.30	39,457.90	20,878.90	42,513.18	4,974.13	11,122.11	12,586.32	13,830.62
Mean cost per patient, RM (SD)	398.59 (1,118.04)	443.18 (784.78)	463.22 (705.56)	453.54 (1,784.82)	264.29 (255.72)	295.23 (383.47)	226.10 (265.55)	383.52 (446.31)	273.62 (399.65)	294.27 (373.86)
Median cost, RM (IQR)	207.70 (105.84, 384.66)	255.29 (111.03, 426.95)	230.72 (122.13, 607.21)	163.56 (92.27, 370.39)	168.74 (104.51, 328.12)	141.50 (51.92, 353.37)	138.46 (47.90, 284.14)	207.70 (103.84, 450.01)	124.76 (47.95, 334.59)	142.79 (53.37, 368.51)

4.3.4 Total Cost in the Treatment of Diabetes Mellitus

Table 12 showed the annual cost of treating diabetes patients. The estimated mean direct healthcare cost per patient per year was RM2,684.24 while for the indirect cost was RM1,062.88. There is no significant difference of mean direct cost spent for ambulatory DM patients between all the facilities in MOH.

The total direct and indirect cost calculated was RM537,460.81 of which the direct cost amounts to 71.9% (RM386, 531.21) and the indirect cost consists of 28.1% for (RM150,929.60) of the total cost.

Analysis on the direct cost showed that direct healthcare cost and direct non-healthcare cost was RM163,436.15 (42.3%) and RM223,095.06 (57.7%) respectively. From the direct healthcare cost of RM163,436.15, ambulatory care cost contributed 76.5% (RM125,003.28) while hospitalisation cost accounted for 23.5% (RM 38,432.87) of the total cost.

Table 12: Cost of treatment for DM per patient per 6-month by types of facility

Cost component	All patients	State Hospitals Patients	Hospitals with Specialist Patients	Hospitals without Specialist Patients	Health Clinics Patients
Direct Cost					
n	288	52	58	92	86
(a) Direct healthcare cost, RM					
Ambulatory (%)	125,003.28 (32.3)	30,902.64 (35.1)	18,266.33 (24.8)	44,108.89 (35.5)	31,725.42 (31.5)
Hospitalisation (%)	38,432.87 (9.9)	10,763.50 (12.2)	10,836.94 (14.7)	15,637.81 (12.6)	1,194.62 (1.2)
(b) Direct non-healthcare cost, RM (%)	223,095.06 (57.7)	46,281.14 (52.6)	44,449.12 (60.4)	64,658.91 (52.0)	67,705.89 (67.3)
(c) Total direct cost per 6-month, RM (a + b)	386,531.21 (71.9%)	87,947.28	73,552.39	124,405.61	100,625.93
Mean direct cost per 6-month ^a , RM (SD)	1,342.12 (1,722.95)	1,691.29 (2,087.16)	1,268.14 (1,393.73)	1,352.23 (1,505.43)	1,170.07 (1,890.04)
Estimation direct cost per year, RM	2,684.24	3,382.58	2,536.28	2,704.46	2,340.14
Indirect Cost					
n	284	53	57	90	84
(d) Total indirect cost per 6-month, RM	150,929.60 (28.1%)	27,576.46	36,599.41	52,044.22	34,709.52
Mean indirect cost per 6-month ^b , RM (SD)	531.44 (1,160.32)	520.31 (782.27)	642.09 (927.13)	578.27 (1,779.63)	413.21 (454.06)
Estimation indirect cost per year, RM	1,062.88	1,040.62	1,284.19	1,156.54	826.42
Total Direct and Indirect Cost per 6-month, RM (c + d)	537,460.81	115,523.74	110,151.80	176,449.83	135,335.45

^a No significant difference of mean direct cost between type of facilities (Kruskal Wallis Test, p-value is 0.280).^b There was no significant difference of mean indirect cost between type of facilities (Kruskal Wallis Test, p-value is 0.261)

5.0 Discussion

The Malaysian government main aim is to ensure a universal health care system that caters for the population. This can be clearly apparent by treatment at the various healthcare facilities is highly subsidised and patients have access to treatment for all kinds of diseases. Healthcare is thus very expensive and diabetes contributed highly in the overall health financing.

There are four main models for healthcare systems namely the Beveridge, Bismarck, National Health Insurance and the Out-of-Pocket model. The Malaysian healthcare system is based to the Beveridge Model where health care is provided and financed by the government through tax payments. In this model, patients only pay a small token to the whole healthcare system. The contribution by the government provider is rarely estimated and this study aims to identify the healthcare cost related to ambulatory patients.

Goosens et al defined healthcare care cost as cost that pertains to direct healthcare cost, direct non-healthcare cost and indirect cost¹². In Malaysia, the direct care cost such as visits to general practice, specialist care and physiotherapy visits is fully funded by the government where patients are only obligated to pay for the small administrative fee. Medications are free and patients have no worries for the supply since it is provided life-long.

The National Medicines Formulary¹⁵ and the Operational Policy On Ambulatory Pharmacy¹⁶ clearly highlight the practice on the medication supply system, categorising medications into four different classes (A*, A, B, C) in the National Medication Formulary is aimed to ensure medications are prescribed

rationally. This provides a mechanism on not only who and when these medications are prescribed but the types of health facilities that have access to these medications. The operational policy on ambulatory pharmacy however outline that medications can only be supplied on a monthly period. This policy is not a restriction but aim to ensure patients are continuously monitored of their health status.

The above healthcare policies can have negative impact to patients. The negative impacts can be monetary loss and even psychological distress. Monetary loss can be income lost due to transport, leave from work and even payment for homecare help. Psychological distress may lead to patients losing confidence to the healthcare treatment and these patients may seek alternative therapies that increase their out-of-pocket costs. Reports by Hurd M and Rohwedder S 2009¹⁷, Mondal et al 2010¹⁸ gave examples where these out-of-pocket posed a high burden to patients healthcare cost.

Acknowledging the above possible scenarios, estimating direct healthcare cost, direct non-healthcare cost and indirect is important so as to ensure that the healthcare system remains cost-effective and accessible to all needy Malaysians.

The respondent rate of 89.5% demonstrated the strength, power and the creditability of this study. This also showed that enrolled patients in this study are representatives of the four healthcare facilities. Statistically, these enrolled patients were homogenous in terms of the demographic characteristics and disease status. Homogeneity across all facilities highlight inter-individual variation is very much controlled.

The number of co-morbidities of diabetic patients affected the number of ambulatory visits. This finding is expected since each co-morbid needs at least one physician visit every three to six months (CPG 2009 MOH)¹¹. A clear example is the report by Zhuo et al 2013 showed that patients on insulin made an average of eight office visits per year¹⁹. On average the mean ambulatory visits is 12 while disease duration had no significant effect to the frequency of ambulatory visit. The high number of ambulatory visits can be translated to cost by a study by Cunningham PJ where Americans with chronic conditions had persistently high out-of-pocket expenses²⁰.

The out-of-pocket cost for direct healthcare cost for payments borne directly by patients for the purchases of healthcare or products (WHO/SHA PG Guide)²¹. This study however categorises these purchases as direct non-healthcare cost. This definition is applied in this study since out-of-pocket cost in Malaysia is not reimbursable. Examples of direct non-healthcare cost incurred by patients were the purchase of diabetic food products, extra medical care at private facilities and complementary medicine.

Indirect cost due to absenteeism is a component to loss of productivity. In this study, loss of productivity of both patients and accompanying persons was evaluated. Indirect cost to patients due to hospitalisation is about six times higher (RM1,890.00 vs RM280.00) than for ambulatory visits. Indirect care for accompanying persons for ambulatory visit and hospitalisation is similar (RM 296.00 vs RM268.00). Extrapolating these values to those patients earning less than RM3,000, the loss of monthly incomes are approximately RM310.00 or 10.3% for

hospitalisation and 1.6% (RM49.30) for ambulatory visits. These findings would definitely burden both these category of patients financially and might affect the outcome of treatment. The so-called out-of-pocket financial burden had been reported in many earlier studies^{22,23}.

The Malaysian Economic Planning Unit 2012 statistics showed that 38.8% of the Malaysian population earns less than RM3,000²⁴. This group of population is categorised as the “urban poor”. Population with income less than RM1,000 contributed to 5% of total Malaysians and is termed as “hardcore poor”. Both these categories contributed to about 65% of the total enrolled patients.

Since 47% of the patients attending the government facilities earned between RM1,000 to RM3,000, clearly showed the “urban poor” patronage to government hospitals is expected. However, although treatment is highly subsidised, the study estimated loss of productivity can cause substantial hardship if they need to attend ambulatory visit or be hospitalised. The impact towards those earning less than RM1,000 or about 19% of the total enrolment (hardcore poor) however would be catastrophic. This is because the estimated loss of productivity amount can be more than 30% of their monthly income.

This study also estimated the direct and indirect cost in six months for diabetic patients. Astoundingly, direct non-healthcare cost is higher than direct healthcare cost across all health facilities. Home help is grossly apparent for patients from the state hospitals while complementary treatment contributes to the highest cost for those at the health clinics. Home help is similarly observed

by the American Diabetic Association in 2012²³ while complementary treatment is reported by Arcury et al 2006²⁵. This study finding clearly showed that patients at all health facilities have to endure a large amount of money to receive treatment.

A 2014 report from the World Bank mentioned that Malaysia per capita Gross Domestic Product (GDP) for 2013 was USD10,500 or RM24,150.00²⁶. Based on this data, the total direct cost (sum of both direct healthcare cost and direct non-healthcare cost) estimates per diabetic ambulatory patient per year ranges from RM 2,340.14 for health clinics to RM3,382.58 for State Hospitals is equivalent between 9.7% to 14.0% of per capita GDP.

The indirect cost estimates was found to be lower than direct cost and the calculated per capita GDP equivalent ranges between 3.4% (health clinics) and 5.3% (hospital with specialist patients). These values clearly showed that healthcare cost for the treatment of diabetes is expensive and needs control.

Finally, this study had managed to show that there is no significant difference in the total healthcare cost for diabetic patients between types of facility. The findings also showed there are wide inter-individual cost variations in both direct and indirect cost. The wide inter-individual variations might be related to MOH policies of discharging stable patients to other lower category health facilities for further treatment. These patients were however still able to access treatment for any complications at all healthcare facilities.

6.0 Study Limitations

This study has several limitations. As a convenient sampling method was utilised in this study during distribution of questionnaire, there are possibilities for selection bias. Random patients that the researchers met were approached for consent may not be representative to the entire population of the country of Malaysia since most of the patients came from those whose income is less than RM3,000. The results obtained in this cost diaries were also based on self-reported information which very much depends on the honesty and recall ability of the respondents, as well as their understanding of the diary. The completeness of the cost diary also might reduce the reliability of data.

The above limitations can be improved by the following recommendations;

- Study sample can be more generalisable if the stratification is also based on income especially to those earning more than RM3,000.
- Period of evaluation be extended to one year since the current study findings might be over extrapolated.

Finally, future studies should be initiated to validate the current findings. These studies can be upgraded by the above recommendations and hopefully complement and verify the current cost of treating DM in ambulatory care patients.

7.0 Conclusion

The total cost of ambulatory patients in the treatment of diabetes mellitus is evaluated at both the healthcare provider and patient's perspective. The cost by the healthcare provider is lower than the expenses made patients by 0.44 times. The estimated mean direct and indirect cost per patient per year for ambulatory DM patients is RM2,684.24 and RM1,062.88 respectively. The values were highest for the state hospitals and lowest for health clinics. The differences in cost was however insignificant.

Finally this study showed although healthcare for diabetes is highly subsidised, patient's out-of-pocket and indirect cost expenses is higher than the amount provided by the healthcare provider. The findings showed patients are still burden of the high cost for the management of diabetes.

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Drug Utilisation Survey (DUS)

Ministry of Health Malaysia

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Appendix 1

List of Facilities According to Facility Type

Type Code	Facility
1	Hospital Kuala Lumpur (HKL)
2	Hospital Tuanku Fauziah, Kangar
	Hospital Sultanah Bahiyah, Alor Setar
	Hospital Pulau Pinang
	Hospital Raja Perempuan Bainun, Ipoh
	Hospital Tengku Ampuan Rahimah, Klang
	Hospital Melaka
	Hospital Sultanah Aminah, Johor Bharu
	Hospital Tengku Ampuan Afzan, Kuantan
	Hospital Sultanah Nur Zahirah, Terengganu
	Hospital Umum Sarawak, Kuching
	Hospital Tuanku Ja'afar, Seremban
	Hospital Queen Elizabeth, Kota Kinabalu
	Hospital Raja Perempuan Zainab II, Kota Bharu
3	Hospital Sultan Abdul Halim, Sungai Petani
	Hospital Seberang Jaya
	Hospital Kepala Batas
	Hospital Seri Manjung
	Hospital Banting
	Hospital Sungai Buloh
	Hospital Ampang
	Hospital Serdang
	Hospital Pakar Sultanah Fatimah, Muar
	Hospital Batu Pahat
	Hospital Segamat
	Hospital Kluang
	Hospital Sultan Ismail, Pandan
	Hospital Sultan Hj. Ahmad Shah, Temerloh
	Hospital Kuala Lipis
	Hospital Kemaman
	Hospital Duchess of Kent, Sandakan
4	Hospital Sibu
	Hospital Miri
	Hospital Yan
	Hospital Sik
	Hospital Sungai Bakap
	Hospital Kuala Kangsar
	Hospital Kampar
	Hospital Grik
	Hospital Changkat Melintang
	Hospital Tanjung Karang
	Hospital Jasin

Type Code	Facility
4	Hospital Mersing
	Hospital T.S. Maharaja Tun Ibrahim, Kulai
	Hospital Pekan
	Hospital Raub
	Hospital Jerantut
	Hospital Tumpat
	Hospital Gua Musang
	Hospital Beaufort
	Hospital Tampin
	Hospital Jempol
	Hospital Alor Gajah
	Hospital Kudat
	Hospital Papar
	Hospital Ranau
5	Hospital Kuala Penyu
	Hospital Sipitang
	Hospital Saratok
	Hospital Kanowit
	KK Kulim
	KK Butterworth
	KK Masai
	KK Kampung Majidee
	KK Kempas
	KK Mahmoodiah
	KK Bandar Kuantan
	KK Kampung Simee
	KK Rawang
	KK Selayang Baru
	KK Taman Ehsan
	KK Serendah
	KK Puchong
	KK Seri Kembangan
	KK Medan Maju Jaya
	KK Shah Alam
	KK Klang
	KK Bukit Kuda
	KK Seremban
	KK Ayer Keroh
	KK Wakaf Bharu
	KK Jalan Masjid
	KK Jalan Oya
	KK Sri Aman

Appendix 2



DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
IN THE MINISTRY OF HEALTH (MOH) FACILITIES

Protocol No.: 3538

PATIENT INFORMATION SHEET

Study Title:	Drug Utilization in the Treatment of Diabetes Mellitus in the Ministry of Health Facilities
Protocol No.:	3538
Sponsor:	Ministry of Health Malaysia
Investigator Name:	
Investigator Contact No.	

Patient Information:

Name:	
Telephone No.:	
Address:	
Identity Card Number:	
Birth Date:	

Introduction

You have been invited to take part in a research study to assess the pattern and costs of drugs used in the treatment of Diabetes Mellitus (DM) in the Ministry of Health (MOH) healthcare facilities.

The outcome of this study will be used to prepare a policy on improving Diabetes treatment in Malaysia.

This information sheet gives you a detailed description of this study and will help you to decide if you would like to participate. Please read this sheet thoroughly and ask any questions that may occur to you. Participation in this research is voluntary.

This study has been approved by the Ethics Committee of MOH.

Q1: What is the study about?

This study aims to determine the utilization pattern and direct cost of treatment of DM in MOH healthcare facilities.

Patients like you who are diagnosed with DM are invited to join the study.

The study is being conducted in Malaysia. There will be a total of 2,500 patients participating in this study. Each patient will participate in this study for about six months. Your treatment details for the past 1 year and coming 6 months will be taken with strict confidentiality.



Q2: What will you have to do?

If you agree to take part in this study, you will have to do the following:

- a) You will be required to come to the clinic to undergo a screening assessment to determine if you are suitable to enter the study.
- b) After the screening assessment and, if you are suitable and agree to participate in this study:
 - i. You will routinely be given medications to manage your disease.
 - ii. You must report to your pharmacist all medications that you are presently taking as well as any additional medications at any time during your participation in the study including those that are not prescribed such as Over-The-Counter (OTC) medications, traditional or herbal remedies.
 - iii. While receiving treatment, if necessary, you will need routine blood tests in determining the disease status.

Q3: Are there any risks?

Since there is no intervention in your disease management, the risk is possibly low. However, if you experience any untoward effect you can withdraw or be withdrawn from the study.

Q4: Are there any benefits?

The outcome of this study will be used to prepare a policy on improving Diabetes treatment in Malaysia.

Q5: What are the alternative treatments?

None, since there is no intervention in your disease management.

Q6: What if you do not want to take part, and when can you leave the study?

Your participation in this study is voluntary and it is entirely your decision. You can choose to leave the study at any time. If you choose not to participate, it will not affect your medical care. Your doctor will continue to treat you in his or her usual way.

Having agreed to participate and having signed the inform consent form, if you change your mind your choice will be respected and it will not affect any future treatment from your study doctor and will result in no penalty or loss of benefits.

You do not have to give a reason to withdraw. However, you should inform your pharmacist or if you withdraw from the study, particularly if this is due to a side effect.

Q7: What if something goes wrong?

Every effort to prevent any injury that could result from this study will be taken by the pharmacist or the attending doctor according to routine management of the related injury which will be addressed by normal hospital practices.

**Q8: What is the cost of the study?**

All medications in the management of your disease will be provided at no cost to you. You will not be paid for taking part in this study.

