STUDY PROTOCOL

Economic evaluation and clinical impact of home medication review (HMR) by community pharmacists among patients with type 2 diabetes mellitus (T2DM)

Version 3: 13/1/2019

INVESTIGATORS

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BACKGROUND

Home Medication Review (HMR), also known as 'pharmacist-led medication review' is defined as 'systematic assessment of consumer's medication and management of those medications with the aim of optimising consumer health outcome and identifying potential medication-related issues within framework of the quality use of medicine'[1]. In many developed countries (i.e. Australia, New Zealand, the United Kingdom, the United State of America), the models of pharmacist-led medication review[1] in the community or residential aged care setting have been developed. Numerous overseas studies have demonstrated that HMR could benefit patients with multiple chronic conditions, age or social circumstance, complexity of their drug regimen, and lack of knowledge or skill on using medication or medication device[2,3,4].

In Malaysia, HMR was initiated by Pharmaceutical Services Division, Ministry of Health (MOH). In 2011, the first protocol for HMR was published to standardise the practice among all pharmacists who can provide HMR services under MOH facilities[5]. The HMR is conducted by MOH pharmacists, either from hospitals or health clinics, focus primarily in these four types of patients; psychiatrics, geriatrics, stroke, and paediatrics. To date, only two studies have been conducted in the local setting; both involved HMR services provided by the MOH pharmacists

to type 2 diabetes mellitus (T2DM)[6,7]. Both studies involved pharmacists from MOH health clinics; finding revealed that HMR significantly reduced the percentage of HbA1c by 1.04%, improved patients' knowledge about the disease and quality of life (QoL).

T2DM patients normally have a complex drug regimen, with or without the use of insulin that is challenging for patient to comply with. As such, HMR would likely benefit this patient population. Of note, the majority of T2DM patients are usually diagnosed with other co-morbidities. More importantly, in Malaysia, diabetes prevalence among adults aged above 18 years old has increased from 15.2% (i.e. an estimated of 2.6 million in 2011[8]) to 17.5% in 2015 (i.e. an estimated population of 3.5 million[9]). The prevalence of diabetes among adults aged above 18 years in Malaysia is much higher than the average prevalence of DM in South-East Asia region where the prevalence only 8.4% in 2014[10]. Uncontrolled blood sugar level have led to both macro- and micro-vascular complications including blindness, kidney failure, lower limb amputation, stroke and heart attack[10]. These will have an impact on the government in terms of cost and manpower in treating the disease and in managing its complications[11,12].

Whilst HMR is a widely researched service worldwide, very few studies evaluated the HMR service provided by community pharmacists[13]. Likewise, little is known about the potential role of community pharmacists in providing such services in Malaysia. Community pharmacist is one of the front liners in primary healthcare setting. The main role of community pharmacists are to make sure the use of medicine is safe, effective and efficient[14,15]. In France, community pharmacists also perform in collaboration with general practitioner (GP), medication review, drug adjustment and repeat dispensing[16]. In Malaysia, the number of community pharmacists has significantly increased in year 2016 (i.e. 3094 community pharmacists) compared to 2011 (i.e. 1854 community pharmacists)[17]. Moreover, MOH recently allows the provisionally registered pharmacists to be trained in the community setting, and thus, the projection of community pharmacies is expected to increase drastically[18]. Accordingly, the new extension in the role of community pharmacists in pharmaceutical care is anticipated, HMR conducted by community pharmacists (HMR-CP), a comprehensive clinical review of a patient's medicines at his/her home by an accredited community pharmacists upon referral from the patient's Family Medicine Specialist (FMS), medical officers (MO) or general practitioner (GP), could have benefit T2DM patients who live independently in the community and this warrants for further investigations[16].

STUDY OBJECTIVES

GENERAL OBJECTIVE:

To develop and evaluate home medication review by community pharmacists (HMR-CP) programme in optimising diabetes care in Malaysia.

SPECIFIC OBJECTIVES:

1. To determine the clinical impact of HMR-CP (i.e. glycaemic control, number of drug related problems, adverse events, readmission rate) among patients with T2DM.
2. To determine the humanistic outcomes of HMR-CP (i.e. medication adherence, QoL, patients' knowledge about the disease, wastage of medicine supplied by MOH) among T2DM patients.
3. To determine the cost-effectiveness of implementing HMR-CP in Malaysia.
4. To explore stake holders' perception on implementation of HMR-CP.

STUDY METHODOLOGY

This study will adopt a randomised clinical study design. During the study, both quantitative and qualitative research will be used. The established protocol of HMR by Pharmaceutical Service Division, MOH will be referred in developing the programme. The EQ-5D-5L instrument will be used to measure patients' quality of life (QoL)[19]. Meanwhile, the Malaysian version of 14-item Michigan Diabetic Knowledge will be used to measure patients' knowledge about the disease[20],[21]. A set of toolkit that comprises of a set of standardised forms, and device (i.e. glucometer and blood pressure monitor) will be provided to ensure that all community pharmacists who involve in this programme deliver the information consistently to all participants. Community pharmacists who agree to join the programme and fulfil the inclusion criteria as stated in community pharmacists agreement (appendix 11) will be recruited and trained. Ethical approval from Medical Research & Ethics Committee (MREC), MOH and UiTM Research Ethics Committee will be obtained prior to the commencement of this study.