In the case of injury or illness resulting from this study, emergency medical treatment is available and routine medical or hospital charges will continue.

Q9: Will the information and your identity remain confidential?

You will be given an identification code to maintain confidentiality of your data. The study pharmacist will record the results of any test or examination performed based on the identification code given. These results will be recorded in a booklet called a DUS Questionnaire (DUSQ). All the results of this study will be treated in complete confidence to the extent permitted by law. All results that relate to you will bear only your identification code that you are assigned at the start of the study.

The DUSQ will be reviewed by the study investigators of the MOH or by a representative acting on behalf of sponsor.

It may also be necessary for representatives of sponsor and Ethics Committee representatives to have access to your medical records to verify the information collected for the study. In such circumstances, confidentiality will be maintained at all times. They will not be used for any other purposes or be disclosed to any other parties without permission.

Q10: How will my personal data be used?

The study pharmacist and his/her staff will use your personal data for purpose of administration and conduct of the study. These individual identifiable health information which is the study data may include your age, weight, sex, race or ethnic origin, relevant medical history and any other personal data obtained during your participation in the study or as a result of any follow up assessments.

The study pharmacist will share your study data with the other relevant authorities for administrative purposes and research and development of policies and guidelines related to the disease management.

You may withdraw your permission to use or share your study data at any time by writing to your study pharmacist. If you do this, you cannot continue to take part in this study. No new study data about you will be gathered after this date. However, study data that was collected before you withdrew your consent may still be used and given to others as described above.

Q11: What happens at the end of study?

At the end of the study you will be managed as in accordance with the study hospital's/health facility's practice for treatment of patients.



DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
IN THE MINISTRY OF HEALTH (MOH) FACILITIES

Protocol No.: 3538

Q12: What happens now if you decided to take part?

If you have agreed to participate in this research you will be asked to sign a consent form containing a statement to the effect that you have been informed about the research, have fully understood the pharmacist's explanation and voluntarily agree to take part. By signing the consent form, you do not alter your legal rights. Before deciding to take part in this study, you may wish to discuss the matter with a relative or friend or with your local doctor. A copy of the consent form will be given to you for your information.

Q13: What if you have more questions or do not understand something?

If during the course of this study, you or your relatives have any questions about the study please contact your study pharmacist.

Mr/Ms.

at

and/or

Mr/Ms.

at

If you experience any side-effects or medical problems now or during the study, please also contact the above pharmacist.



LEMBARAN INFORMASI PESAKIT

Tajuk Kajian:	Penggunaan Ubat-ubatan di Dalam Rawatan Diabetes Mellitus di Fasiliti Kementerian Kesihatan Malaysia
No. Protokol:	3538
Penaja:	Kementerian Kesihatan Malaysia
Nama Penyelidik:	
No. Telefon Penyelidik:	

Maklumat Pesakit:

Nama:	
No. Telefon:	
Alamat:	
Nombor K/P:	
Tarikh Lahir:	

Pengenalan

Anda telah dijemput untuk mengambil bahagian dalam satu kajian penyelidikan yang bertujuan untuk menilai corak penggunaan ubat dan kos rawatan Diabetes Mellitus (DM) di fasiliti kesihatan Kementerian Kesihatan Malaysia (KKM).

Keputusan daripada kajian ini akan digunakan untuk menyediakan polisi dalam mempertingkatkan rawatan Diabetes di Malaysia.

Lembaran informasi ini memberi maklumat lanjut mengenai kajian ini dan dapat membantu anda sekiranya anda membuat keputusan untuk menyertai kajian ini. Sila baca lembaran informasi ini sepenuhnya dan sila bertanya sekiranya ada sebarang persoalan. Penyertaan adalah secara sukarela.

Kajian ini telah diluluskan oleh Jawatankuasa Etika KKM.

Q1: Apakah kajian ini sebenarnya?

Matlamat kajian ini adalah untuk menentukan corak penggunaan ubat dan kos rawatan DM di fasiliti kesihatan KKM.

Pesakit seperti anda yang telah didiagnos dengan DM adalah dijemput untuk mengambil bahagian dalam kajian ini.

Kajian ini sedang dijalankan di Malaysia. Jumlah keseluruhan pesakit yang akan menyertai kajian ini ialah seramai 2,500 pesakit. Setiap pesakit akan menyertai kajian ini selama 6 bulan. Butiran rawatan anda untuk setahun yang lepas dan 6 bulan akan datang akan diambil dengan jaminan kerahsiaan.



Q2: Apakah yang perlu saya lakukan?

Sekiranya anda bersetuju untuk menyertai kajian ini, anda perlu melakukan beberapa perkara seperti:

- a) Anda perlu datang ke klinik untuk menjalani pemeriksaan penyaringan untuk memastikan sama ada anda sesuai untuk menyertai kajian ini.
- b) Selepas menjalani pemeriksaan penyaringan, sekiranya anda sesuai dan bersetuju mengambil bahagian dalam kajian ini:
 - i. Anda akan diberi ubat-ubatan anda secara rutin untuk menguruskan penyakit anda.
 - ii. Anda hendaklah memberitahu pegawai farmasi anda semua ubat-ubatan yang anda ambil sekarang dan juga ubat-ubatan tambahan di sepanjang penglibatan anda di dalam kajian ini termasuk ubat-ubatan yang tidak dipreskrib seperti ubat *Over-the-Counter (OTC)*, ubat tradisional atau ubat herba.
 - iii. Semasa mendapatkan rawatan, sekiranya anda perlu, anda akan menjalani ujian darah rutin untuk menilai status penyakit anda.

Q3: Adakah terdapat sebarang risiko?

Memandangkan tiada sebarang campur tangan di dalam pengurusan penyakit anda, kebarangkalian risiko adalah rendah. Walau bagaimanapun, sekiranya anda mengalami sebarang kesan yang tidak diingini, anda boleh keluar atau dikeluarkan daripada kajian ini.

Q4: Apakah faedahnya?

Keputusan daripada kajian ini akan digunakan untuk menyediakan polisi dalam mempertingkatkan rawatan Diabetes di Malaysia.

Q5: Apa rawatan alternatif yang ada?

Tiada, memandangkan tidak ada sebarang campur tangan di dalam pengurusan penyakit anda.

Q6: Bagaimanakah sekiranya saya tidak mahu menyertai, dan bilakah saya boleh meninggalkan kajian ini?

Penyertaan anda dalam kajian ini adalah secara sukarela dan tertakluk kepada keputusan anda. Anda boleh meninggalkan kajian ini pada bila-bila masa sahaja. Sekiranya anda memilih untuk tidak mengambil bahagian, ini tidak akan menjejaskan perkhidmatan kesihatan yang diterima oleh anda. Doktor anda akan meneruskan rawatan anda seperti biasa.

Walaupun anda telah bersetuju untuk menyertai kajian ini dan telah menandatangani borang kebenaran tersebut, sekiranya anda bertukar fikiran, keputusan anda akan dihormati. Ini tidak akan menjejaskan sebarang rawatan daripada doktor anda pada masa hadapan dan anda tidak akan dikenakan sebarang denda ataupun kehilangan manfaat yang anda terima.

Anda tidak perlu memberi sebarang alasan untuk menarik diri. Walau bagaimanapun, anda harus memberitahu pegawai farmasi anda atau sekiranya anda ingin menarik diri dari kajian ini, terutamanya apabila ia melibatkan kesan sampingan.



Q7: Apakah yang akan terjadi sekiranya berlaku apa-apa yang tidak diingini?

Setiap usaha yang dilakukan bagi mengelakkan sebarang kecederaan yang mungkin disebabkan oleh kajian ini akan diambil kira oleh pegawai farmasi atau pegawai perubatan yang berkenaan berdasarkan kepada rutin pengurusan kecederaan berkaitan yang mana akan dirawat mengikut amalan kebiasaan hospital.

Q8: Berapakah kos kajian ini?

Kesemua ubat-ubatan yang dibekalkan dalam menguruskan penyakit anda sepanjang tempoh kajian ini adalah percuma. Anda tidak akan dibayar untuk menyertai kajian ini.

Sekiranya berlaku kecederaan atau penyakit yang disebabkan oleh kajian ini, perkhidmatan rawatan kecemasan adalah disediakan dan rutin caj perubatan atau hospital akan dikenakan.

Q9: Adakah segala maklumat dan identiti saya kekal sebagai perkara sulit?

Anda akan diberikan Kod Indentifikasi bagi mengekalkan kesulitan maklumat anda. Pegawai Farmasi yang terlibat akan merekodkan keputusan segala ujian atau pemeriksaan yang telah dijalankan berdasarkan kepada kod indentifikasi yang telah diberikan. Keputusan ini akan direkodkan di dalam sebuah buku kecil bertajuk "DUS Questionnaire (DUSQ)". Kesemua keputusan kajian ini akan ditangani secara sulit sejauh mana dibenarkan dari sisi undang-undang. Segala keputusan yang berkenaan dengan anda hanya akan mempunyai kod pengenalan pesakit anda yang telah ditetapkan semasa permulaan kajian.

DUSQ hanya akan dapat disemak oleh penyelidik kajian daripada KKM atau wakil yang bertindak bagi pihak penaja.

Ia juga akan menjadi keperluan untuk wakil penaja dan wakil Jawatankuasa Etika untuk meneliti rekod perubatan anda bagi mengesahkan segala maklumat yang telah dikumpul untuk kajian ini. Dalam keadaan sedemikian, kesulitan maklumat dan identiti anda akan sentiasa dipelihara. Maklumat tersebut tidak akan digunakan untuk tujuan lain atau dimaklumkan kepada pihak lain tanpa kebenaran anda.

Q10: Bagaimana maklumat peribadi saya digunakan?

Pegawai Farmasi kajian dan pembantunya akan menggunakan maklumat peribadi anda untuk tujuan pengurusan dan pengendalian kajian ini. Maklumat-maklumat kesihatan ini adalah seperti umur anda, berat, jantina, bangsa atau etnik, sejarah perubatan yang berkaitan dan segala maklumat peribadi yang lain, yang diperolehi semasa penglibatan anda dalam kajian ini atau keputusan daripada sebarang penilaian rawatan susulan.

Pegawai Farmasi kajian akan berkongsi maklumat kajian anda dengan pihak berkuasa yang berkaitan untuk tujuan pengurusan dan membangunkan polisi dan panduan penyelidikan yang berkaitan dengan pengurusan penyakit.

Anda boleh membatalkan persetujuan anda untuk menggunakan dan berkongsi maklumat kajian anda pada bila-bila masa dengan memaklumkan secara bertulis kepada pegawai farmasi kajian. Sekiranya anda melakukan ini, anda tidak boleh meneruskan penglibatan dalam kajian ini. Tidak akan ada sebarang maklumat baru berkenaan anda yang akan dikumpul selepas tarikh tersebut. Walau bagaimanapun, maklumat kajian yang telah dikumpul sebelum anda menarik balik persetujuan mungkin akan masih digunakan dan diberikan kepada pihak yang telah disebutkan di atas.



Q11: Apakah yang terjadi di akhir kajian?

Di akhir kajian, anda akan diuruskan mengikut amalan hospital/fasiliti kesihatan berkenaan untuk rawatan pesakit.

Q12: Apakah yang akan terjadi sekiranya saya memilih untuk mengambil bahagian?

Sekiranya anda bersetuju untuk menyertai kajian ini, anda akan diminta untuk menandatangani satu borang kebenaran yang menyatakan bahawa anda telah diberitahu tentang kajian ini, dan telah memahami dengan sepenuhnya dengan penjelasan Pegawai Farmasi serta dengan sukarela mengambil bahagian dalam kajian ini. Dengan menandatangani borang kebenaran ini, anda tidak mengubah sebarang hak undang-undang anda. Sebelum membuat keputusan untuk menyertai kajian ini, anda boleh berbincang dengan keluarga, sahabat atau doktor anda. Satu salinan borang kebenaran ini akan diberikan kepada anda untuk maklumat anda.

Q13: Bagaimanakah sekiranya saya masih mempunyai pertanyaan atau tidak jelas akan sesuatu?

Sekiranya semasa tempoh kajian ini anda atau keluarga anda masih mempunyai sebarang pertanyaan tentang kajian ini, sila hubungi Pegawai Farmasi kajian.

Nama

di talian

dan/atau

Nama

di talian

Sekiranya anda mengalami sebarang kesan sampingan atau masalah perubatan sekarang atau sepanjang tempoh kajian, sila berhubung dengan Pegawai Farmasi seperti di atas.

Appendix 3



DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
IN THE MINISTRY OF HEALTH (MOH) FACILITIES

Protocol No.: 3538

INFORMED CONSENT FORM

STUDY TITLE

Drug Utilization in the Treatment of Diabetes Mellitus in the Ministry of Health Facilities
(Protocol Number: 3538)

CERTIFICATION BY INVESTIGATOR

I, being the study pharmacist, confirm that I have fully explained the nature, purpose and reasonably foreseeable risks of taking part in this study to the patient or legal representative. He/she has read and kept a copy of the Patient Information Sheet and signed the Informed Consent Form. He/she has freely agreed to participate in the study.

Name of Investigator

Signature of Investigator

Date

CONSENT BY PARTICIPANT

I have read and understood the Patient Information Sheet about this research and have been given the chance to ask any questions. I understand and accept the answers that have been given.

I confirm that I have been given enough time to think about and have freely agreed to take part in this research and know that I can at any time, ask for more information from the pharmacist and doctor, and cease to participate in the research without affecting my usual medical care in any way.

I also understand that should I decide to stop taking part in this study, I do not need to give any reason why, except if it is due to the effects of the medication. In this case I must report the details to the pharmacist.

Finally, I agree to participate in the research and to closely follow the instructions I am given. I have received a copy of the Patient Information Sheet and Informed Consent Form.

Name of Study Participant

Signature of Study Participant

Date

Identification Card Number

IF REQUIRED IMPARTIAL WITNESS

Name of Witness

Signature of Witness

Date

Identification Card Number of Witness

FACILITY COPY

Page 1 of 1

DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
IN THE MINISTRY OF HEALTH (MOH) FACILITIES

Protocol No.: 3538

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Signature of Investigator

Date

CONSENT BY PARTICIPANT

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I confirm that I have been given enough time to think about and have freely agreed to take part in this research and know that I can at any time, ask for more information from the pharmacist and doctor, and cease to participate in the research without affecting my usual medical care in any way.

I also understand that should I decide to stop taking part in this study, I do not need to give any reason why, except if it is due to the effects of the medication. In this case I must report the details to the pharmacist.

Finally, I agree to participate in the research and to closely follow the instructions I am given. I have received a copy of the Patient Information Sheet and Informed Consent Form.

Name of Study Participant

Signature of Study Participant

Date

Identification Card Number

IF REQUIRED IMPARTIAL WITNESS

Name of Witness

Signature of Witness

Date

Identification Card Number of Witness

PATIENT COPY

Page 1 of 1

**BORANG KEBENARAN PESAKIT****TAJUK KAJIAN**

Penggunaan Ubat-ubatan di Dalam Rawatan Diabetes Mellitus di Fasiliti Kementerian Kesihatan Malaysia (**Nombor Protokol: 3538**)

PENGESAHAN DARI PIHAK PENYELIDIK

Saya, selaku pegawai farmasi kajian, mengesahkan bahawa saya telah menerangkan dengan sepenuhnya jenis, tujuan dan risiko boleh jangka yang munasabah ketika mengambil bahagian dalam kajian ini kepada pesakit atau wakil di sisi undang-undang. Beliau telah membaca dan menyimpan satu salinan Lembaran Informasi Pesakit dan telah menandatangani Borang Kebenaran. Beliau telah setuju secara sukarela untuk menyertai kajian ini.

Nama Penyelidik

Tandatangan Penyelidik

Tarikh

KEBENARAN DARI PESAKIT

Saya telah membaca dan memahami Lembaran Informasi Pesakit tentang kajian ini dan telah diberi peluang untuk menanyakan sebarang soalan. Saya memahami dan menerima semua jawapan yang telah diberikan.

Saya mengesahkan bahawa saya telah diberi masa untuk berfikir dan telah bersetuju secara sukarela untuk mengambil bahagian dalam kajian ini dan mengetahui bahawa saya boleh bertanya dengan lebih lanjut pada bila-bila masa kepada penyelidik serta berhenti menyertai kajian ini tanpa menjejaskan rawatan perubatan saya dalam apa jua cara sekalipun.

Saya juga faham bahawa sekiranya saya memilih untuk menarik diri dari kajian ini, saya tidak perlu memberikan alasan, kecuali sekiranya ia disebabkan oleh kesan sampingan daripada ubatan. Dalam keadaan ini, saya harus melaporkan kepada pegawai farmasi kajian.

Akhir sekali, saya bersetuju untuk menyertai kajian ini dan mengikut arahan yang telah diberikan. Saya telah mendapat satu salinan Borang Maklumat Pesakit dan Borang Kebenaran.

Nama Peserta Kajian

Tandatangan Peserta Kajian

Tarikh

Nombor Kad Pengenalan

PENGESAHAN DARI SAKSI YANG SAKSAMA (Jika Ada)

Nama Saksi

Tandatangan Saksi

Tarikh

Nombor Kad Pengenalan Saksi



PENGUNAAN UBAT-UBATAN DI DALAM RAWATAN DIABETES MELLITUS
DI FASILITI KEMENTERIAN KESIHATAN MALAYSIA

Protokol No.: 3538

BORANG KEBENARAN PESAKIT

TAJUK KAJIAN

Penggunaan Ubat-ubatan di Dalam Rawatan Diabetes Mellitus di Fasiliti Kementerian Kesihatan Malaysia (**Nombor Protokol: 3538**)

PENGESAHAN DARI PIHAK PENYELIDIK

Saya, selaku pegawai farmasi kajian, mengesahkan bahawa saya telah menerangkan dengan sepenuhnya jenis, tujuan dan risiko boleh jangka yang munasabah ketika mengambil bahagian dalam kajian ini kepada pesakit atau wakil di sisi undang-undang. Beliau telah membaca dan menyimpan satu salinan Lembaran Informasi Pesakit dan telah menandatangani Borang Kebenaran. Beliau telah setuju secara sukarela untuk menyertai kajian ini.

Nama Penyelidik

Tandatangan Penyelidik

Tarikh

KEBENARAN DARI PESAKIT

Saya telah membaca dan memahami Lembaran Informasi Pesakit tentang kajian ini dan telah diberi peluang untuk menanyakan sebarang soalan. Saya memahami dan menerima semua jawapan yang telah diberikan.

Saya mengesahkan bahawa saya telah diberi masa untuk berfikir dan telah bersetuju secara sukarela untuk mengambil bahagian dalam kajian ini dan mengetahui bahawa saya boleh bertanya dengan lebih lanjut pada bila-bila masa kepada penyelidik serta berhenti menyertai kajian ini tanpa menjejaskan rawatan perubatan saya dalam apa jua cara sekalipun.

Saya juga faham bahawa sekiranya saya memilih untuk menarik diri dari kajian ini, saya tidak perlu memberikan alasan, kecuali sekiranya ia disebabkan oleh kesan sampingan daripada ubatan. Dalam keadaan ini, saya harus melaporkan kepada pegawai farmasi kajian.

Akhir sekali, saya bersetuju untuk menyertai kajian ini dan mengikut arahan yang telah diberikan. Saya telah mendapat satu salinan Borang Maklumat Pesakit dan Borang Kebenaran.

Nama Peserta Kajian

Tandatangan Peserta Kajian

Tarikh

Nombor Kad Pengenalan

PENGESAHAN DARI SAKSI YANG SAKSAMA (Jika Ada)

Nama Saksi

Tandatangan Saksi

Tarikh

Nombor Kad Pengenalan Saksi

SALINAN PESAKIT

Mukasurat 1 dari 1

- - -
State Type Facility Patient Number

**DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
IN THE MINISTRY OF HEALTH (MOH) FACILITIES**
Protocol No.: 3538

SEKSYEN A: MAKLUMAT PESAKIT DUS FASA 2

SECTION A: DUS PHASE 2 PATIENT DETAILS

Nama *Name:*

[illegible]No. Kad Pengenalan *Identification Card No.:*[illegible]

No. Pendaftaran *Registration No. (RN):*

[illegible]

Alamat Surat-Menyurat *Corresponding Address:*

[illegible]

Poskod							Negeri	
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No. Telefon Rumah *House Phone No.:*[illegible]

No. Telefon Bimbit *Handphone No.:*

[illegible]

Berat *Weight* : kg

11

Tinggi *Height* : cm

11

Adakah pesakit ini baru dalam DUS yang tidak pernah menyertai DUS Fasa 1? *Is the patient a new DUS patient who was **not in DUS Phase 1?***

☐ **Ya** *Yes* (Sila ke Seksyen B *Proceed to Section B*)☐ Tidak *No* (Borang Tamat *End of Form*)

- - -

State

Type

Facility

Patient Number

DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
IN THE MINISTRY OF HEALTH (MOH) FACILITIES

Protocol No.: 3538

Muka surat 2 - 5: Diisi untuk **pesakit baru** dalam **DUS** yang tidak pernah menyertai DUS Fasa 1**Page 2 - 5:** To be filled in for **ONLY NEW DUS** patients who were **NOT** in DUS Phase 1**SEKSYEN B: MAKLUMAT TAMBAHAN****SECTION B: ADDITIONAL INFORMATION****MAKLUMAT DEMOGRAFI** **DEMOGRAPHIC DATA**

MAKLUMAT DEMOGRAFI DEMOGRAPHIC DATA			For Official Use Only
1	Tarikh lahir <i>Date of Birth</i>	hh <i>dd</i> bb <i>mm</i> tt <i>yy</i>	1
2	Jantina <i>Gender</i>	1 ☐ Lelaki <i>Male</i> 2 ☐ Perempuan <i>Female</i>	2
3	Bangsa <i>Race</i>	1 ☐ Melayu <i>Malay</i> 2 ☐ Cina <i>Chinese</i> 3 ☐ India/Punjabi <i>Indian/Punjabi</i> 4 ☐ Orang Asli Semenanjung Malaysia <i>Peninsular Indigenous</i> 5 ☐ Kadazan <i>Kadazan</i> 6 ☐ Dusun <i>Dusun</i> 7 ☐ Bajau <i>Bajau</i> 8 ☐ Murut <i>Murut</i> 9 ☐ Bumiputera Lain-Sabah <i>Other Sabahan Bumiputera</i> 10 ☐ Iban <i>Iban</i> 11 ☐ Bidayuh <i>Bidayuh</i> 12 ☐ Melanau <i>Melanau</i> 13 ☐ Bumiputera Lain-Sarawak <i>Other Sarawakian Bumiputera</i> 14 ☐ Lain-lain, nyatakan <i>Others, specify:</i> _____	3

- - -
 State Type Facility Patient Number

DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
 IN THE MINISTRY OF HEALTH (MOH) FACILITIES
 Protocol No.: 3538

MAKLUMAT DEMOGRAFI <i>DEMOGRAPHIC DATA</i>			For Official Use Only
4	Status Perkahwinan <i>Current Marital Status</i>	1 ☐ Belum Berkahwin <i>Not married</i> 2 ☐ Berkahwin <i>Married</i> 3 ☐ Balu/Duda/Janda <i>Widowed</i> 4 ☐ Bercerai/Duduk Berasingan <i>Divorced/Separated</i>	4
5	Jumlah Pendapatan Isi Rumah Sebulan <i>Total Household Income Per Month</i>	RM , .	5
6	Pekerjaan Utama <i>Main Occupation</i>	1 ☐ Kakitangan Kerajaan <i>Government Employee</i> 2 ☐ Pekerja Swasta <i>Private employee</i> 3 ☐ Separa Kerajaan <i>Semi Government</i> 4 ☐ Bekerja Sendiri <i>Self-employed</i> 5 ☐ Lain-lain, nyatakan <i>Others, specify:</i> _____ 6 ☐ Pesara <i>Retiree</i> (Sila ke Soalan 9 <i>Proceed to Question 9</i>) 7 ☐ Pelajar <i>Student</i> (Sila ke Soalan 9 <i>Proceed to Question 9</i>) 8 ☐ Suri Rumah <i>Housewife</i> (Sila ke Soalan 9 <i>Proceed to Question 9</i>) 99 ☐ Tidak Bekerja <i>Not working</i> (Sila ke Soalan 9 <i>Proceed to Question 9</i>)	6
7	Tempoh Masa Bekerja Dalam Sehari <i>Working Duration in a Day</i>	jam <i>hour(s)</i> minit <i>minute(s)</i>	7 hr(s) min(s)
8	Jumlah Hari Bekerja Dalam Seminggu <i>Number of Working Days in a Week</i>	hari <i>day(s)</i>	8

- - -

State

Type

Facility

Patient Number

DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
IN THE MINISTRY OF HEALTH (MOH) FACILITIES
Protocol No.: 3538

PROFIL DIABETES **DIABETIC PROFILE**

PROFIL DIABETES DIABETIC PROFILE			For Official Use Only
9	Berapa lamakah anda telah disahkan menghidap diabetes (dalam tahun)? <i>How long have you been diagnosed with diabetes (in years)?</i>	tahun <i>year(s)</i>	9
10	Adakah anda mengguna insulin? <i>Are you on insulin?</i>	1 ☐ Ya <i>Yes</i> 2 ☐ Tidak <i>No</i> Jika ya, pada tahun bila anda mula menggunakan insulin? <i>If yes, in which year were you first started on insulin?</i> tttt <i>yyyy</i>	10
11	Adakah anda mengalami penyakit lain selain diabetes? <i>Do you have any other disease(s) apart from diabetes?</i>	Ya <i>Yes</i> Tidak <i>No</i> 1 ☐ 0 ☐ (1) Darah Tinggi <i>Hypertension</i> 1 ☐ 0 ☐ (2) Ischemic heart disease 1 ☐ 0 ☐ (3) Angin Ahmar <i>Stroke</i> 1 ☐ 0 ☐ (4) Peripheral vascular disease 1 ☐ 0 ☐ (5) Neuropathy 1 ☐ 0 ☐ (6) Nephropathy 1 ☐ 0 ☐ (7) Retinopathy 1 ☐ 0 ☐ (8) Lain-lain, nyatakan: <i>Others, specify:.....</i>	11 (1) (2) (3) (4) (5) (6) (7) (8)
12	Pernakah anda dimasukkan ke hospital dalam tempoh 1 tahun yang lalu kerana penyakit diabetes atau komplikasi diabetes? <i>Have you ever been admitted to a hospital in the past 1 year due to diabetes or its complications?</i>	1 ☐ Ya <i>Yes</i> 0 ☐ Tidak <i>No</i> Jika ya, sila tanda dari hospital mana. Boleh tanda lebih dari satu. <i>If yes, specify from which hospital. You may tick more than one.</i> 1 ☐ Kerajaan <i>Government</i> 2 ☐ Swasta <i>Private</i>	12

- - -

State

Type

Facility

Patient Number

DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
IN THE MINISTRY OF HEALTH (MOH) FACILITIES
Protocol No.: 3538

PROFIL DIABETES <i>DIABETIC PROFILE</i>			For Official Use Only
13	Pernahkah anda mendapatkan rawatan diabetes dalam tempoh 1 tahun lalu daripada klinik pakar atau sebagai pesakit luar di hospital/klinik yang lain? <i>Have you ever sought diabetic treatment in the past 1 year at any specialist clinic or as an out-patient at other hospitals/clinics?</i>	1 ☐ Ya <i>Yes</i> 0 ☐ Tidak <i>No</i>	13
14	Berapa kali anda pergi ke farmasi di mana-mana hospital/klinik dalam tempoh 1 tahun lalu untuk mendapatkan ubat-ubat bagi rawatan diabetes dan komplikasinya? <i>How many times did you go to the pharmacy at any hospital/clinic in the past 1 year to take your medicines for the treatment of diabetes and its complications?</i>	☐ kali <i>time(s)</i> 0 ☐ Tidak pernah <i>Never</i>	14 time(s)
15	Pernahkah anda mendapatkan rawatan untuk penyakit diabetes atau komplikasinya dalam tempoh 1 tahun lalu dari mana-mana pengamal perubatan alternative/tradisional? <i>Have you sought treatment for diabetes or its complications in the past 1 year from any alternative medicine/traditional practitioner?</i>	1 ☐ Ya <i>Yes</i>. Nyatakan <i>Specify</i>, _____ 0 ☐ Tidak <i>No</i>	15
16	Pernahkah anda membeli atau mendapatkan sebarang ubat untuk rawatan sendiri bagi penyakit diabetes dalam tempoh 1 tahun lalu? <i>Have you ever bought any medicines for diabetic treatment as self-medication in the past 1 year?</i>	1 ☐ Ya <i>Yes</i> 0 ☐ Tidak <i>No</i>	16

TAMAT *END*

Appendix 5

		-		-			-				
NEGERI			JENIS		FASILITI			NOMBOR PESAKIT			



KEMENTERIAN KESIHATAN MALAYSIA

PROJEK NASIONAL

Kajian Penggunaan Ubat - Ubatan di dalam Rawatan Diabetes Mellitus di Fasiliti
Kementerian Kesihatan Malaysia (No. Protokol: 3538)

DIARI PERBELANJAAN RAWATAN PESAKIT DIABETES MELLITUS TYPE 2

TEMPOH DIARI (UNTUK MINGGU)

		-			-	2	0				
hh			bb			tttt					

SEHINGGA

		-			-	2	0				
hh			bb			tttt					

TARIKH TEMU JANJI DIARI

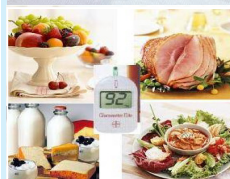
		-			-	2	0				
hh			bb			tttt					

SEMUA MAKLUMAT AKAN DISIMPAN SECARA SULIT

SILA RUJUK ARAHAN PENTING DI MUKA SURAT 3 SEBELUM MENGISI

DIARI INI ADALAH HAK MILIK KEMENTERIAN KESIHATAN MALAYSIA

Sesiapa yang menjumpai diari ini, sila pulangkan kepada pegawai
di alamat yang tertera di muka surat 2. Terima kasih.



Projek Kajian Ini

Objektif kajian ini adalah untuk menilai corak dan kos ubat - ubatan serta kos rawatan secara menyeluruh penyakit *diabetes mellitus 2*.

Hasil kajian ini akan:

- Digunakan untuk meningkatkan mutu perawatan penyakit *diabetes mellitus 2*.
- Digunakan untuk penggubalan polisi bagi perawatan penyakit *diabetes mellitus 2* di fasiliti Kementerian Kesihatan Malaysia.

MAKLUMAT PESAKIT

(Diisi oleh Pegawai Farmasi Penyelidik DUS)



NO. KAD PENGENALAN (IC)

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RN

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NAMA (seperti dalam kad pengenalan/kad ID rasmi yang lain)



ALAMAT SURAT - MENYURAT

Poskod

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Negeri

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TELEFON RUMAH

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TELEFON BIMBIT

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ANGGARAN PENDAPATAN BULANAN (Tandakan (✓) pada yang berkenaan)

- ☐ < RM1000
☐ RM1000 - 3000
☐ RM3001 - 5000
☐ > RM5000

PENERANGAN

DIARI ini bertujuan untuk mendapatkan **semua jenis perbelanjaan** yang anda lakukan untuk rawatan penyakit **diabetes mellitus** dalam tempoh masa yang dinyatakan di muka surat hadapan.



Rawatan penyakit diabetes mellitus

APA YANG PERLU ANDA LAKUKAN?



Sila tuliskan dalam diari ini **semua jenis maklumat perbelanjaan** yang berkaitan dengan **rawatan penyakit diabetes mellitus** dalam bahagian yang telah disediakan. **Rujuk Arahan Penting** di muka surat 3.



Buku diari yang telah lengkap diisi hendaklah **diserahkan kepada Pegawai Farmasi Penyelidik** yang terlibat dalam kajian ini pada tarikh temujanji mengambil ubat susulan atau seperti yang diterangkan / dipersetujui seperti tarikh di muka hadapan.



kesilapan

Jika terdapat sebarang kesilapan atau pindaan semasa mencatat diari, gariskan dan tandatangan. **Jangan gunakan cecair pemadam (liquid paper) atau pemadam dakwat.**



Setiap minggu, anda akan diberikan **diari yang baru** oleh Pegawai Farmasi Penyelidik yang terlibat dalam kajian ini semasa tarikh temu janji doktor atau semasa mengambil ubat ulangan di farmasi.



Jika terdapat sebarang pertanyaan / masalah dalam mengisi diari ini, sila hubungi Pegawai berikut:

Waktu Pejabat: Isnin hingga Jumaat 8.30am - 4.30pm

Tidak termasuk waktu rehat:

Isnin hingga Khamis 1.00 - 2.00pm, Jumaat 12.15 - 2.45pm

Nama Pegawai Farmasi Penyelidik :

Nama dan Alamat Hospital / Klinik Kesihatan :

.....

.....

Poskod :

Negeri :

No. Telephone :

Email :

ARAHAN PENTING MENGISI DIARI

Sila pastikan Bahagian yang BETUL diisi:

I. AKTIVITI 1 - 8

Diisi untuk sebarang aktiviti (KECUALI kemasukan wad) yang dijalankan kerana penyakit *diabetes mellitus* dan komplikasinya. Contohnya:

AKTIVITI	CONTOH
Temu janji / konsultasi	Doktor, ahli farmasi, pakar diet, pakar senaman, bomoh / pawang, sinseh, ayurvedik dll
Mendapatkan rawatan	Moden, tradisional, komplementari, dialisis, ujian darah, cuci luka dll
Membeli keperluan perubatan	Alat perubatan, ubat, herba, nutrisi, alat pakai buang dll

II. KEMASUKAN WAD 1 - 2

Diisi sekiranya terdapat sebarang kemasukan wad kerana *diabetes mellitus* dan komplikasinya.

III. BANTUAN TAMBAHAN

Diisi apabila terdapat perbelanjaan untuk mendapatkan bantuan tambahan di rumah kerana

- Penyakit *diabetes mellitus* dan komplikasinya, ataupun
- Kesulitan yang dihadapi kerana menghadapi penyakit *diabetes mellitus* dan komplikasinya

Contoh bantuan tambahan adalah seperti berikut:

CONTOH BANTUAN TAMBAHAN DI RUMAH

	Dobi
	Bantuan penjagaan pesakit (<i>Nursing Care</i>) - penjagaan kaki, mencuci luka, penjagaan pengambilan ubat, bantuan mandi dll
	Fisioterapi, Urut
	Pembantu cuci / kemas rumah
	Bantuan memasak / katering
	Dialisis di rumah

AKTIVITI 1

AKTIVITI 2

AKTIVITI 3

AKTIVITI 4

AKTIVITI 5

AKTIVITI 6

AKTIVITI 7

AKTIVITI 8

KEMASUKAN WAD 1

KEMASUKAN WAD 2

BANTUAN TAMBAHAN

AKTIVITI 1

Diisi untuk sebarang aktiviti (KECUALI kemasukan wad) yang dijalankan kerana penyakit *diabetes mellitus* dan komplikasinya. Contohnya

AKTIVITI	CONTOH
TEMU JANJI / KONSULTASI	Doktor, ahli farmasi, pakar diet, pakar senaman, bomoh / pawang, sinseh, ayurvedik dll
MENDAPATKAN RAWATAN	Moden, tradisional, komplementari, dialisis, ujian darah, cuci luka dll
MEMBELI KEPERLUAN PERUBATAN	Alat perubatan, ubat, herba, nutrisi, alat pakai buang dll

Catatkan **SEBARANG** aktiviti yang dijalankan disebabkan penyakit diabetes mellitus dan komplikasinya

A2 - A3

JENIS AKTIVITI	TUJUAN AKTIVITI
Temu janji / konsultasi	Doktor, ahli farmasi, pakar diet, pakar senaman, bomoh / pawang, sineh, ayurvedik dll.
Mendapatkan rawatan	Moden, tradisional, komplementari, <i>chiropractic</i> , dialisis, ujian darah, mencuci luka dll.
Membeli keperluan perubatan	Alat perubatan, ubat, herba, nutrisi, alat pakai buang dll.