The study is mainly divided into 5 stages:

Stage 1
- Pre-Intervention Phase

Stage 2
- Training the community pharmacists

Stage 3
- Pilot Study and Intervention phase

Stage 4
- Economic Evaluation
  - Activity based costing, Cost effectiveness Analysis
  - Perspective and outcomes

Stage 5
- Qualitative review from healthcare profesionals and patients

STAGE 1: PRE-INTERVENTION PHASE

Objective:

To develop a programme procedure and manual for HMR-CP

Methodology:

Development of programme and manual:

In Malaysia, there is no extension of pharmaceutical care programme such as HMR done by community pharmacists for the MOH patients. This programme is a pioneer programme that integrates both public and private organisations. The MOH through Pharmaceutical Service Division launched the first protocol of HMR in 2011 and this programme will adopt the HMR protocol with minor modifications[5].

The forms that will be used in HMR-CP programme are as following:

a. Appendix 1 : HMR-CP 1 Review Referral Form (Referral form from FMS/MO to community pharmacists)
b. Appendix 2: HMR-CP 2 Participant/ Caregiver Consent Form (To get consent from patient or caregiver)
c. Appendix 3: HMR-CP 3 Review Appointment Record (Master record for all subjects)
d. Appendix 4:HMR-CP 4 Home and Community Visit Risk Assessment (To be filled up by researcher to assess the risk for each subject)
e. Appendix 5: HMR-CP 5 Medication Identification Chart (List of medication prescribe by FMS)
f. Appendix 6: HMR-CP 6 Information Gathering Form. (To be filled up by community pharmacists during first visit for HMR-CP, consists of patient profile, medical status, issues related to medication used, patients' current medication include OTC, medication related issues, and pharmaceutical care issues.
g. Appendix 7: HMR-CP7 Information Gathering Form (To be filled up by community pharmacists during second and third visit for HMR-CP, consists of patient profile, patients' current medication include OTC, medication related issues, and pharmaceutical care issues.
h. Appendix 8: HMR-CP8 Report Writing (Report by community pharmacist to FMS/MO)
i. Appendix 9: HMR-CP 9 Pill Count Data Collection Sheet for Patients on Oral Medications (To count the medication balance, missing dose and wastage)
j. Appendix 10: HMR-CP 10 Activities Checklist. (Checklist for the whole activity)
k. Appendix 11: HMR-CP Agreement with Community Pharmacy
l. Appendix 12: HMR-CP Consent for Focus Group from participant
m. Appendix 13: HMR-CP for Quality of life tools (EQ-5D-5L)
n. Appendix 14: HMR-CP for Patients' Knowledge about Diabetes (14-item MDKT)

STAGE 2: TRAINING THE COMMUNITY PHARMACISTS

Objective:

To run a training session on HMR-CP procedures and forms for community pharmacists who volunteered to participate in the programme.

Methodology:

The community pharmacists in Kelantan will be invited to join this programme through Malaysian Community Pharmacy Guild (MCPG) Kelantan branch. The community pharmacists who agree to join HMR-CP programme will be trained on how to use HMR-CP forms. Below are the inclusion and exclusion criteria of community pharmacists who can join this programme.

Inclusion Criteria:
- Community Pharmacists with valid Licence A.
- Working at community pharmacy
- Communicate in Malay and English.
- Willing to follow the terms and conditions in Community Pharmacist Agreement (appendix 11)

Exclusion Criteria:
- Have no transport to visit patients at home

STAGE 3: PILOT STUDY AND INTERVENTION PHASE

STUDY DESIGN:

A randomised study design will be adopted in this study. The consent will be taken from patients during their visit to health clinic and the data collected on that day will be used as pre-intervention/baseline.

STUDY PLACE:

a. Bandar Pasir Mas Health Clinic.
b. The medication review will be done at patients' house located within 25km radius from the Bandar Pasir Mas Health Clinic.

RECRUITMENT METHOD:

The researcher will screen for eligible patients based on inclusion and exclusion criteria. A total of 166 patients who agree to participate in this programme will be randomly assigned into two groups: (1) intervention group (who will receive HMR-CP at 0-month, 3-month and 6-month) and (2) control group (will not receive HMR-CP but will followed up at 3 and 6 months interval). The randomization will be done using Microsoft Excel.

STUDY POPULATION:

T2DM patients from Bandar Pasir Mas Health Clinic who fulfil the following inclusion and exclusion criteria will be recruited for the study.