A4: Nama Fasiliti, contohnya klinik, farmasi, hospital, makmal, pusat dialisis, toko ubat, pusat kebajikan dll

A5: Jumlah masa yang dihabiskan di fasiliti

A6: Sekiranya **BEKERJA** sahaja, nyatakan jumlah hari cuti atau 'time - off' yang diambil untuk datang ke fasiliti



A. BUTIR - BUTIR AKTIVITI

A1. Tarikh Aktiviti :

hh	-	bb	-	2	0	tt	tt
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A2. Jenis Aktiviti :
(Tandakan (✓) pada yang berkenaan)

- ☐ Temujanji atau konsultasi
☐ Mendapatkan rawatan
☐ Membeli keperluan perubatan
☐ Lain - lain. Nyatakan

A3. Tujuan Aktiviti :

A4. Nama Fasiliti :

A5. Tempoh masa anda berada di fasiliti di atas :

..... **min / jam / hari** (Bulatkan unit yang berkenaan)

A6. Jumlah hari cuti atau 'time - off' yang diambil untuk aktiviti ini (jika ada):

..... **min / jam / hari** (Bulatkan unit yang berkenaan)

PENERANGAN

B2: Jumlah masa yang dihabiskan untuk perjalanan **PERGI** ke fasiliti dari rumah / tempat kerja

B3: Anggaran jarak perjalanan **PERGI** ke fasiliti dari rumah / tempat kerja

B4: Nyatakan **SEMUA** jenis pengangkutan yang digunakan untuk **PERGI** ke fasiliti dari rumah / tempat kerja. Contohnya, teksi, bot, LRT, jalan kaki, kereta dll

B5: Anggaran **JUMLAH** kos keseluruhan perjalanan **PERGI** ke fasiliti dari rumah / tempat kerja

Kos Keseluruhan Perjalanan (RM) =
Kos Petrol + Kos Lain (Contoh: Tol)

Nota:

Sekiranya menggunakan kereta sendiri,
Kos Petrol (RM) = Jarak (km) x 0.70

Sekiranya menggunakan motosikal,
Kos Petrol (RM) = Jarak (km) x 0.50



B. PERJALANAN PERGI KE FASILITI DARI RUMAH / TEMPAT KERJA

B1. Tarikh Bertolak ke Fasiliti :

hh	-	bb	-	2	0	tt	tt
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B2. Masa Untuk Perjalanan : **min / jam / hari**
(Bulatkan unit yang berkenaan)

B3. Jarak Perjalanan ke Fasiliti : **kilometer**

B4. Jenis Pengangkutan :

(Boleh nyatakan lebih dari satu jenis)

B5. Jumlah Kos Keseluruhan Perjalanan PERGI : RM

PENERANGAN

- C2:** Jumlah masa yang dihabiskan untuk perjalanan **PULANG** ke rumah / tempat kerja dari fasiliti
- C3:** Anggaran jarak perjalanan **PULANG** ke rumah / tempat kerja dari fasiliti
- C4:** Nyatakan **SEMUA** jenis pengangkutan yang digunakan untuk **PULANG** ke rumah / tempat kerja dari fasiliti. Contohnya, teksi, bot, LRT, jalan kaki, kereta dll
- C5:** Anggaran **JUMLAH** kos keseluruhan perjalanan **PULANG** ke rumah / tempat kerja dari fasiliti
- Kos Keseluruhan Perjalanan (RM) =
Kos Petrol + Kos Lain (Contoh: Tol)
- Nota:**
Sekiranya menggunakan kereta sendiri,
Kos Petrol (RM) = Jarak (km) x 0.70
Sekiranya menggunakan motosikal,
Kos Petrol (RM) = Jarak (km) x 0.50
- C6:** Diisi sekiranya anda perlu menginap disebabkan **AKTIVITI INI**
- C7:** Diisi sekiranya anda perlu menginap disebabkan **AKTIVITI INI** dan **PENGINAPAN** tersebut perlu **DIBAYAR**



C. PERJALANAN PULANG KE RUMAH / TEMPAT KERJA DARI FASILITI

C1. Tarikh Bertolak dari Fasiliti :

hh	-	bb	-	2	0	tt	tt
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C2. Masa Untuk Perjalanan : min / jam / hari
(Bulatkan unit yang berkenaan)

C3. Jarak Perjalanan ke Rumah/ Tempat Kerja : kilometer

C4. Jenis Pengangkutan :
(Boleh nyatakan lebih dari satu jenis)

C5. Jumlah Kos Keseluruhan Perjalanan PULANG : RM.....

C6. Jumlah Malam Menginap (Jika menginap): malam

C7. Kos Penginapan : RM..... (satu malam)
(Jika menginap dan penginapan perlu dibayar)

PENERANGAN

D1-D4:

Sekiranya terdapat lebih daripada seorang ahli keluarga atau orang yang menemani anda ke fasiliti, nyatakan **SEORANG** yang dianggap **UTAMA** sahaja

D2: Catatkan pekerjaan beliau yang **UTAMA** sahaja

D3: Sekiranya beliau **BEKERJA** sahaja, nyatakan jumlah hari cuti atau 'time-off' yang diambil untuk menemani anda ke fasiliti



D. MAKLUMAT AHLI KELUARGA ATAU ORANG YANG MENEMANI ANDA KE FASILITI (JIKA ADA)

D1. Siapakah yang menemani anda? (Nyatakan seorang yang utama sahaja, jika ada)
.....

D2. Apakah pekerjaan beliau? : ☐ Kakitangan Kerajaan

(Tandakan (✓) pada yang berkenaan)

☐ Pekerja Swasta

☐ Bekerja Sendiri

☐ Lain - lain. Nyatakan
.....

D3. Jumlah hari cuti atau 'time-off' yang diambil oleh beliau untuk menemani anda bagi aktiviti ini (jika ada): min / jam / hari
(Bulatkan unit yang berkenaan)

D4. Anggaran Pendapatan Bulanan Beliau: (Tandakan (✓) pada yang berkenaan)

☐ Kurang RM1000

☐ RM3001 - RM5000

☐ RM1000 - RM3000

☐ Melebihi RM5000

E. KOS PERBELANJAAN AKTIVITI
(Sila sertakan resit bayaran sekiranya ada)

E1. Kos Membayar Khidmat Konsultasi (RM)

[illegible]

E2. Kos Membayar Perbelanjaan Rawatan (RM)

[illegible]

E2: Nyatakan kos sebarang rawatan yang diberikan di fasiliti

(Sila sertakan resit bayaran sekiranya ada)

E3. Kos Perbelanjaan Untuk Keperluan Perubatan (RM)

[illegible]

E4. Kos Keseluruhan Aktiviti Ini : RM.....

E5. Siapakah yang membayar KOS KESELURUHAN aktiviti ini?

11

7

7

7

7

7

7

7

Tidak berkaitan

KEMASUKAN WAD¹

Diisi sekiranya terdapat sebarang kemasukan wad kerana *diabetes mellitus* dan komplikasinya.

PENERANGAN

Catatkan **SEBARANG** kemasukan wad disebabkan **penyakit diabetes mellitus dan komplikasinya**

A2: Catatkan *symptom* / tanda - tanda yang dialami / tujuan kemasukan wad

A3: **Diagnosis**, catatkan sekiranya tahu

A4: Nama hospital

A5: Jumlah masa berada di wad

A6: Sekiranya **BEKERJA** sahaja, nyatakan jumlah hari cuti sakit (MC) atau 'time - off' yang diambil kerana dimasukkan ke wad

**A. BUTIR - BUTIR KEMASUKAN WAD**

A1. Tarikh Masuk Wad:

hh	-	bb	-	2	0	tt	tt
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A2. Sebab Masuk Hospital :

A3. Diagnosis :
(Diisi oleh Pegawai Farmasi Penyelidik DUS)

A4. Nama Hospital :

A5. Tempoh masa dimasukkan ke wad : jam / hari
(Bulatkan unit yang berkenaan)

A6. Jumlah hari cuti sakit (MC) atau 'time - off' yang diambil kerana dimasukkan ke wad (jika ada): jam / hari
(Bulatkan unit yang berkenaan)

PENERANGAN

B2: Jumlah masa yang dihabiskan untuk perjalanan **PERGI** ke hospital dari rumah / tempat kerja

B3: Anggaran jarak perjalanan **PERGI** ke hospital dari rumah / tempat kerja

B4: Nyatakan **SEMUA** jenis pengangkutan yang digunakan untuk **PERGI** ke hospital dari rumah / tempat kerja. Contohnya, teksi, bot, LRT, jalan kaki, kereta dll

B5: Anggaran **JUMLAH** kos keseluruhan perjalanan **PERGI** ke hospital dari rumah / tempat kerja.

Kos Keseluruhan Perjalanan (RM) =
Kos Petrol + Kos Lain (Contoh: Tol)

Nota:

Sekiranya menggunakan kereta sendiri,
Kos Petrol (RM) = Jarak (km) x 0.70

Sekiranya menggunakan motosikal,
Kos Petrol (RM) = Jarak (km) x 0.50

**B. PERJALANAN PERGI KE HOSPITAL
DARI RUMAH / TEMPAT KERJA**

B1. Tarikh Bertolak ke Hospital:

hh	-	bb	-	2	0	tt	tt
----	---	----	---	---	---	----	----

B2. Masa Untuk Perjalanan : min / jam / hari
(Bulatkan unit yang berkenaan)

B3. Jarak Perjalanan ke Hospital : kilometer

B4. Jenis Pengangkutan :

(Boleh nyatakan lebih dari satu jenis)

B5. Jumlah Kos Keseluruhan Perjalanan PERGI : RM

PENERANGAN

C2: Jumlah masa yang dihabiskan untuk perjalanan **PULANG** ke rumah / tempat kerja dari hospital selepas discaj dari wad

C3: Anggaran jarak perjalanan **PULANG** ke rumah / tempat kerja dari hospital selepas discaj dari wad

C4: Nyatakan **SEMUA** jenis pengangkutan yang digunakan untuk **PULANG** ke rumah / tempat kerja dari hospital. Contohnya, teksi, bot, LRT, jalan kaki, kereta dll

C5: Anggaran **JUMLAH** kos keseluruhan perjalanan **PULANG** ke rumah / tempat kerja dari hospital

Kos Keseluruhan Perjalanan (RM) =
Kos Petrol + Kos Lain (Contoh: Tol)

Nota:

Sekiranya menggunakan kereta sendiri,
Kos Petrol (RM) = Jarak (km) x 0.70

Sekiranya menggunakan motosikal,
Kos Petrol (RM) = Jarak (km) x 0.50



C. PERJALANAN PULANG KE RUMAH / TEMPAT KERJA DARI HOSPITAL

C1. Tarikh Keluar Wad :

hh	-	bb	-	2	0		
----	---	----	---	---	---	--	--

C2. Masa Untuk Perjalanan : min / jam / hari
(Bulatkan unit yang berkenaan)

C3. Jarak Perjalanan ke Rumah / Tempat Kerja : kilometer

C4. Jenis Pengangkutan :

(Boleh nyatakan lebih dari satu jenis)

C5. Jumlah Kos Keseluruhan Perjalanan PULANG : RM

PENERANGAN

D1-D4:

Sekiranya terdapat lebih daripada seorang ahli keluarga atau orang yang menemani anda di wad, nyatakan **SEORANG** sahaja yang dianggap **UTAMA** dan paling kerap menemani/menjaga anda di wad

D2: Catatkan pekerjaan beliau yang **UTAMA** sahaja

D3: Sekiranya beliau **BEKERJA** sahaja, nyatakan jumlah hari cuti atau 'time-off' yang diambil untuk menemani anda di hospital semasa kemasukan wad ini



D. MAKLUMAT AHLI KELUARGA ATAU ORANG YANG MENEMANI ANDA DI WAD (JIKA ADA)

D1. Siapakah yang menemani anda? (Nyatakan seorang yang utama sahaja, jika ada)

.....

D2. Apakah pekerjaan beliau? : ☐ Kakitangan Kerajaan
(Tandakan (✓) pada yang berkenaan)

☐ Pekerja Swasta

☐ Bekerja Sendiri

☐ Lain - lain. Nyatakan

.....

D3. Jumlah hari cuti atau 'time-off' yang diambil oleh beliau untuk menemani anda semasa kemasukan wad ini (jika ada):

.....min / jam / hari (Bulatkan unit yang berkenaan)

D4. Anggaran Pendapatan Bulanan Beliau: (Tandakan (✓) pada yang berkenaan)

☐ kurang RM1000

☐ RM3001 - RM5000

☐ RM1000 - RM3000

☐ melebihi RM5000

PENERANGAN

F1- F11:

Untuk diisi oleh Pegawai Penyelidik DUS
bagi memasukkan wad di **HOSPITAL**
KERAJAAN sahaja

UNTUK DIISI OLEH PEGAWAI FARMASI PENYELIDIK DUS



F. MEDICAL RECORD REVIEW

(For Ward Admissions in the Ministry of Health Facilities ONLY)

F1. Height : m
F2. Weight : kg
F3. Waist Circumference : cm
F4. Body Mass Index (BMI) : kg/m²
F5. Blood Pressure : / mmHg

F6. Diagnosis

ICD Code
For Official Use Only

F6.1 Primary Diagnosis	F6.1
F6.2 Co - Morbid 1	F6.2
F6.3 Co - Morbid 2	F6.3
F6.4 Co - Morbid 3	F6.4
F6.5 Co - Morbid 4	F6.5
F6.6 Co - Morbid 5	F6.6
F6.7 Co - Morbid 6	F6.7

F7. Prescriber Category

(Category of the prescriber(s) who had examined the patient during the entire admission. You may (√) more than one.)

- ☐ Consultant
☐ Specialist
☐ Family Medicine Specialist
☐ Medical Officer
☐ Assistant Medical Officer
☐ Others, please specify:

UNTUK DIISI OLEH PEGAWAI FARMASI PENYELIDIK DUS

[illegible]

UNTUK DIISI OLEH PEGAWAI FARMASI PENYELIDIK DUS

F9. Discharge Medications (Attach extra sheets if necessary)

[illegible]

F10. Diagnostic Procedures / Tests (E.g. Blood test, urine test , ultrasound, ECG etc)

[illegible]

F11. Treatment Procedures (E.g. Surgery, wound dressing, physiotherapy etc)

[illegible]

III. BANTUAN TAMBAHAN

Diisi apabila terdapat perbelanjaan untuk mendapatkan bantuan tambahan di rumah kerana

- Penyakit *diabetes mellitus* dan komplikasinya, ataupun
- Kesulitan yang dihadapi kerana menghadapi penyakit *diabetes mellitus* dan komplikasinya

Contoh bantuan tambahan adalah seperti berikut:

CONTOH BANTUAN TAMBAHAN DI RUMAH	
	Dobi
	Bantuan penjagaan pesakit (<i>Nursing Care</i>) - penjagaan kaki, mencuci luka, penjagaan pengambilan ubat, bantuan mandi dll
	Fisioterapi , Urut
	Pembantu cuci / kemas rumah
	Bantuan memasak / katering
	Dialisis di rumah

PENERANGAN

Catatkan SEBARANG bayaran bagi tujuan mendapatkan bantuan tambahan di rumah (sekiranya ada) kerana kesulitan yang dihadapi akibat menghadapi penyakit *diabetes mellitus* anda dan komplikasinya

(ii) **Tarikh**, tarikh bermulanya bantuan tambahan

(iv) **Bantuan** boleh merangkumi aktiviti kehidupan harian, penjagaan kerana penyakit *diabetes mellitus* dan komplikasinya, aktiviti tambahan di rumah dll

Contohnya:



- Dobi



- Bantuan Penjagaan Pesakit (Nursing Care)

- penjagaan kaki, mencuci luka, penjagaan pengambilan ubat, bantuan mandi dll



- Fisioterapi

- Urut



- Pembantu cuci / kemas rumah



- Bantuan memasak / katering



- Dialisis di rumah

[illegible]

OGOS 2011 - JULAI 2012

OGOS 2011						
A	I	S	R	K	J	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

SEPTEMBER 2011						
A	I	S	R	K	J	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

OKTOBER 2011						
A	I	S	R	K	J	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

NOVEMBER 2011						
A	I	S	R	K	J	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

DISEMBER 2011						
A	I	S	R	K	J	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

JANUARI 2012						
A	I	S	R	K	J	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

FEBRUARI 2012						
A	I	S	R	K	J	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29			

MAC 2012						
A	I	S	R	K	J	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

APRIL 2012						
A	I	S	R	K	J	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

MEI 2012						
A	I	S	R	K	J	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

JUN 2012						
A	I	S	R	K	J	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

JULAI 2012						
A	I	S	R	K	J	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				



KEMENTERIAN KESIHATAN MALAYSIA
PROJEK NASIONAL

Kajian Penggunaan Ubat - Ubatan di dalam Rawatan Diabetes Mellitus di Fasiliti Kementerian Kesihatan Malaysia (No. Protokol: 3538)

Appendix 6

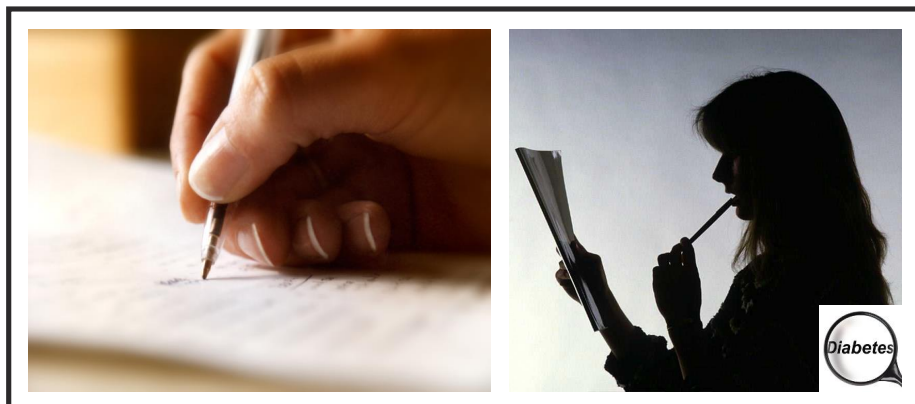


MINISTRY OF HEALTH MALAYSIA
**DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
IN THE MINISTRY OF HEALTH (MOH) FACILITIES**
Protocol No.: 3538

PROCEDURE MANUAL

FOR PHASE 2 DATA COLLECTION

This document may not be used, divulged, published or otherwise disclosed without the consent of the Drug Utilization Study (DUS) Committee.



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Procedure Manual for Phase 2 Data Collection

Instruction

This procedure manual is intended to assist DUS Research Pharmacists in data collection using the **DUS Cost Diary**.

No.	Variable	Description	Instruction(s) to Data Collectors
COVER PAGE			
Cover Page (Header)	<i>Negeri</i>	State code	To be filled in by DUS Research Pharmacist Refer to the Code Index-State (Appendix 1)
	<i>Jenis</i>	Facility type: 1.National Referral Hospital / Hospital Kuala Lumpur 2.State Hospital 3.Hospital with Specialist 4.Hospital without Specialist 5. Health Clinic	To be filled in by DUS Research Pharmacist Refer to the Code Index- Facility Type (Appendix 2)
	<i>Fasiliti</i>	Facility code	To be filled in by DUS Research Pharmacist Refer to the Code Index- Facility (Appendix 3)
	<i>Nombor Pesakit</i>	The patient's number at their respective facility	To be filled in by DUS Research Pharmacist Patients from DUS Phase 1 who joined Phase 2: Use the 4-digit number previously assigned in Phase 1. Refer to the photocopied Selected Patient Registry Master List (Phase 1). New patients who just joined DUS Phase 2 but was not in Phase 1: Assign a unique 4-digit number for each patient which is in continuous running sequence starting from 2001 E.g. Patient 1: 2001 Patient 2: 2002 Patient 3: 2003

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No.	Variable	Description	Instruction(s) to Data Collectors
Cover Page	<i>Tempoh Diari</i>	The time allocated for recording all activities carried out by the patient, due to diabetes and its complications, in the given diary	To be filled in by DUS Research Pharmacist Estimate an appropriate duration within which the particular diary given would be sufficient to record all activities for the given patient, based on the patients': • Disease profile • Disease severity • Frequency of diabetes-related activities • etc E.g. Well controlled diabetic patient, a duration of 4 weeks/diary may be appropriate Diabetic patient with kidney failure and frequent dialysis sessions, a duration of 2 weeks/diary may be appropriate Format: dd-mm-20yy sehingga dd-mm-20yy
Cover Page	<i>Tarikh Temu Janji Diari</i>	The date on which the patient agreed to come to the pharmacy to collect a new cost diary	To be filled in by DUS Research Pharmacist This date could be the patient's next medication refill TCA or medical check-up TCA or a date preferred by the patient Format: dd-mm-20yy
Page 1: MAKLUMAT PESAKIT			
<i>Maklumat Pesakit Page 1</i>	<i>No. Kad Pengenalan (IC)</i>	National Registration Identification Card number or Police/Army Registration Identification Card number	To be filled in by DUS Research Pharmacist State in numerals without any spacing
<i>Maklumat Pesakit Page 1</i>	<i>RN</i>	The patient's reference number in the facility	To be filled in by DUS Research Pharmacist State in numerals without any spacing
<i>Maklumat Pesakit Page 1</i>	<i>Nama</i>	The patient's full name as specified on his/her IC or any other official identification card	To be filled in by DUS Research Pharmacist Format: CAPITAL LETTERS
<i>Maklumat Pesakit Page 1</i>	<i>Alamat Surat-Menyurat</i>	The patient's preferred corresponding address	To be filled in by DUS Research Pharmacist Format: CAPITAL LETTERS
<i>Maklumat Pesakit Page 1</i>	<i>Poskod</i>	The post code of the address specified under <i>Alamat Surat-Menyurat</i>	To be filled in by DUS Research Pharmacist State in numerals

No.	Variable	Description	Instruction(s) to Data Collectors
Maklumat Pesakit Page 1	Negeri	The State in which the location specified under <i>Alamat Surat-Menyurat</i> resides	To be filled in by DUS Research Pharmacist Format: CAPITAL LETTERS
Maklumat Pesakit Page 1	Telefon Rumah	The patient's house phone number	To be filled in by DUS Research Pharmacist State in numerals without any spacing
Maklumat Pesakit Page 1	Telefon Bimbit	The patient's mobile phone number	To be filled in by DUS Research Pharmacist State in numerals without any spacing
Maklumat Pesakit Page 1	Anggaran Pendapatan Bulanan	The estimated monthly income range of the patient's main and current occupation	To be filled in by DUS Research Pharmacist Tick (✓) only one
Page 3: PENERANGAN			
Penerangan Page 2	Setiap ____ minggu....	The frequency in which it would be convenient for the patient to come to the facility and be given a new diary	To be filled in by DUS Research Pharmacist State in numerals
Penerangan Page 2	Nama Pegawai Farmasi Penyelidik	Name of data collector	To be filled in by DUS Research Pharmacist Format: CAPITAL LETTERS
Penerangan Page 2	Nama dan Alamat Hospital / Klinik Kesihatan	Facility name and address	To be filled in by DUS Research Pharmacist Format: CAPITAL LETTERS
Penerangan Page 2	Poskod	The post code of the address specified under <i>Nama dan Alamat Hospital / Klinik Kesihatan</i>	To be filled in by DUS Research Pharmacist State in numerals
Penerangan Page 2	Negeri	The State in which the location specified under <i>Nama dan Alamat Hospital / Klinik Kesihatan</i> resides	To be filled in by DUS Research Pharmacist Format: CAPITAL LETTERS
Penerangan Page 2	No. Telefon	Official phone number of the pharmacy at the facility	To be filled in by DUS Research Pharmacist State in numerals
Penerangan Page 2	Email	DUS Research Pharmacist's email address	To be filled in by DUS Research Pharmacist
AKTIVITI 1 - 8			
A. Butir-butir Aktiviti			
A1	Tarikh Aktiviti	The date on which the activity was carried out	Format: dd-mm-20yy

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No.	Variable	Description	Instruction(s) to Data Collectors										
A2	Jenis Aktiviti	The type/classification of the activity purpose specified in A3	Refer to the table below for the type/classification of the activity purpose <table><tr><th>Jenis Aktiviti</th><th>Tujuan Aktiviti</th></tr><tr><td>1 Temu janji / konsultasi</td><td>Doktor Ahli farmasi, Pakar diet, Pakar senaman, Bomoh / pawang, Sinseh, Ayurvedik dll</td></tr><tr><td>2 Mendapatkan rawatan</td><td>Moden, Traditional, Komplementari, Chiropractic, Dialisis, Ujian darah, Mencuci luka dll</td></tr><tr><td>3 Membeli Keperluan perubatan</td><td>Alat perubatan, Ubat, Herba, Nutrisi, Alat pakai, buang dll</td></tr><tr><td>4 Lain-lain</td><td>Other activities carried out that cannot be classified under Jenis Aktiviti 1-3</td></tr></table>	Jenis Aktiviti	Tujuan Aktiviti	1 Temu janji / konsultasi	Doktor Ahli farmasi, Pakar diet, Pakar senaman, Bomoh / pawang, Sinseh, Ayurvedik dll	2 Mendapatkan rawatan	Moden, Traditional, Komplementari, Chiropractic, Dialisis, Ujian darah, Mencuci luka dll	3 Membeli Keperluan perubatan	Alat perubatan, Ubat, Herba, Nutrisi, Alat pakai, buang dll	4 Lain-lain	Other activities carried out that cannot be classified under Jenis Aktiviti 1-3
Jenis Aktiviti	Tujuan Aktiviti												
1 Temu janji / konsultasi	Doktor Ahli farmasi, Pakar diet, Pakar senaman, Bomoh / pawang, Sinseh, Ayurvedik dll												
2 Mendapatkan rawatan	Moden, Traditional, Komplementari, Chiropractic, Dialisis, Ujian darah, Mencuci luka dll												
3 Membeli Keperluan perubatan	Alat perubatan, Ubat, Herba, Nutrisi, Alat pakai, buang dll												
4 Lain-lain	Other activities carried out that cannot be classified under Jenis Aktiviti 1-3												
A3	Tujuan Aktiviti	The purpose of the activity	Encourage the patient to be more specific on the purpose of his/her activity E.g. <i>Membeli beras merah</i> <i>Membeli syringe dan jarum</i> <i>Mendapat rawatan tradisional untuk kebas kaki</i>										
A4	Nama Fasiliti	The name of the facility	State the NAME of the facility. E.g. <i>Klinik Aman</i> <i>Farmasi Guardian</i> Facilities may include: <i>Klinik, Makmal, Pusat Dianostik, Farmasi, Toko ubat, Hospital</i> <i>Pusat kebajikan, Pusat dialisis, etc.</i>										
A5	Tempoh masa	Total time that was spent at the facility	State the duration and circle either minute(s) or hour(s) or day(s)										
A6	Jumlah hari cuti atau ‘time-off’	Total duration of leave or time-off taken by the patient to carry out the activity	To be answered only if the patient is working State the duration and circle either minute(s) or hour(s) or day(s)										

No.	Variable	Description	Instruction(s) to Data Collectors
B. Perjalanan PERGI Ke Fasilitas Dari Rumah / Tempat Kerja			
B1	<i>Tarikh Bertolak Ke Fasilitas</i>	The date on which the patient departed from his/her house/workplace to the facility	Format: dd-mm-20yy
B2	<i>Masa Untuk Perjalanan</i>	The length of time taken by the patient to travel from his/her house/workplace to the facility	State the duration and circle either minute(s) or hour(s) or day(s)
B3	<i>Jarak Perjalanan Ke Fasilitas</i>	The distance from the patient's house/workplace to the facility	State the distance in kilometer(s)
B4	<i>Jenis Pengangkutan</i>	ALL modes of transport used by the patient to get from his/her house/workplace to the facility	More than one mode of transport may be specified E.g. Motorbike Car Taxi Bus LRT ERL Train Commuter Boat By Foot
B5	<i>Jumlah Kos Keseluruhan Perjalanan PERGI</i>	The total travelling cost to get from the patient's house/workplace to the facility	State the cost in RM Kos Keseluruhan Perjalanan (RM) = Kos Perjalanan* + Kos Lain (Contoh: Tol) *Kereta Sendiri: $Kos\ Perjalanan\ (RM) = jarak\ (km) \times 0.70$ *Motosikal: $Kos\ Perjalanan\ (RM) = jarak\ (km) \times 0.50$
C. Perjalanan PULANG Ke Rumah / Tempat Kerja Dari Fasilitas			
C1	<i>Tarikh Bertolak dari Fasilitas</i>	The date on which the patient departed from the facility to his/her house/workplace	Format: dd-mm-20yy
C2	<i>Masa Untuk Perjalanan</i>	The length of time taken by the patient to travel from the facility to his/her house/workplace	State the duration and circle either minute(s) or hour(s) or day(s)
C3	<i>Jarak Perjalanan ke Rumah / Tempat Kerja</i>	The distance from the facility to the patient's house/workplace	State the distance in kilometer(s)
C4	<i>Jenis Pengangkutan</i>	ALL modes of transport used by the patient to get from the facility to his/her house/workplace	More than one mode of transport may be specified E.g. Motorbike Car Taxi Bus LRT ERL Train Commuter Boat By Foot

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No.	Variable	Description	Instruction(s) to Data Collectors
C5	Jumlah Kos Keseluruhan Perjalanan PULANG	The total travelling cost to get to from the facility to the patient's house/workplace	State the cost in RM Kos KESELURUHAN Perjalanan (RM) = Kos Perjalanan* + Kos Lain (Contoh: Tol) *Kereta: Kos Perjalanan (RM) = jarak (km) x 0.70 *Motosikal: Kos Perjalanan (RM) = jarak (km) x 0.50
C6	Jumlah Malam Menginap	Lodgings required by the patient due to this activity (if applicable)	State in numerals the number of nights spent
C7	Kos Penginapan	Cost of lodging per night (if required to pay for lodging)	State the cost per night in RM
D. Maklumat Ahli Keluarga atau Orang yang Menemani Anda Ke Fasiliti			
If the patient was accompanied by more than one person, state only ONE main person			
D1	Ahli Keluarga / Orang yang Menemani	The main family member/ accompanying person who came with the patient to the facility	State only ONE main person. E.g. Ibu Anak Bapa Sahabat Isteri Saudara Suami Pembantu Rumah
D2	Pekerjaan	The main and current occupation of the main family member/accompanying person	Tick (✓) only one
D3	Jumlah hari cuti atau 'time-off'	Total duration of leave or time off taken by the main family member/accompanying person to come with the patient to the facility	To be answered only if the family member/accompanying person is working State the duration and circle either minute(s) or hour(s) or day(s)
D4	Anggaran Pendapatan	The estimated monthly income range of the main family member's/accompanying person's main and current occupation	Tick (✓) only one
E. Kos Perbelanjaan Aktiviti			
E1 – E3: Fill in the cost breakdown of the activity according to category. (If E1 – E3 not applicable or cost breakdown is unknown, only fill in E4 and E5)			

No.	Variable	Description	Instruction(s) to Data Collectors
E1	<i>Kos Membayar Khidmat Konsultasi</i>	Any consultation cost incurred due to diabetes mellitus and its complications	Fill in only if applicable State the type of consultation and the cost in RM E.g. <i>Doktor Pakar Senaman</i> <i>Ahli Farmasi Bomoh/Pawang</i> <i>Pakar Diet Sinseh</i> <i>Ayurvedik etc.</i>
E2	<i>Kos Membayar Perbelanjaan Rawatan</i>	Any treatment cost incurred due to diabetes mellitus and its complications	Fill in only if applicable State/describe the treatment received and the cost in RM E.g. <i>Rawatan Urut Tradisional</i> <i>Rawatan acupuncture</i> <i>Mencuci luka</i> <i>Dialisis</i> <i>Menjalani ujian glukos darah</i> <i>etc.</i>
E3	<i>Kos Perbelanjaan Untuk Keperluan Perubatan</i>	Cost of any requirements/ products needed due to diabetes mellitus and its complications, which were self-purchased through the patient's own initiative or were bought as advised by a modern/traditional practitioner	Fill in only if applicable State the requirements/products and the cost in RM E.g. <i>Ubat Kencing Manis Metformin</i> <i>Supplemen Fish Oil</i> <i>Beras merah</i> <i>Daun herba untuk kencing manis</i> <i>Jarum insulin</i> <i>Glukometer</i> <i>etc.</i>
E4	<i>Kos Keseluruhan Aktiviti Ini</i>	Overall cost of the activity, as stated on the receipt of payment for this activity/ Total cost for E1, E2 and E3	State the overall cost in RM
E5	<i>Pembayar Kos Keseluruhan</i>	The person who paid/ person(s) who shared to pay for the overall cost of the activity	You may tick (✓) more than one
KEMASUKAN WAD 1 - 2			
A. Butir-butir Kemasukan Wad			
A1	<i>Tarikh Masuk Wad</i>	The date on which the patient was admitted to the ward	Format: dd-mm-20yy
A2	<i>Sebab Masuk Hospital</i>	The reason(s) the patient was admitted/symptom(s) experienced by the patient that justified the need for admission	State the reason(s)/symptoms(s)

DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
IN THE MINISTRY OF HEALTH (MOH) FACILITIES
Protocol No.: 3538

No.	Variable	Description	Instruction(s) to Data Collectors
A3	Diagnosis	Diagnosis of the patient's condition at the ward	To be filled in by the DUS Research Pharmacist if the patient does not know his/her diagnosis and was admitted into a government hospital
A4	<i>Nama Hospital</i>	The name of the hospital where the admission took place	State the NAME of the hospital E.g. <i>Hospital Raja Permaisuri Bainun</i> <i>Hospital Kuala Lumpur</i> <i>Hospital Pantai Puteri</i>
A5	<i>Tempoh masa</i>	Duration of admission	State the duration and circle either hour(s) or day(s)
A6	<i>Jumlah hari cuti sakit (MC) atau 'time-off'</i>	Total duration of medical leave or time-off taken by the patient due to the hospital admission	To be answered only if the patient is working State the duration and circle either hour(s) or day(s)
B. Perjalanan PERGI Ke Hospital Dari Rumah / Tempat Kerja			
B1	<i>Tarikh Masuk Wad</i>	The date on which the patient was admitted to the ward	Format: dd-mm-20yy
B2	<i>Masa Untuk Perjalanan</i>	The length of time taken by the patient to travel from his/her house/workplace to the hospital	State the duration and circle either minute(s) or hour(s) or day(s)
B3	<i>Jarak Perjalanan Ke Hospital</i>	The distance from the patient's house/workplace to the hospital	State the distance in kilometer(s)
B4	<i>Jenis Pengangkutan</i>	ALL modes of transport used by the patient to get from his/her house/workplace to the hospital	More than one mode of transport may be specified E.g. Motorbike Car Taxi Bus LRT ERL Train Commuter Boat By Foot
B5	<i>Jumlah Kos Keseluruhan Perjalanan PERGI</i>	The total travelling cost to get from the patient's house/workplace to the hospital	State the cost in RM <i>Kos Keseluruhan Perjalanan (RM) = Kos Petrol* + Kos Lain (Contoh: Tol)</i> *Kereta: <i>Kos Petrol (RM) = jarak (km) x 0.70</i> *Motosikal: <i>Kos Petrol (RM) = jarak (km) x 0.50</i>
C. Perjalanan PULANG Ke Rumah / Tempat Kerja Dari Hospital			
C1	<i>Tarikh Keluar Wad</i>	The date on which the patient was discharged from the ward	Format: dd-mm-20yy