Inclusion criteria for participants are:
1. Adult patients (more than 18 years old) diagnosed with Type 2 Diabetes Mellitus.
2. Patients with current HbA1c more than 6.5%
3. Patients taking five (5) or more medications for long term therapy or taking more than twelve (12) doses of medications daily.
4. Patients stayed in 25 km radius from Bandar Pasir Mas Health Clinic

Exclusion criteria:

1. Enduring mental health problems or dependant with caretaker
2. Insufficient understanding of English/ Bahasa Malaysia.
3. Patients who are homeless or do not have a proper place to stay.
4. Foreign workers or non-permanents residents.
5. Patients with blood disorders (i.e. haemolytic anemia, haemoglobinopathy[22], chronic lymphocytic leukemia).
6. Patients diagnosed with chronic kidney disease.

SAMPLE SIZE CALCULATION:

The level of glycaemic in the participants' body is a primary outcome for this study. Glycaemic value is measured through HbA1c. A reduction of 1% HbA1c is associated with 21% death related to diabetes, 37% risk reduction for microvascular complications, 21% risk reduction of diabetes related-end point and 14% myocardial infarction[23]. Hence, a 1% reduction in HbA_{1c} is considered to be clinically relevant. Based on an expected average value of HbA1c at 9.23% for the control group, an expected average reduction of 1.04% HbA1c in intervention group, with standard deviation of 2.16%[7], a power of 80% and a two-tailed alpha of 0.05, the required sample size is 69 intervention subjects and 69 control subjects. Allowing for a dropout/loss to follow-up rate of 20%, at least 166 participants will be recruited, 83 experimental subjects and 83 control subjects. This was calculated using PS Power and Sample Size Calculations (Version 3.0, Dupont & Plummer, 2009).

DATA COLLECTION:
Measuring outcomes and Instruments

The conceptualisation in healthcare outcome was divided into three different type of outcome; economic, clinical, and humanistic outcome (ECHO)[24]. Clinical outcomes were defined as medical events that occur as a result of disease or treatment; humanistic outcomes were defined as consequences of disease or treatment on functional status, health status or quality of life; and economic outcomes were defined as total costs of medical care associated with treatment alternatives balanced against clinical or humanistic outcomes[24].
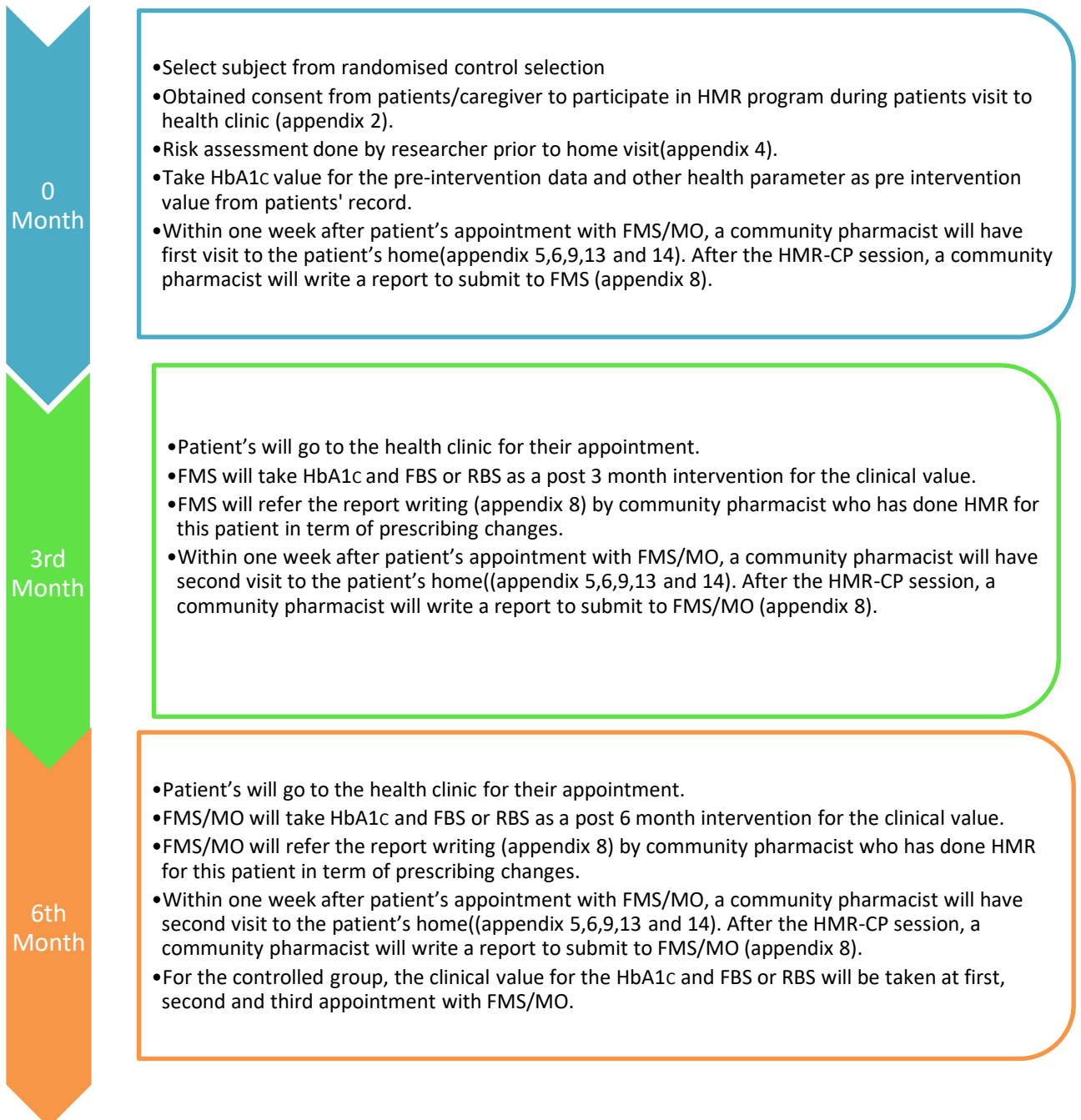
Primary outcome:

1. HbA_{1c}

    a. Participants will be reminded to fast for 10 hours from previous night.
    b. 5 mL venous blood will be withdrawn by appointed nurse/medical doctor at baseline (Pre- HMR-CP, first appointment with FMS/MO), post HMR-CP at 3 months (during second appointment with FMS/MO) and post HMR-CP at 6 months (during third appointment with FMS/MO).
    – Blood samples will be sent to an appointed laboratory and results will be obtained by investigators for documentation.
    – Results will be documented in investigators-developed data collection form.

Secondary outcomes:

All secondary outcomes will be measured at baseline (0 month during HMR-CP), post HMR-CP at 3 and 6 months during HMR by community pharmacists.

1. Clinical parameters –Fasting blood glucose, blood pressure and body mass index (BMI) (appendix 6 and 7, part 1).
   – To be documented in investigators-developed data collection form.

2. Medication / medical related issues (Part 5 appendix 6 and 7,)
   – To be measured with screening tools adapted from HMR guideline from MOH.

3. Medication Adherence (Appendix 9)
   – To be measured based on Pill Count
   – Measurement is based on mean percentage different of number of medicines left and number of medicines should be left.

4. Wastage of medication (Appendix 9)
   – To be calculated based on the over stock of medication hold by patient and price based on current price purchased by government.

5. Quality of Life will be measured using EQ-5D-5L tools (Appendix 13).

6. Patient's knowledge about the disease will be measured using Malaysian version 14-item Michigan Diabetes Knowledge Test (Appendix 14).

Interventions

0 Month
- Select subject from randomised control selection
- Obtained consent from patients/caregiver to participate in HMR program during patients visit to health clinic (appendix 2).
- Risk assessment done by researcher prior to home visit(appendix 4).
- Take HbA1c value for the pre-intervention data and other health parameter as pre intervention value from patients' record.
- Within one week after patient's appointment with FMS/MO, a community pharmacist will have first visit to the patient's home(appendix 5,6,9,13 and 14). After the HMR-CP session, a community pharmacist will write a report to submit to FMS (appendix 8).

3rd Month
- Patient's will go to the health clinic for their appointment.
- FMS will take HbA1c and FBS or RBS as a post 3 month intervention for the clinical value.
- FMS will refer the report writing (appendix 8) by community pharmacist who has done HMR for this patient in term of prescribing changes.
- Within one week after patient's appointment with FMS/MO, a community pharmacist will have second visit to the patient's home((appendix 5,6,9,13 and 14). After the HMR-CP session, a community pharmacist will write a report to submit to FMS/MO (appendix 8).

6th Month
- Patient's will go to the health clinic for their appointment.
- FMS/MO will take HbA1c and FBS or RBS as a post 6 month intervention for the clinical value.
- FMS/MO will refer the report writing (appendix 8) by community pharmacist who has done HMR for this patient in term of prescribing changes.
- Within one week after patient's appointment with FMS/MO, a community pharmacist will have second visit to the patient's home((appendix 5,6,9,13 and 14). After the HMR-CP session, a community pharmacist will write a report to submit to FMS/MO (appendix 8).
- For the controlled group, the clinical value for the HbA1c and FBS or RBS will be taken at first, second and third appointment with FMS/MO.

Data management and analysis:

All collected data will be analysed using statistical software IBM SPSS version 22. Categorical variables will be presented using descriptive statistics (frequency, percentage, median) whereas continuous data will be presented as mean ± standard deviation. For continuous data, independent t-test (Mann-Whitney test if non-parametric) and two-way repeated measures ANOVA (Friedman test if non-parametric) will be used accordingly to compare the differences between different time-points. On the other hand, chi-square test will be used for comparisons of categorical data. A significance level for this study is set at 0.05.

STAGE 4: ECONOMIC EVALUATION
Objective:

To evaluate the cost incurred for HMR-CP and its cost effectiveness analysis.

Methodology:

Economic evaluation is used to address the fundamental question in pharmacoeconomics on how much to allocate a limited resources of healthcare to maximise health gain[25]. Activity based costing (ABC) is the most suitable method to be used in analysing a true cost for the specific programme or activity[26]. This study will focus on cost and cost-effectiveness of HMR-CP from the perspective of healthcare provider. The cost analysis will be conducted based on primary data collection during intervention[27]. In determining the cost-effectiveness, the effect of clinical parameter will base on percentage of HbA1C[28]. The analysis of the cost will be done prospectively during 6 month of HMR-CP programme. All the cost will be calculated in ringgit Malaysia (RM). Future cost and clinical benefit will be discounted at the rate of 3% with sensitivity analysis (0% and 5%), in accordance with pharmacoeconomic guideline in Malaysia[29]. Healthcare cost from provider perspective in HMR-CP programme will be divided into 5 cost centre; consultation with FMS, monitoring of clinical outcomes, HMR service, drug dispensing, and adverse event[30]. Each cost centre will have their own cost of activities such as personal cost, drug cost, co-morbidity cost and readmission cost. The cost of drugs will obtain from Bandar Pasir Mas Health Clinic.

STAGE 5: QUALITATIVE REVIEW

Objective:

To explore the view of the stakeholders; patients, community pharmacists, medical officers and family medicine specialist on HMR-CP

Methodology:

After the HMR-CP programme, the researcher will conduct a focus group discussion between the healthcare professional (i.e. FMS, medical officers and community pharmacists). One to one interview will be carried out for the patients who received HMR-CP services. The qualitative study aims to explore views from all stakeholders involved in this programme. The focus group survey will be conducted by moderator and will be recorded, and transcribed. The number of participants will be between 6-8 per focus group and it will be repeated until data saturation point is reached[31],[32]. A semi-guided questionnaire will be used to stimulate the point of discussion among the participants. Open-ended questions will be used in both focus group discussion and interview to allow the participant to give their feedback[33]. The sample size is for qualitative study based on data saturation point. The inclusion and exclusion criteria are as following:

Inclusion criteria:
   a. Stakeholders who were involved in HMR-CP programme.
   b. Willing to join focused group survey and giving consent (appendix 12).
   c. Sufficient understanding of English / Bahasa Malaysia

Exclusion criteria:
   a. Patients who did not willing to be interviewed.

PUBLICATION AND REPORTING OF RESULTS

The outcome of this work will be published in appropriate peer-reviewed journals and presented at conferences. A report will also be submitted to MREC as needed. All data will be de-identified and pooled for analysis and publication of results.

ADVERSE EVENTS – RISK AND MANAGEMENTS

The chance of an adverse event or unforeseen events occurring is minimal to negligible given the nature of this project. Researchers will extract information that readily available in patients' medical records. Thus, there is no adverse reaction or unforeseen events anticipated. Any unforeseen events in relation to the information privacy will be reported to MREC as appropriate.

ETHICAL ISSUES TO CONSIDER

Identification and Consent of Patients

The identity of the patients is of no interest in this study. Only demographic and clinical data will be collected. To avoid duplication of data collection, each patient will be given a study code number. All links between study codes and the unique identifiers will be held in locked office at the Pharmacy Department for 5 years and will be destroyed according to the legal requirements. Therefore, it is impossible to identify an individual from the final data. Data will not be used in future study. The participants will not be informed about the findings of the study unless they requested for it.

GANTT CHART

Economic evaluation and clinical impact of home medication review (HMR) by community pharmacists among patients with type 2 diabetes mellitus (T2DM)

Month	Year	DRP	Data Collections at 0-month	Data Collections at 3-month	Data Collections at 6-month	Quantitative Data Analysis	Qualitative Study (focus group and	Data Collection for Economic Evaluation	Qualitatvive Data Analysis	Cost-Effectiveness Analysis	Thesis Write-Up
	SEPTEMBER										■
	OCTOBER										■
	NOVEMBER	■	■								■
	DECEMBER		■								■
2018	JANUARY										■
	FEBRUARY			■							■
	MARCH			■							■
	APRIL										■
	MAY				■	■					■
	JUN				■	■	■	■	■	■	■
	JULY					■	■	■	■	■	■
	AUGUST					■	■	■	■	■	■
	SEPTEMBER								■	■	■
	OCTOBER								■	■	■
	NOVEMBER								■	■	■
	DECEMBER								■	■	■
2019	JANUARY										■
	FEBRUARY										■
	MARCH										■
	APRIL										■

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Appendix 1 : HMR-CP 1 Review Referral Form

HOME MEDICATION REVIEW REFERRAL FORM TO COMMUNITY PHARMACIST	

NAME :
MRN/IC :
AGE :
PHONE :
ADDRESS :

Consent form : ☐   Risk Assessment : ☐

Reason(s) For Referral :

Name :

Signature :

Stamp :

Date :