No.	Variable	Description	Instruction(s) to Data Collectors
C2	<i>Masa Untuk Perjalanan</i>	The length of time taken by the patient to travel from the hospital to his/her house/workplace	State the duration and circle either minute(s) or hour(s) or day(s)
C3	<i>Jarak Perjalanan ke Rumah / Tempat Kerja</i>	The distance from the hospital to the patient's house/workplace	State the distance in kilometer(s)
C4	<i>Jenis Pengangkutan</i>	ALL modes of transport used by the patient to get from the hospital to his/her house/workplace	More than one mode of transport may be specified E.g. Motorbike Car Taxi Bus LRT ERL Train Commuter Boat By Foot
C5	<i>Jumlah Kos Keseluruhan Perjalanan PULANG</i>	The total travelling cost to get from the hospital to the patient's house/workplace	State the cost in RM Kos KESELURUHAN Perjalanan (RM) = Kos Perjalanan* + Kos Lain (Contoh: Tol) *Kereta: <i>Kos Perjalanan (RM) = jarak (km) x 0.70</i> *Motosikal: <i>Kos Perjalanan (RM) = jarak (km) x 0.50</i>
D. Maklumat Ahli Keluarga atau Orang yang Menemani Anda Di Wad			
If the patient was accompanied in the wad by more than one person, state only ONE main person			
D1	<i>Ahli Keluarga / Orang yang Menemani</i>	The main family member / person who most frequently accompanied the patient in the ward	Name the accompanying person. State only ONE main person. E.g. <i>Ibu Anak</i> <i>Bapa Sahabat</i> <i>Isteri Saudara</i> <i>Suami Pembantu Rumah</i>
D2	<i>Pekerjaan</i>	The main and current occupation of the main family member/accompanying person	Tick (✓) only one
D3	<i>Jumlah hari cuti atau 'time-off'</i>	Total duration of leave or time-off taken by the main family member/accompanying person to accompany the patient in the ward	State the duration and circle either minute(s) or hour(s) or day(s)
D4	<i>Anggaran Pendapatan</i>	The estimated monthly income range of the main family member's/accompanying person's main and current occupation	Tick (✓) only one

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No.	Variable	Description	Instruction(s) to Data Collectors								
E. Kos Perbelanjaan Kemasukan Wad											
E1 – E3: Fill in the cost breakdown of the hospital admission according to category. Only fill in E1 and E2, if E3 not applicable or cost breakdown is unknown.											
E1	<i>Kos Keseluruhan Aktiviti Ini</i>	Overall cost of the patient's hospital admission, as stated in the receipt of payment upon discharge	State the overall cost in RM This cost does not include travel cost								
E2	<i>Pembayar Kos Keseluruhan</i>	The person who paid / person(s) who shared to pay for the overall cost of the patient's hospital admission	You may tick (✓) more than one								
E3	<i>Huraian Kos Perbelanjaan Kemasukan Wad</i>	The cost breakdown of the hospital admission, as stated on the receipt of payment upon discharge	Refer to the payment receipt. State the type of cost(s) incurred during the hospital admission and its cost in RM E.g. Types of charges in a typical hospital admission: <table border="0" style="width: 100%;"> <tr> <td>Consultation</td><td>Procedure</td></tr> <tr> <td>Laboratory</td><td>Pharmacy</td></tr> <tr> <td>Diagnostics/Imaging</td><td>Treatment</td></tr> <tr> <td>Nursing Procedure/Care</td><td>Others</td></tr> </table>	Consultation	Procedure	Laboratory	Pharmacy	Diagnostics/Imaging	Treatment	Nursing Procedure/Care	Others
Consultation	Procedure										
Laboratory	Pharmacy										
Diagnostics/Imaging	Treatment										
Nursing Procedure/Care	Others										
F. Medical Record Review											
To be filled in by DUS Research Pharmacist											
Complete F1 – F11 ONLY if the patient was admitted to a Government Hospital / Facility .											
F1	Height	The height of the patient	State measurement in meter(s)								
F2	Weight	The weight of the patient	State measurement in kilograms								
F3	Waist Circumference	Waist measurement of the patient	State measurements in centimeters								
F4	Body Mass Index (BMI)	The measurement of the patient's body fat based on health and weight using the standard method	State measurement in kg/m ²								
F5	Blood Pressure	Measurement of the systolic and diastolic pressure of the blood of the patient with a sphygmomanometer	State measurement in mmHg								
F6	Diagnosis	Identification of the primary diagnosis being made during that particular admission and any other co-morbid disease(s)	The primary diagnosis (F6.1) is diabetes mellitus type 2; and there may be more than one co-morbid diagnosis (F6.2 - F6.7) for the admission								
F7	Prescriber Category	The category of the prescriber(s) who had examined the patient during the entire admission	You may tick (✓) more than one								

No.	Variable	Description	Instruction(s) to Data Collectors
F8	Ward Medications	Detailed information of the drug(s) or medication(s) for diabetes and co-morbid disease treatment that were prescribed on the patient's drug chart throughout the hospital admission	<u>Date Started</u> Format: dd/mm/yy <u>Date Stopped</u> Format: dd/mm/yy <u>Prescribed Drug</u> Format: Dosage Form_Drug Name_Dose_Frequency Dosage Form Specify - Tablet, Syrup, IV, Sachet etc. Drug Name State the name of the prescribed drug supplied at the pharmacy in Generic name and Trade name in brackets E.g. Paracetamol (Uphamol) Paracetamol (Panadol) Perindopril (Coversyl) Perindopril (Covapril) Dose Specify the dose in numerals and its respective unit E.g. mcg/mg/g/1U Frequency Specify the frequency in standard latin prescription abbreviation E.g. OD (once a day) BD (twice a day) TDS (three times a day) QID (four times a day) etc. <u>Strength(s) Supplied</u> Specify every strength for the particular drug and dosage form that was presumably supplied/dispensed to the patient to achieve the dose prescribed E.g. Prescribed : T. Prazosin 3mg Strength(s) : 1mg, 2mg Supplied <u>Quantity Supplied</u> State in numerals the quantity supplied for each dosage form for a given strength that would have been presumably supplied/dispensed to the patient for the entire prescription duration

DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
IN THE MINISTRY OF HEALTH (MOH) FACILITIES
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No.	Variable	Description	Instruction(s) to Data Collectors
F9	Discharge Medications	Detailed information of the discharge drug(s) or medication(s) for diabetes and co-morbid disease treatment that were prescribed for the patient	<u>Prescribed Drug</u> Format: Dosage Form_ Drug Name_ Dose_ Frequency Dosage Form Specify - Tablet, Syrup, IV, Sachet etc. Drug Name State the name of the prescribed drug supplied at the pharmacy in Generic name and Trade name in brackets E.g. Paracetamol (Uphamol) Paracetamol (Panadol) Perindopril (Coversyl) Perindopril (Covapril) Dose Specify the dose in numerals and its respective unit E.g. mcg/mg/g/IU Frequency Specify the frequency in standard latin prescription abbreviation E.g. OD (once a day) BD (twice a day) TDS (three times a day) QID (four times a day) etc. <u>Prescribed Duration</u> State the duration in full E.g. 1 week 1 month 3 months <u>Strength(s) Supplied</u> Specify every strength for the particular drug and dosage form that was presumably supplied/dispensed to the patient to achieve the dose prescribed E.g. Prescribed : T. Prazosin 3mg Strength(s) : 1mg, 2mg Supplied <u>Quantity Supplied</u> State in numerals the quantity supplied for each dosage form for a given strength that would have been presumably supplied/dispensed to the patient for the entire prescription duration

No.	Variable	Description	Instruction(s) to Data Collectors
F10	Diagnostic Procedures/Tests	Diagnostic/investigational procedures and tests that were conducted throughout the patient's hospital admission	Parameter Name the procedure/test done E.g. HbA1c Serum Creatinine Abdominal Ultrasound ECG Date Format: dd/mm/yy Result State the results (if any) with units
F11	Treatment Procedures	Treatment procedures that were carried out during the patient's hospital admission	Date Format: dd/mm/yy Treatment Procedure Specify the name of the treatment procedure E.g. Wound dressing Physiotherapy of the leg Bypass Surgery Angiogram Result State the results (if any)
BANTUAN TAMBAHAN			
(ii)	<i>Tarikh</i>	The date on which additional help at home was needed as a result of any inconvenience cause by the patient's diabetic disease or its complications	Format: dd/mm/yy
(iii)	<i>Tempoh Bantuan</i>	Duration of the additional help received at home as a result of any inconvenience cause by the patient's diabetic disease or its complications	State the duration and circle either hour(s) or day(s)
(iv)	<i>Jenis Bantuan</i>	The type/form of additional help needed at home as a result of any inconvenience cause directly or indirectly by the patient's diabetic disease or its complications	Specify the type of help received E.g. Laundry Services Nursing Care (foot care, wound dressing, medication administration etc.) Physiotherapy Massage Maid Catering Home dialysis

DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
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No.	Variable	Description	Instruction(s) to Data Collectors
(v)	Kos Keseluruhan	The overall cost for the additional help which was needed at home (iv), for the specified duration (iii)	State the cost in RM

Collaboration:

Bahagian Perkhidmatan Farmasi, KKM
Jabatan Kesihatan Wilayah Persekutuan Kuala Lumpur & Putrajaya
Fakulti Farmasi, Universiti Teknologi Malaysia

Jabatan Farmasi, Hospital Melaka
Jabatan Farmasi, Hospital Putrajaya
Jabatan Farmasi, Universiti Malaya
Institut Penyelidikan Kesihatan, KKM

Appendix 1: CODE INDEX – STATE

State Code*	State
01	Johor
02	Kedah
03	Kelantan
04	Melaka
05	Negeri Sembilan
06	Pahang
07	Pulau Pinang
08	Perak
09	Perlis
10	Selangor
11	Terengganu
12	Sabah
13	Sarawak
14	Wilayah Persekutuan Kuala Lumpur (Federal Territory of Kuala Lumpur)

* Inter-Agency Technical Committee Meeting 3/2007

DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
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Appendix 2: CODE INDEX – FACILITY TYPE

Type Code	Facility
1	Hospital Kuala Lumpur (HKL)
2	Hospital Tuanku Fauziah, Kangar
	Hospital Sultanah Bahiyah, Alor Setar
	Hospital Pulau Pinang
	Hospital Raja Perempuan Bainun, Ipoh
	Hospital Tengku Ampuan Rahimah, Klang
	Hospital Melaka
	Hospital Sultanah Aminah, Johor Bharu
	Hospital Tengku Ampuan Afzan, Kuantan
	Hospital Sultanah Nur Zahirah, Terengganu
	Hospital Umum Sarawak, Kuching
	Hospital Tuanku Ja'afar, Seremban
	Hospital Queen Elizabeth, Kota Kinabalu
	Hospital Raja Perempuan Zainab II, Kota Bharu
	Hospital Sultan Abdul Halim, Sungai Petani
3	Hospital Kulim
	Hospital Seberang Jaya
	Hospital Kepala Batas
	Hospital Seri Manjung
	Hospital Banting
	Hospital Sungai Buloh
	Hospital Ampang
	Hospital Serdang
	Hospital Pakar Sultanah Fatimah, Muar
	Hospital Batu Pahat
	Hospital Segamat
	Hospital Kluang
	Hospital Sultan Ismail, Pandan
	Hospital Sultan Hj. Ahmad Shah, Temerloh
4	Hospital Kuala Lipis
	Hospital Kemaman
	Hospital Duchess of Kent, Sandakan
	Hospital Keningau
	Hospital Sibui
	Hospital Miri
	Hospital Baling
	Hospital Yan
	Hospital Sik
	Hospital Sungai Bakap
	Hospital Kuala Kangsar
	Hospital Kampar
	Hospital Grik
	Hospital Selama
5	Hospital Changkat Melintang
	Hospital Tanjung Karang
	Hospital Jasin

Type Code	Facility
4	Hospital Mersing
	Hospital T.S. Maharaja Tun Ibrahim, Kulai
	Hospital Pekan
	Hospital Raub
	Hospital Jerantut
	Hospital Sultanah Hajjah Kalsom, Cameron Highlands
	Hospital Tumpat
	Hospital Gua Musang
	Hospital Beaufort
	Hospital Tampin
	Hospital Jempol
	Hospital Alor Gajah
	Hospital Kudat
	Hospital Papar
5	Hospital Ranau
	Hospital Kuala Penyu
	Hospital Sipitang
	Hospital Saratok
	Hospital Kanowit
	KK Kulim
	KK Butterworth
	KK Seberang Jaya
	KK Masai
	KK Kampung Majidee
	KK Ulu Tiram
	KK Pasir Gudang
	KK Kempas
	KK Mahmoodiah
	KK Bandar Kuantan
	KK Kampung Simee
	KK Rawang
	KK Selayang Baru
	KK Taman Ehsan
	KK Serendah
	KK Puchong
	KK Seri Kembangan
	KK Medan Maju Jaya
	KK Shah Alam
	KK Klang
	KK Bukit Kuda
	KK Seremban
	KK Ayer Keroh
	KK Wakaf Bharu
	KK Jalan Masjid
	KK Jalan Oya
	KK Sri Aman

1 **National Referral Hospital / HKL** | 2 **State Hospital** | 3 **Hospital with Specialist** | 4 **Hospital without Specialist** | 5 **Health Clinic**

Appendix 3: CODE INDEX – FACILITY

Facility Code	State	Facility
01	Johor	Hospital Sultanah Aminah, Johor Bharu
02	Johor	Hospital Pakar Sultanah Fatimah, Muar
03	Johor	Hospital Batu Pahat
04	Johor	Hospital Segamat
05	Johor	Hospital Kluang
06	Johor	Hospital Sultan Ismail, Pandan
07	Johor	Hospital Mersing
08	Johor	Hospital T.S. Maharaja Tun Ibrahim, Kulai
09	Johor	KK Masai
10	Johor	KK Kampung Majidee
11	Johor	KK Ulu Tiram
12	Johor	KK Pasir Gudang
13	Johor	KK Kempas
14	Johor	KK Mahmoodiah
15	Kedah	Hospital Sultanah Bahiyah, Alor Setar
16	Kedah	Hospital Sultan Abdul Halim, Sg Petani
17	Kedah	Hospital Kulim
18	Kedah	Hospital Baling
19	Kedah	Hospital Yan
20	Kedah	Hospital Sik
21	Kedah	KK Kulim
22	Kelantan	Hospital Raja Perempuan Zainab II, Kota Bharu
23	Kelantan	Hospital Tumpat
24	Kelantan	Hospital Gua Musang
25	Kelantan	KK Wakaf Bharu
26	Kuala Lumpur	Hospital Kuala Lumpur
27	Melaka	Hospital Melaka
28	Melaka	Hospital Alor Gajah
29	Melaka	Hospital Jasin
30	Melaka	KK Ayer Keroh
31	Negeri Sembilan	Hospital Tuanku Ja'afar, Seremban
32	Negeri Sembilan	Hospital Tampin
33	Negeri Sembilan	Hospital Jempol
34	Negeri Sembilan	KK Seremban
35	Pahang	Hospital Tengku Ampuan Afzan, Kuantan
36	Pahang	Hospital Sultan Hj. Ahmad Shah, Temerloh
37	Pahang	Hospital Kuala Lipis
38	Pahang	Hospital Pekan
39	Pahang	Hospital Raub
40	Pahang	Hospital Jerantut
41	Pahang	Hospital Sultanah Hajjah Kalsom, Cameron Highlands
42	Pahang	KK Bandar Kuantan
43	Perak	Hospital Raja Perempuan Bainun, Ipoh
44	Perak	Hospital Seri Manjung
45	Perak	Hospital Kuala Kangsar
46	Perak	Hospital Kampar
47	Perak	Hospital Grik

DRUG UTILIZATION IN THE TREATMENT OF DIABETES MELLITUS
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Protocol No.: 3538

Appendix 3: CODE INDEX – FACILITY (cont.)