Appendix 1 : HMR-CP 1 Review Referral Form

| **SURAT RUJUKAN HOME MEDICATION REVIEW KEPADA AHLI FARMASI KOMUNITI** | |

NAMA :
MRN/IC :
UMUR :
TEL :
ALAMAT :

Surat Kebenaran : [ ]   Penilaian Risiko :   [ ]

Sebab-sebab Rujukan :

Nama :

Tandatangan :

Cop :

Tarikh :

Appendix 2: HMR-CP 2 Participants/ Caregiver Consent Form

Participants/Caregiver Consent Form

HOME MEDICATION REVIEW PROGRAMME BY COMMUNITY PHARMACIST

I am ………………………………………………………. with I/C No ……………………………………

          (as full name in identity card)

agree to participate in the Home Medication Review (HMR) Programme offered by ………………………………. Health Clinic, Ministry of Health and Community Pharmacy. The Programme will be conducted by a Pharmacist from Community ……………………………………and I will give full cooperation. Full explanation about the programme has already been explained by pharmacist in-charge and I understand it well. I agree and allow the HMR pharmacist to visit me at home when necessary.

……………………………………………….

Name: ……………………………….   Name of Participant : ………………………………………….

I/C No : ……………………………….   I/C No : ……………………………………………

Date : ……………………….   Date : …………………………………

Pharmacist in-charge,

……………………………………………………………

Name :

Stamp:

Date :

(Fill in two copies: original copy will be kept by pharmacist, second copy will be kept by patient)

Appendix 2: HMR-CP 2 Participants/ Caregiver Consent Form

BORANG KEBENARAN MENJADI PESERTA

PROGRAMME 'HOME MEDICATION REVIEW BY COMMUNITY PHARMACISTS'

Saya ……………………………………………………… bernombor kad pengenalan ………………………………

(nama seperti kad pengenalan)

bersetuju untuk mengikuti Program Home Medication Review (HMR) anjuran Klinik Kesihatan …………………………………………… yang akan dijalankan oleh Pegawai Farmasi Komuniti ……………………………………………………………… dan akan memberikan kerjasama sepenuhnya. Saya telah diberi penerangan berkaitan program ini dan faham penjelasan yang telah diberikan. Saya juga membenarkan Pegawai Farmasi yang terlibat menjalankan aktiviti lawatan ke rumah saya sekiranya perlu.

……………………………………………………

Nama : ………………………………………………   Nama Peserta : ………………………………………….

No.KP:…………………………………………   No.KP   :   ………………………………………….

Tarikh : ……………………………………..   Tarikh : ……………………………………….

Pegawai Farmasi Yang

Bertanggungjawab,

          ……………………………………………..

Nama :

Cop Jawatan :

Tarikh :

(Di isi di dalam dua salinan: asal-disimpan oleh Pegawai Farmasi, pendua-diserah kepada peserta)

Appendix 3: HMR-CP 3 Review Appointment Record

HOME MEDICATION REVIEW APPOINTMENT RECORD

NO.	REF NO.	PATIENT NAME	RN/IC	ADDRESS	CONTACT NO.	PHARMACIST INCHARGE	DATE	DATE	DATE	DATE

Appendix 4: HMR-CP 4 Home and Community Visit risk Assessment

HOME AND COMMUNITY VISIT RISK ASSESSMENT	Name : RN : Age : Phone : Address :

(A) ACCOMODATION- tick type, indicates floor level

House ☐

Residential Care Unit ☐

Public Housing ☐

Commercial Premises ☐

Flat/unit ☐

Other details (e.g. level) …………………………………………………………………………………………………

(B) OCCUPANTS				If Yes, List
Are other people likely to be present during the visit?	Y	N	U	
Will these people have an effect on our safety or patient/client treatment	Y	N	U	
Are there any indicators of risk to staff from the patient? i.e. psych Hx, D&A?(can be asked directly or gleaned from medical history)	Y	N	U	
(C) ACCESS TO PREMISES				
It is difficult to see the number of the house from the street?	Y	N	U	
Is there difficulty accessing or packing near the property?(i.e. specific instruction/comments about entering/exciting the property)	Y	N	U	
(D) ANIMALS				
Are there any animal inside or outside the premises that need to be isolated prior the visit?	Y	N	U	
(E) OTHER				
Are there any potential hazards?	Y	N	U	

Risk/s Assessed? ☐
Are Risk/s acceptable? ☐
Visit to proceed ☐

Signature : ……………………………………………………..   Date : ……………………………………………….

Appendix 5: HMR-CP 5 Medication Identification Chart

MEDICATION IDENTIFICATION CHART

NO	NAME & STRENGTH (TRADE NAME) (affix actual drug if necessary)	INDICATION	TO BE TAKEN BEFORE/AFTER FOOD	AMOUNT/TIME OF ADMINISTRATION				OTHER SPECIAL INSTRUCTION
				Morning	Afternoon	Evening	Night	
			BEFORE/AFTER					
			BEFORE/AFTER					
			BEFORE/AFTER					
			BEFORE/ AFTER					
			BEFORE/AFTER					
			BEFORE/AFTER					
			BEFORE/AFTER					
			BEFORE/AFTER					

Appendix 6: HMR-CP 6 Information Gathering Form.