Facility Code	State	Facility
48	Perak	Hospital Selama
49	Perak	Hospital Changkat Melintang
50	Perak	KK Tapah
51	Perak	KK Kampung Simee
52	Perlis	Hospital Tuanku Fauziah, Kangar
53	Pulau Pinang	Hospital Pulau Pinang
54	Pulau Pinang	Hospital Seberang Jaya
55	Pulau Pinang	Hospital Kepala Batas
56	Pulau Pinang	Hospital Sungai Bakap
57	Pulau Pinang	KK Butterworth
58	Pulau Pinang	KK Seberang Jaya
59	Sabah	Hospital Queen Elizabeth, Kota Kinabalu
60	Sabah	Hospital Duchess of Kent, Sandakan
61	Sabah	Hospital Keningau
62	Sabah	Hospital Beaufort
63	Sabah	Hospital Kudat
64	Sabah	Hospital Papar
65	Sabah	Hospital Ranau
66	Sabah	Hospital Kuala Penyu
67	Sabah	Hospital Sipitang
68	Sarawak	Hospital Umum Sarawak, Kuching
69	Sarawak	Hospital Sri Aman
70	Sarawak	Hospital Sibu
71	Sarawak	Hospital Miri
72	Sarawak	Hospital Saratok
73	Sarawak	Hospital Kanowit
74	Sarawak	KK Jalan Masjid
75	Sarawak	KK Jalan Oya
76	Sarawak	KK Sri Aman
77	Selangor	Hospital Tengku Ampuan Rahimah, Klang
78	Selangor	Hospital Banting
79	Selangor	Hospital Sungai Buloh
80	Selangor	Hospital Ampang
81	Selangor	Hospital Serdang
82	Selangor	Hospital Tanjung Karang
83	Selangor	KK Rawang
84	Selangor	KK Selayang Baru
85	Selangor	KK Taman Ehsan
86	Selangor	KK Serendah
87	Selangor	KK Puchong
88	Selangor	KK Seri Kembangan
89	Selangor	KK Medan Maju Jaya
90	Selangor	KK Shah Alam
91	Selangor	KK Klang
92	Selangor	KK Bukit Kuda
93	Terengganu	Hospital Sultanah Nur Zahirah, Terengganu
94	Terengganu	Hospital Kemaman

Data Collection Training Log DUS Phase II

#	Date	Training	Location	No. of Data Collectors Trained
1	18-19 April 2011	DUS Phase 2 National Training Workshop	Dewan Serai Wangi, BPFK	84
2	11/14/2011	DUS Phase 2 Refresher Training	Bilik Mesyuarat Baiduri BPF KKM	11

BPF: Bahagian Perkhidmatan Farmasi/ *Pharmaceutical Services Division*BPFK: Biro Pengawalan Farmaseutikal Kebangsaan / *National Pharmaceutical Control Bureau*DUS: *Drug Utilisation Survey*

Appendix 8

DUS Phase II Site Monitoring Log

#	Date	Site Monitoring Meeting	Location	Investigator / Secretariat	Number of Research Pharmacists
1	2/28/2012	Mesyuarat Pengutipan Data DUS Fasa 2 - Peringkat Negeri Sabah	BPF Sabah	Mdm. Zaiton bt Kamarruddin Mdm. Sahidah bt Said	8
2	2/29/2012	Mesyuarat Pengutipan Data DUS Fasa 2 - Peringkat Negeri Johor	Pejabat TPKN(F) Johor	Prof. Dr. Mohamed Mansor bin Manan	12
3	3/1/2012	Mesyuarat Pengutipan Data DUS Fasa 2 - Peringkat Negeri Melaka & Negeri Sembilan	Hospital Melaka	Mr. Abdol Malek bin Abd Aziz Dr. Faridah Aryani bt Md. Yusof	8
4	3/6/2012	Mesyuarat Pengutipan Data DUS Fasa 2 - Peringkat Negeri Selangor	BPF KKM	Prof. Dr. Samsinah bt Hj Hussain Dr. Ramli bin Zainal	17
5	3/9/2012	Mesyuarat Pengutipan Data DUS Fasa 2 - Peringkat Negeri Sarawak	Dewan Rajawali Hospital Umum Sarawak, Kuching	Mr. Chow Thin Sun Ms. Raine Jay Chinniah	8
6	3/23/2012	Mesyuarat Pengutipan Data DUS Fasa 2 - Peringkat Negeri Zon Timur	BPF Pahang	Mr. Chow Thin Sun Ms. Raine Jay Chinniah	13
7	3/27/2012	Mesyuarat Pengutipan Data DUS Fasa 2 - Peringkat Negeri Zon Utara	BPF Pulau Pinang	Mr. Chow Thin Sun Ms. Raine Jay Chinniah	11
8	3/28/2012	Mesyuarat Pengutipan Data DUS Fasa 2 - Peringkat Negeri Perak	BPF Perak	Mdm. Zaiton bt Kamarruddin Mdm. Sahidah bt Said	7

BPF: Bahagian Perkhidmatan Farmasi/ Pharmaceutical Services Division
DUS: Drug Utilisation Survey

Appendix 9

31/03/2010 10:25 FAX

NIH SECR ETARIAT

001



PEJABAT TIMBALAN KETUA PENGARAH KESIHATAN
 OFFICE OF THE DEPUTY DIRECTOR-GENERAL OF HEALTH
 (PENYELIDIKAN & SOKONGAN TEKNIKAL)
 (RESEARCH & TECHNICAL SUPPORT)
 KEMENTERIAN KESIHATAN MALAYSIA
 MINISTRY OF HEALTH MALAYSIA
 Aras 12, Blok E7, Parcel E, Presint 1
 Level 12, Block E7, Parcel E, Precinct 1
 Pusat Pentadbiran Kerajaan Persekutuan
 Federal Government Administrative Centre
 62590 PUTRAJAYA

Tel : 03 88832643
 Faks : 03 88895184

JAWATANKUASA ETIKA & PENYELIDIKAN
 PERUBATAN
 KEMENTERIAN KESIHATAN MALAYSIA
 d/a Institut Pengurusan Kesihatan
 Jalan Rumah Sakit, Bangsar
 59000 Kuala Lumpur

Ruj. Kami (5) dlm.KKM/NIHSEC/08/0804/P09-244

Tarikh : 30 Mac 2010

Tn Hj Abdul Malek Bin Abd Aziz
 Jabatan Farmasi
 Hospital Melaka
 06 - 283 3500
 Tuan,

NMRR-09-298-3638

Drug utilisation in the treatment of Diabetes Mellitus in the Ministry of Health (MOH) facilities (DUDM)

Dengan hormatnya perkara di atas adalah dirujuk.

2. Bersama dengan surat ini dilampirkan surat kesimpulan saintifik dan etika bagi projek ini.
3. Penyelidik-penyelidik bersama yang terlibat dalam projek ini adalah seperti di **LAMPIRAN 1**.
4. Adalah dimaklumkan bahawa Puan perlu mengemukakan laporan tahunan, laporan tamat kajian dan juga laporan mengenai "All adverse events, both serious and unexpected" kepada Jawatankuasa Etika & Penyelidikan Perubatan, KKM.

Sekian terima kasih.

BERKHIDMAT UNTUK NEGARA

Saya yang menutus perintah,

(DATO' DR CHANG KIAN MENG)
 Pengerusi
 Jawatankuasa Etika & Penyelidikan Perubatan
 Kementerian Kesihatan Malaysia

31/03 2010 10:26 FAX

NIH SECRETARIAT

002



PEJABAT TIMBALAN KETUA PANGRAH KESIHATAN
OFFICE OF THE DEPUTY DIRECTOR-GENERAL OF HEALTH
(PENYELIDIKAN & SOKONGAN TEKNIKAL)
(RESEARCH & TECHNICAL SUPPORT)
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA
Aras 12, Blok E7, Parsel E, Presint 1
Level 12, Block E7, Parcel E, Precinct 1
Pusat Pentadbiran Kerajaan Persekutuan
Federal Government Administrative Centre
62590 PUTRAJAYA

Tel : 03 88832543
Faks : 03 88895184

MEDICAL RESEARCH & ETHICS COMMITTEE
MINISTRY OF HEALTH MALAYSIA
c/o Institute for Health Management
Jalan Rumah Sakit, Bangsar
59000 Kuala Lumpur

Ruj. Kami : (4)dlm.KKM/NIHSEC/08/0804/P09-244

Tarikh : 30 March 2010

Protocol Title :
Drug utilisation in the treatment of Diabetes Mellitus in the Ministry of Health (MOH)
facilities (DUDM)

Principal Investigator : Tn Hj Abdul Malek Bin Abd Aziz
Department of Pharmacy
Hospital Melaka

Documents received and reviewed with reference to the above study:

1. Study Proposal
2. JTP/KKM3ver1.1
3. Patient Information Sheet & Informed Consent Form - English & Malay
4. Curriculum Vitae of Investigators

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.

Comments (if any):

Project Sites: Hospital Melaka

Decision by Medical Research & Ethics Committee.

- (☒) Approved
() Conditionally Approved
() Disapproved

Date of Decision : 30 March 2010

DR CHANG KIAN MENG
Chairman
Medical Research & Ethics Committee
Ministry of Health Malaysia



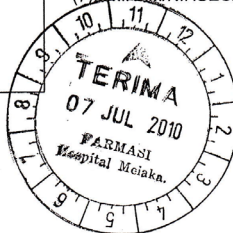
PEJABAT TIMBALAN KETUA PENGARAH KESIHATAN
 OFFICE OF THE DEPUTY DIRECTOR-GENERAL OF HEALTH
 (PENYELIDIKAN & SOKONGAN TEKNIKAL)
 (RESEARCH & TECHNICAL SUPPORT)
 KEMENTERIAN KESIHATAN MALAYSIA
 MINISTRY OF HEALTH MALAYSIA
 Aras 12, Blok E7, Parsel E, Presint 1
 Level 12, Block E7, Parcel E, Precinct 1
 Pusat Pentadbiran Kerajaan Persekutuan
 Federal Government Administrative Centre
 62590 PUTRAJAYA

Tel : 03 88832543
 Faks : 03 88895184

MEDICAL RESEARCH & ETHICS COMMITTEE
MINISTRY OF HEALTH MALAYSIA
 Urusetia NIH

d/a Institut Pengurusan Kesihatan
 Jalan Rumah Sakit, Bangsar
 59000 Kuala Lumpur

(7)dlm KKM/NIHSEC/08/0804/P09-244
 10 Jun 2010



Tuan Hj Abdul Malek Bin Abdul Aziz
 Jabatan Farmasi
 Hospital Melaka

Tuan,

NMRR-09-298-3538

Drug utilisation in the treatment of Diabetes Mellitus in the Ministry of Health (MOH) facilities (DUDM) .

Dengan hormatnya dimaklumkan bahawa Jawatankuasa Etika & Penyelidikan Perubatan, Kementerian Kesihatan Malaysia tiada halangan ke atas permohonan Tuan untuk menambahkan sembilan puluh empat (94) lagi pusat penyelidikan iaitu :

"SEPERTI DI LAMPIRAN A"

Tuan juga perlu menyediakan laporan "All adverse events, both serious and unexpected" kepada jawatankuasa Etika & Penyelidikan Perubatan, KKM.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

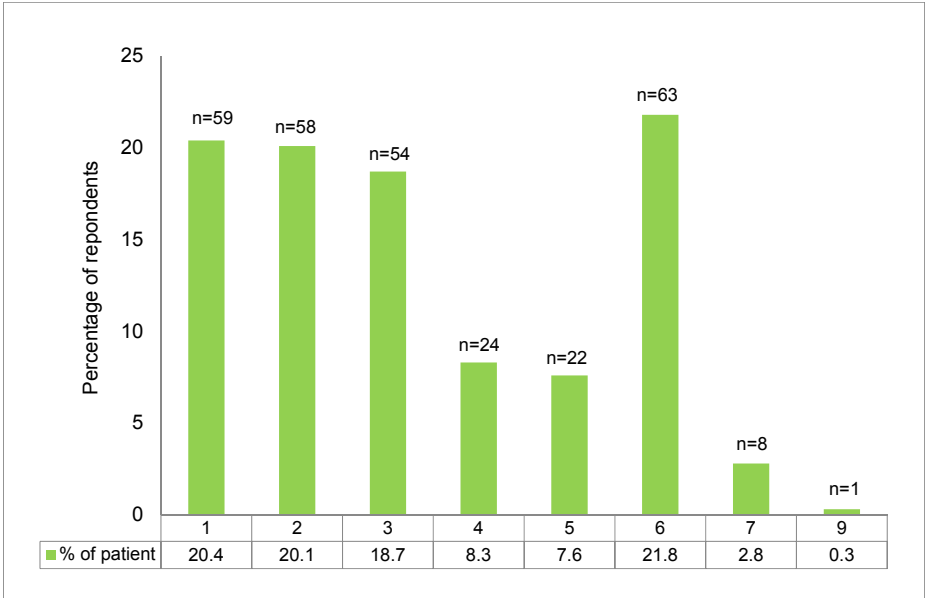
Saya yang menurut perintah,

(DATO' DR CHANG KIAN MENG)

Pengerusi
 Jawatankuasa Etika & Penyelidikan Perubatan
 Kementerian Kesihatan Malaysia

Appendix 10

Percentage of respondents with number of cost diary completed and returned (n=289).



Direct healthcare cost: Cost of ambulatory care per patient per 6-month (n=268).

Details on Cost	All Patients (n=268)				State Hospitals Patients (n=47)				Hospitals with Specialist Patients (n=53)				Hospitals without Specialist Patients (n=85)				Health Clinics Patients (n=83)				
	Consultation Cost *	Laboratory & Investigation	Other Procedures ^b	Medicines	Total	Consultation Cost *	Laboratory & Investigation	Other Procedures ^b	Medicines	Total	Consultation Cost *	Laboratory & Investigation	Other Procedures ^b	Medicines	Total	Consultation Cost *	Laboratory & Investigation	Other Procedures ^b	Medicines	Total	
Total number of visits/ tests	523	671	126	NA	1,320	70	146	4	NA	220	89	105	40	NA	234	148	273	45	NA	466	400
Total Cost of visits/ tests/ Drugs, RM	47,070.00	21,995.00	1,306.00	54,632.28	125,003.28	6,300.00	6,002.00	4.00	16,596.64	30,902.44	8,010.00	2,367.00	143.00	7,746.33	18,266.33	13,320.00	11,286.00	525.00	18,978.89	44,108.89	31,726.42
Mean cost patient per 6-month, RM (SD)	179.63 (167.63)	82.07 (93.40)	4.87 (44.99)	203.85 (450.94)	466.42 (611.42)	134.04 (141.52)	127.7 (262.09)	0.09 (0.35)	395.67 (867.62)	657.50 (1,097.88)	151.13 (147.44)	44.66 (109.77)	2.70 (52.03)	146.16 (226.92)	344.65 (382.43)	155.71 (149.02)	139.76 (250.27)	6.16 (43.54)	293.38 (373.32)	516.93 (612.95)	362.23 (384.35)
Median cost patient per 6-month, RM	180.00	0.00	0.00	26.21	261.47	90.00	0.00	0.00	0.00	180.00	0.00	0.00	3.00	19.23	271.00	180.00	0.00	0.00	91.44	367.94	272.00

*For each doctor visit, consultation cost incurred was RM90.00. (Source: Malaysia. Laws of Malaysia. Fees ACT 1951. Fees (Medical) (Full Paying Patient) Order, 2007. P.U. (A) 252/2007. Peretakan Nasional Malaysia Berhad, Kuala Lumpur)

^bOther treatments refer to physiotherapy, wound dressing, minor surgery and etc.

NA – Not applicable

Appendix 12

Direct healthcare cost: Expenditure on drugs by item (n=289).

Drug Items	n (%)	Total Cost, RM	Mean cost per person, RM (SD)	Median, RM
Metformin	106 (36.7)	3,959.20	37.35 (46.92)	26.72
Sulfonamide, urea derivatives	66 (22.8)	4,178.86	63.57 (51.70)	50.70
Insulin	69 (23.8)	25,100.81	363.78 (584.96)	173.37
Acarbose	9 (3.1)	1,538.99	171.00 (61.97)	179.35
Glucovance	7 (2.4)	273.70	39.10 (30.44)	53.33
DPP4- Inhibitor	1 (0.3)	281.09	281.09	0.00
Other drugs	144 (49.8)	21,397.95	148.60 (178.91)	94.09
Total	149 (51.6)	56,730.59	380.74 (549.19)	232.67

Direct healthcare cost: Cost of hospitalisation in public hospitals, per patient per 6-month (n=20).

Details on Cost	All Patients (n=20) (Total days of admission = 173 days)				State Hospitals Patients (n=5) (Total days of admission = 48 days)				Hospitals with Specialist Patients (n=5) (Total days of admission = 39 days)				Hospitals without Specialist Patients (n=7) (Total days of admission = 79 days)				Health Clinics Patients (n=3) (Total days of admission = 7 days)			
	Admission Fee ^a	Laboratory & Investigation	Drugs	Total	Admission Fee ^a	Laboratory & Investigation	Drugs	Total	Admission Fee ^a	Laboratory & Investigation	Drugs	Total	Admission Fee ^a	Laboratory & Investigation	Drugs	Total	Admission Fee ^a	Laboratory & Investigation	Drugs	Total
Total Cost of admission, RM	27,680.00	5,597.00	5,166.87	38,432.87	7,660.00	1,134.00	1,946.50	10,763.50	6,240.00	3,736.00	860.94	10,836.94	12,640.00	712.00	2,265.81	15,637.81	1,120.00	5.00	69.62	1,194.62
Mean cost patient per 6-month, RM (SD)	1,384.00 (1,965.21)	279.35 (615.35)	258.29 (446.90)	1,921.64 (2,477.31)	1,536.00 (1,200.33)	226.80 (278.59)	386.90 (725.66)	2,152.70 (1,464.17)	1,248.00 (1,423.91)	747.20 (1,141.01)	172.19 (192.01)	2,167.39 (2,571.66)	1,806.71 (3,066.96)	101.71 (138.99)	326.54 (443.96)	2,233.96 (3,468.99)	373.33 (164.75)	1.67 (2.89)	23.21 (37.61)	398.21 (268.36)
Median cost patient per 6-month, RM	640.00	37.5	72.96	851.44	960.00	110.00	386.90	2,400.00	480.00	422.00	103.75	976.52	640.00	45.00	70.61	861.75	480.00	0.00	3.02	488.02

^a Admission fee per-day was RM160.00 (Source: Malaysia, Laws of Malaysia, Fees Act 1951, Fees (Medical) (Full Paying Patient) Order, 2007, P.U. (A) 252/2007, Percetakan Nasional Malaysia Berhad, Kuala Lumpur.)