1. PATIENTS PROFILE

<table>
<tr><td colspan="4">HOME MEDICATION REVIEW FORM</td></tr>
<tr><td>Full name</td><td></td><td>Gender</td><td>Male/Female</td></tr>
<tr><td>Address</td><td></td><td>Weight</td><td>kg</td></tr>
<tr><td>DOB</td><td>Age</td><td>Height</td><td></td></tr>
<tr><td>Race</td><td>Malay/Chinese/India/Others_____</td><td>BMI : wt(kg)/ht(m)</td><td></td></tr>
<tr><td>HbA1c value</td><td></td><td>FBS or RBS</td><td></td></tr>
</table>

Interviewing Pharmacist		Contact Point (Address/Phone Number)	
Location of Interview			

Patients referred to:	
Medical Officer	
Family Medicine specialist	
Dietician	
Diabetic Educators	

2. MEDICAL STATUS:

Current Medical conditions : (state those not listed on referral)
Surgical condition : (state those not listed on referral)
Allergies/adverse reactions : (include date and reaction)
Relevant social history :

<table>
<tr><td colspan="4" align="center">Smoking</td><td colspan="4" align="center">Caffeine</td></tr>
<tr><td>Never</td><td>Stopped</td><td>Yes</td><td>Cigs/day</td><td>Never</td><td>Stopped</td><td>Yes</td><td>Drinks/day</td></tr>
<tr><td colspan="4" align="center">Second Hand Smoker</td><td colspan="4" align="center">Alcohol</td></tr>
<tr><td colspan="2">Yes</td><td colspan="2">No</td><td>Never</td><td>Stopped</td><td>Yes</td><td>Drinks/day</td></tr>
<tr><td colspan="4" align="center">Pregnant</td><td colspan="4" align="center">Breastfeeding</td></tr>
<tr><td colspan="2">Yes</td><td colspan="2">No</td><td colspan="2">Yes</td><td colspan="2">No</td></tr>
<tr><td colspan="4" align="center">Diet</td><td colspan="4"></td></tr>
<tr><td colspan="4">Meals/day :</td><td colspan="4">Restriction :</td></tr>
</table>

3. ISSUES THAT MAY INFLUENCE EFFECTIVENESS OF MEDICATIONS USED

Vision (Label-can they be read?) ☐ Good ☐ Poor	**Dose administration:** Self/partner/carer
Hearing ☐ Good ☐ Poor ☐ With aids	**Medication Administration Kits :** ☐ No ☐ Yes (e.g Medication box) Able to open the medication container? ☐ No ☐ Yes
Speech ☐ Clear ☐ Not clear ☐ No speech	**Administration of Medication :** Swallowing/tablet crushed/chewing/ Others:_____
Swallowing ☐ Yes ☐ No	**Devices :** ☐ Inhaler ☐ Insulin pen ☐ Blood glucose monitor set ☐ Blood pressure monitor set ☐ Other(s)_____
Cognition (e.g. memory & comprehension) ☐ Good ☐ Poor	
Mobility (e.g. walking stick, wheelchair, amputee)-Falls? ☐ ADL independent ☐ ADL dependent ☐ With aid(s) _____	
Insight (eg. Patient belief about medication Rx ☐ Good ☐ Poor	**Exercise:** ☐ Yes ☐ No

4. CURRENT MEDICATION (including OTC & complementary medicines) :

Medication Type & Date Dispensed (from label)	Prescribed Dose	Prescribed Frequency	Balance from previous supply	Comments (e.g. dosage discrepancies, knowledge, labelling, unwanted effects, compliance, storage issues etc)	
Amount Stock : Under stock ☐ Adequate Stock ☐ Over Stock ☐		Any issues of Adherence/compliance (use Pill Count Chart to evaluate)(refer Appendix 9)		Y/N Score:	
Any problem of handling of Therapeutic Device	Y/N				

5 . SCREENING TOOLS: MEDICATION/MEDICAL RELATED ISSUES (TICK ON RELEVANT QUESTIONS)