Appendix 14

Direct non-healthcare cost per patient per 6-month, for ambulatory care and hospitalisation (n=268)

Details on Cost	All Patients (n=289) *						State Hospitals Patients (n=53) *						Hospitals with Specialist Patients (n=68)					
	Consumables	Complementary Treatment	Transportation	Lodging	Homehelp	Total	Consumables	Complementary Treatment	Transportation	Lodging	Homehelp	Total	Consumables	Complementary Treatment	Transportation	Lodging	Homehelp	Total
n (%)	209 (72.3)	38 (13.1)	284 (98.3)	8 (2.8)	12 (4.2)	286 (99.0)	40 (75.5)	7 (13.2)	51 (96.2)	0 (0.0)	2 (3.8)	52 (98.1)	50 (86.2)	8 (13.8)	58 (100.0)	2 (3.4)	4 (6.9)	58 (100.0)
Total Direct Non-healthcare Cost, RM	106,290.79	19,451.20	67,888.39	1,363.50	10,096.90	205,090.78	19,875.79	2,025.20	12,869.25	NA	5,600.00	40,370.24	22,487.81	2,047.00	16,305.01	254.00	925.00	42,018.82
Mean cost patient per 6-month, RM (SD)	508.57 (1,041.49)	511.87 (1,402.07)	239.04 (342.82)	170.44 (328.72)	841.41 (1,348.76)	2,271.33	496.89 (1,468.78)	289.31 (317.20)	252.34 (317.89)	NA	2,800.00 (2,969.85)	3,838.54	449.76 (617.76)	265.88 (377.66)	281.12 (377.66)	127.00 (159.81)	231.25 (230.55)	1,345.01
Median cost patient per 6-month, RM	215.00	111.00	239.04	33.75	430.00	327.55	252.80	256.00	131.50	NA	2,800.00	412.30	253.00	152.20	140.70	127.00	242.00	490.70

* These patients were not included due to missing data.

NA – Not Applicable

Appendix 14

continue

Details on Cost	Hospitals without Specialist Patients (n=92) ^a						Health Clinics Patients (n=86) ^a					
	Consumables	Complementary Treatment	Transportation	Lodging	Homehelp	Total	Consumables	Complementary Treatment	Transportation	Lodging	Homehelp	Total
n (%)	54 (58.7)	13 (14.1)	91 (98.9)	4 (4.3)	3 (3.3)	91 (98.9)	65 (75.6)	10 (11.6)	84 (97.7)	2 (2.3)	3 (3.5)	85 (98.8)
Total Direct Non-Healthcare Cost, RM	33,088.54	2,287.00	22,101.10	134.50	1,554.90	59,166.04	30,838.65	13,092.00	16,613.03	975.00	2,017.00	63,535.68
Mean cost patient per 6-month, RM (SD)	612.75 (958.01)	175.92 (231.85)	242.87 (296.93)	33.63 (39.31)	518.30 722.18	1,583.47	474.44 (1,070.19)	1,309.20 (2,754.27)	196.77 (378.43)	487.50 (688.22)	672.33 (462.49)	3,140.24
Median cost patient per 6-month, RM	274.50	80.00	147.00	26.75	154.90	277.20	146.88	87.50	117.75	487.50	617.00	230.30

^a Three patients were not included due to missing data.

NA – Not Applicable

Appendix 15

Direct non-healthcare cost: Cost of miscellaneous on ambulatory care per patient per 6-month (n=268)

Details on Cost	All Patients (n=268)				State Hospitals Patients (n=47)				Hospitals with Specialist Patients (n=83)				Hospitals without Specialist Patients (n=85)				Health Clinics Patients (n=83)			
	Clinic Visit Charges	Private Lab	Drugs	Total	Clinic Visit Charges ^a	Private Lab	Drugs	Total	Clinic Visit Charges ^a	Private Lab	Drugs	Total	Clinic Visit Charges ^b	Private Lab	Drugs	Total	Clinic Visit Charges ^b	Private Lab	Drugs	Total
n (%)	117 (43.7)	21 (7.8)	38 (14.2)	153 (57.1)	18 (38.3)	2 (4.3)	5 (10.6)	27 (57.5)	24 (45.3)	2 (3.8)	7 (12.1)	30 (56.6)	35 (41.2)	9 (10.6)	11 (12.9)	44 (51.8)	40 (48.2)	8 (9.6)	15 (18.1)	51 (61.5)
Total number of visit	689	68	0	757	94	3	0	97	143	9	0	152	243	43	0	286	209	13	0	222
Total Miscellaneous Cost, RM	5,505.00	1,477.00	6,131.28	13,113.28	547.00	13.00	459.90	1,019.90	1,419.50	88.00	922.80	2,430.30	936.50	536.00	4,020.36	5,492.86	2,602.00	840.00	728.22	4,170.22
Mean cost patient per 6-month, RM (SD)	47.05 (165.19)	70.33 (92.90)	161.35 (288.68)	278.73	30.39 (68.34)	6.50 (2.12)	91.98 (69.06)	128.87	59.15 (90.69)	44.00 (5.66)	131.83 (109.64)	234.98	26.76 (62.82)	59.56 (84.78)	365.49 (476.08)	451.81	65.05 (264.41)	105.00 (116.41)	48.55 (57.47)	218.60
Median cost patient per 6-month, RM	5.00	35.00	70.60	10.00	10.00	6.50	71.20	15.00	17.50	44.00	106.00	20.00	2.00	30.00	110.00	3.50	3.00	39.00	20.00	7.35

^aRM5.00 Clinic Visit Charges

^bRM1.00 Clinic Visit Charges

Direct non-healthcare cost: Cost of drugs by items (n=289)

Drug Items	n (%)	Total Cost, RM	Mean cost per person, RM (SD)	Median, RM
Metformin	6 (2.1)	296.78	49.46 (110.02)	5.71
Sulfonamide, urea derivatives	4 (1.4)	48.92	12.23 (7.09)	12.68
Vildagliptin	2 (0.7)	668.30	334.15 (210.93)	334.15
Acarbose	1 (0.3)	35.87	35.87	0.00
Glucovance	1 (0.3)	73.33	73.33	0.00
DPP4 - Inhibitor	1 (0.3)	875.00	875.00	0.00
Other DM Drugs	4 (1.4)	1667.40	416.85 (634.20)	130.00
Non-DM Drugs (Others)	39 (13.5)	3,835.10	98.34 (154.54)	39.65
Total	44 (15.2)	7,500.70	170.47 (292.09)	70.60

Direct non-healthcare cost: Expenses of consumables (by consumables category), per patient per 6-month (n=289)

[illegible]

^a Medical : Insulin needle, lancet, strip, alcohol swab, medical device, bandage & cotton.

^b Complementary medicine : Multivitamins, Supplements, Glucosamine, Fish Oils, Spirullina and Herbal.

^c Food: Oats, Rice (multigrain), Diabetic Milk.

^d Others: Exercise Equipment, Shoes and others.

Direct non-healthcare cost: Detailed expenses on consumables (n=289)

Consumables	n (%)	Total Cost, RM	Mean cost per person, RM (SD)	Median, RM
Insulin needle	147(50.9)	11,175.62	76.02(59.16)	60.00
Lancet	23 (8.0)	865.80	37.64 (23.39)	30.00
Strip	84 (29.1)	11,616.43	138.29 (113.76)	97.00
Alcohol Swab	32 (11.1)	994.90	31.09 (39.04)	17.00
Medical Device	20 (6.9)	3,788.80	189.44 (149.09)	171.15
Exercise Equipment	6 (2.1)	24,154.00	4,025.67 (3,194.28)	3197.00
Bandage & Cotton	22 (7.6)	1,504.13	68.37 (80.04)	40.00
Supplements	36 (12.5)	11,131.77	309.22 (451.51)	128.00
Multivitamins	22 (7.6)	3,605.40	163.88 (179.51)	97.45
Glucosamine	9 (3.1)	1,305.20	145.02 (118.35)	108.00
Fish Oil/ Olive Oil /Spirulina	17 (5.9)	6,109.92	359.41 (608.37)	120.00
Diabetic Milk	41 (14.2)	6,031.87	147.12 (132.80)	116.00
Rice (multigrain)	36 (12.5)	2,731.19	75.87 (61.62)	56.85
Oats	22 (7.6)	2,181.17	99.14 (134.52)	64.25
Herbal	76 (26.3)	15,998.29	210.50 (346.58)	120.29
Others*	21 (7.3)	3,096.30	147.44 (303.93)	38.00
Total	209 (72.3)	106,290.79	508.57 (1,041.49)	215.00

*Others: Example diabetic shoes, diapers, exercise equipments, glucometer battery etc.

Appendix 19

Estimation of total cost for treatment of DM (based on patients characteristics)

Patient characteristics	Direct Cost, RM (n= 289)				Indirect Cost, RM (n= 285)					
	n (%)	6-month		Estimation per month (SD)	Estimation total cost per patient per year	n (%)	6-month		Estimation per month (SD)	Estimation total cost per patient per year
		Mean per patient (SD)	Mean per patient (SD)				Mean per patient (SD)	Mean per patient (SD)		
Gender										
Male	118(40.8)	1,418.63 (2,493.64)	236.44 (415.61)	2,837.26	117(41.1)	1,533.04 (984.50)	85.65 (164.08)	3,066.08		
Female	171(59.2)	1,463.79 (1,856.23)	243.97 (309.37)	2,927.58	168(58.9)	673.71 (1,483.74)	112.29 (247.29)	1,347.42		
Age, years										
< 45	48(16.6)	1,021.79 (1,045.93)	170.30 (174.32)	2,043.58	48(16.8)	555.79 (847.39)	92.63 (141.23)	1,111.58		
45 to 49	30(10.4)	1,922.67 (2,966.09)	320.45 (494.35)	3,845.34	30(10.5)	761.01 (1,306.23)	126.84 (217.71)	1,522.02		
50 to 54	73(25.2)	1,248.21 (1,597.00)	208.04 (266.17)	2,496.42	72(25.3)	737.36 (2,103.99)	122.89 (350.67)	1,474.72		
55 to 59	77(26.6)	1,545.59 (2,775.50)	257.60 (462.58)	3,091.18	75(26.3)	600.64 (977.45)	100.11 (162.91)	1,201.28		
60 to 64	49(17.0)	1,826.25 (2,034.92)	304.38 (339.15)	3,652.51	48(16.8)	445.19 (433.05)	74.20(72.18)	890.38		
≥ 65	12(4.2)	947.04 (947.87)	157.84 (157.98)	1,894.08	12(4.2)	358.02 (258.21)	59.67 (43.04)	716.04		
Race										
Malay	186(64.4)	1,457.86 (2,375.25)	242.98 (395.88)	2,915.72	182(63.9)	635.26 (1,489.18)	106.14 (248.86)	1,270.52		
Chinese	40(13.8)	1,219.21 (1,107.79)	203.20 (184.63)	2,438.42	40(14.0)	465.61 (419.15)	77.60 (69.86)	931.22		
Indian/Punjabi	33(11.4)	1,600.87 (1,791.66)	266.81 (298.61)	3,201.74	33(11.6)	675.01 (1,042.91)	112.50 (173.82)	1,350.02		
Others	30(10.4)	1,498.26 (2,001.34)	249.71 (333.56)	2,996.52	30(10.5)	559.83 (1,139.06)	93.30 (189.84)	1,119.66		
Occupation										
Government Employee	89(33.7)	1,413.53 (1,841.41)	235.59 (306.90)	2,827.06	88(33.6)	777.67 (2,007.55)	129.61 (334.59)	1,555.34		
Private Employee	32(12.1)	1,251.75 (2,218.32)	208.63 (369.72)	2,503.50	32(12.2)	377.49 (397.79)	62.92 (66.30)	754.98		
Self Employed	28(10.6)	906.50 (669.54)	151.08 (111.59)	1,813.00	28(10.7)	326.06 (362.77)	54.34 (60.46)	652.12		
Retiree	48(18.2)	1,597.67 (1,853.93)	266.28 (308.99)	3,195.34	48(18.3)	496.31 (430.35)	82.72 (71.73)	992.62		
Housewife	37(14.0)	1,213.82 (1,390.94)	202.30 (231.82)	2,427.64	36(13.7)	727.98 (868.40)	121.33 (144.73)	1,455.96		
Unemployed	30(11.4)	1,449.41 (1,789.64)	241.57 (298.27)	2,898.82	30(11.5)	353.43 (288.86)	58.91 (48.14)	706.86		

continue

Patient characteristics	Direct Cost, RM (n= 289)				Indirect Cost, RM (n= 285)					
	n (%)	6-month		Estimation per month (SD)	Estimation total cost per patient per year	n (%)	6-month		Estimation per month (SD)	Estimation total cost per patient per year
		Mean per patient (SD)					Mean per patient (SD)			
Household Income, RM										
< 1,000	54(19.8)	1,825.88 (3,221.19)	304.31 (536.87)	3,651.76	54(19.9)	424.04 (1,111.15)	70.67 (185.19)	848.08		
1,000 – 3,000	134(49.1)	1,196.05 (1,415.75)	199.34 (235.96)	2,392.10	133(48.9)	609.15 (1,569.20)	101.53 (261.53)	1,218.30		
3,001 – 5,000	49(17.9)	1,143.55 (1,646.74)	190.59 (274.46)	2,287.10	48(18.0)	586.66 (872.30)	97.78 (145.38)	1,173.32		
> 5,000	36(13.2)	2,180.27 (2,830.24)	363.38 (471.71)	4,360.54	36(13.2)	971.04 (1,120.60)	161.84 (186.77)	1,942.08		
Duration of DM, years										
≤ 5	97(37.6)	1,091.41 (1,514.86)	181.90 (252.48)	2,182.82	96(37.5)	486.96 (799.12)	81.16 (133.19)	973.92		
> 5 to < 10	48(18.6)	1,271.78 (1,252.39)	211.96 (208.73)	2,543.56	48(18.8)	573.11 (1,071.40)	95.52 (178.57)	1,146.22		
≥ 10	113(43.8)	1,509.33 (1,880.52)	251.56 (313.42)	3,018.66	112(43.8)	649.55 (1,610.45)	108.26 (268.41)	1,299.10		
Insulin										
Yes	138(47.8)	1,509.03 (1,668.08)	251.51 (278.01)	3,018.06	137(48.1)	688.33 (1,558.01)	113.89 (258.90)	1,376.66		
No	151(52.2)	1,387.15 (2,491.53)	231.19 (415.26)	2,774.30	148(51.9)	533.85 (1,010.21)	88.975 (168.37)	1,067.70		
Number of co-morbidities										
0	67(23.2)	1,242.95 (1,606.02)	207.16 (267.67)	2,485.90	66(23.1)	531.60 (702.81)	88.60 (117.14)	1,063.20		
1	123(42.6)	1,588.47 (2,783.31)	264.75 (463.89)	3,176.94	121(42.3)	630.36 (1,728.26)	105.06 (288.04)	1,260.72		
> 1	99(34.3)	1,404.51 (1,402.08)	234.09 (233.68)	2,809.02	99(34.6)	631.15 (965.28)	105.19 (160.88)	1,262.30		

*Estimation per-month was calculated by dividing the 6-month Mean Direct Cost per patient

GLOSSARY

Ambulatory Care	Ambulatory care is a type of medical care that is provided to patients who do not need to be admitted to a hospital for treatment (e.g., traditional treatment, blood test, wound dressing).
Ambulatory visit	Ambulatory visit is patient's visit to ambulatory care facilities (e.g., visits to GP, specialist care).
Complementary treatment	Complementary medicine is defined as health care which lies for the most part outside the mainstream of conventional medicine.
Dietary supplement	Dietary supplement is a preparation intended to supplement the diet and provide nutrients that may be missing or may not be consumed in sufficient quantities in a person's diet.
Direct healthcare cost	The use of health care services, (e.g., visits to the GP, specialist care, medications), cost incurred by the patients and family, costs of health activities, hours paid and unpaid household help, transportation and value of out-of-pocket expenses.
Direct non-healthcare cost	Costs incurred by the patient and family to seek treatment (e.g., costs of over-the-counter medication, costs of health activities, hours of paid and unpaid household help, transportation, and the value of other out-of-pocket expenses).
Disposable	A disposable is a product designed for a single use after which it recycled or is disposed as a solid waste. It including test-strips, lancets, needles, alcohol swabs and gauzes.
Drugs	All prescription and pharmacy items including OTC items (e.g., Cough syrups, Paracetamol, Antacids, etc).
Herbs	Herbs are any plants use for food (or drink) or medicine.
Home help	Home help is healthcare or supportive care provided in the patient's home and may include daily tasks (e.g., nursing care, physiotherapy, laundry, cleaning the home and preparing meals).

Indirect cost	The costs refer to the value of production lost due to illness-related absence (e.g., no. of days absent from housekeeping and other related activities).
Laboratory & monitoring	Laboratory analysis performed on sample that is usually extracted from patient to determine physiological and biochemical states (e.g., disease, mineral content, drug effectiveness and organ function).
Medical device	Any device designed to aid in the diagnosis, monitoring or treatment of medical conditions.
Modern treatment	Medicine is the applied science or practice of diagnosis, treatment, and prevention of disease.
Out-of-pocket	Spending made individual or family for the purchases of healthcare service or products.
Reflexology	Reflexology is an alternative medicine involving the physical act of applying pressure to the feet, hands or ears with specific hand techniques without the use of oil or lotion.
Traditional treatment	Traditional treatment refers to health practices, approached, knowledge and beliefs incorporating plant, animal and mineral-based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being.
Treatment procedures	A treatment procedure is a course of action with the intention of determining, measuring or diagnosing a patient condition or parameter.



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