Known kidney problem?	Y	N	Unusual bleeding or bruising?	Y	N
Frequent urinary infections?	Y	N	Anaemia?	Y	N
Difficulty in urination?	Y	N	Sores/ulcers on leg or feet?	Y	N
Frequent urination at night?	Y	N	Leg pain or swelling?	Y	N
Known liver problems/hepatitis?	Y	N	Thyroid problem?	Y	N
Trouble eating certain foods?	Y	N	Known hormone problems?	Y	N
Nausea or vomiting?	Y	N	Arthritis or joint problems?	Y	N
Constipation?	Y	N	Muscle cramps?	Y	N
Diarrhoea?	Y	N	Muscle pain/aches or weakness?	Y	N
Bloody or black bowel movement?	Y	N	Memory problems?	Y	N
Abdominal pain or cramp?	Y	N	Dizziness?	Y	N
Frequent heart burn/indigestion?	Y	N	Hearing or visual problems?	Y	N
Stomach ulcer in the past?	Y	N	Frequent headaches?	Y	N
Shortness of breath	Y	N	Rash or hives?	Y	N
Coughing up phlegm or blood?	Y	N	Change In appetite or taste?	Y	N
Chest pain or tightness?	Y	N	Dry mouth?	Y	N
Fainting spells or passing out?	Y	N	Walking or balance problems?	Y	N
Thumping or racing heart?			Other problems? (details)		

OTHERS PROBLEM : IF YES, PLEASE SPECIFIED
1.
2.
3.
4.
5.

6. **PHARMACEUTICAL CARE ISSUES**

Issues	Recommendation	Outcomes

HMR Conducted by:

Name of pharmacist:

Signature and stamp:

Date:

Time start: Time end:

Appendix 7: HMR-CP7 Information Gathering Form (continuation sheet)

HOME MEDICATION REVIEW FORM

Full name			Gender	Male/Female
Address			Weight	kg
DOB		Age	Height	
Race	Malay/Chinese/India/Others_____		BMI : wt(kg)/ht(m)	
HbA1c value			FBS or RBS	

Interviewing Pharmacist		Contact Point (Address/Phone Number)	
Location of Interview			

Date of visit:

No. of visit:

4. CURRENT MEDICATION (including OTC & complementary medicines)

Medication type & Date dispensed (from label)	Prescribed Dose	Prescribed Frequency	Balance from previous supply	Comments (e.g. dosage discrepancies, knowledge, labelling, unwanted effects, compliance, storage issues etc)
Amount Stock		Any issues of Adherence/compliance		Y/N
Medication Type & Date dispensed (from label)	Prescribed Dose	Prescribed Frequency	Balance from previous supply	Comments (e.g. dosage discrepancies, knowledge, labelling, unwanted effects, compliance, storage issues etc)
☐ Under-stock ☐ Adequate stock ☐ Over-stock		Any issues of Adherence/compliance (use Pill Count Chart to evaluate)(refer Appendix 9)		Score :

Any Problem of Handling of Therapeutic Device	Y/N		

5. SCREENING TOOLS: MEDICATION/MEDICAL RELATED ISSUES (TICK ON RELEVANT QUESTIONS)

Known kidney problem?	Y	N	Unusual bleeding or bruising?	Y	N
Frequent urinary infections?	Y	N	Anaemia?	Y	N
Difficulty in urination?	Y	N	Sores/ulcers on leg or feet?	Y	N
Frequent urination at night?	Y	N	Leg pain or swelling?	Y	N
Known liver problems/hepatitis?	Y	N	Thyroid problem?	Y	N
Trouble eating certain foods?	Y	N	Known hormone problems?	Y	N
Nausea or vomiting?	Y	N	Arthritis or joint problems?	Y	N
Constipation?	Y	N	Muscle cramps?	Y	N
Diarrhoea?	Y	N	Muscle pain/aches or weakness?	Y	N
Bloody or black bowel movement?	Y	N	Memory problems?	Y	N
Abdominal pain or cramp?	Y	N	Dizziness?	Y	N
Frequent heart burn/indigestion?	Y	N	Hearing or visual problems?	Y	N
Stomach ulcer in the past?	Y	N	Frequent headaches?	Y	N
Shortness of breath	Y	N	Rash or hives?	Y	N
Coughing up phlegm or blood?	Y	N	Change In appetite or taste?	Y	N
Chest pain or tightness?	Y	N	Dry mouth?	Y	N
Fainting spells or passing out?	Y	N	Walking or balance problems?	Y	N
Thumping or racing heart?			Other problems? (details)		

OTHERS PROBLEM : IF YES, PLEASE SPECIFIED
1.
2.
3.
4.
5.

6. **PHARMACEUTICAL CARE ISSUES**

Issues	Recommendation	Outcomes

HMR Conducted by:

Name of pharmacist:

Signature and stamp:

Date:

Time start: Time end:

Appendix 8: HMR-CP8 Report Writing

HOME MEDICATION REVIEW FORM

Referral by: …………………………………… Date of visit: …………………………. Visit no. …………………….

Patient's particulars: Name: ………………………………………… MRN/IC no.: ………………………………. Age: …………………………………. Sex: M/F Diagnosis :	Rx

Pharmaceutical Care Issue:

Pharmaceutical Care Plan:

………………………………………………………..

Name:

FOLLOW UP VISIT : ☐ YES, in_____month(s) ☐ NO

Stamp:

Date:

HMR Pill Count Data Collection Sheet for Patients on Oral Medications

Patient's name: _____   Total No. of Readmission (In the last 6 months): _____

Total No. of Medication: _____

Date of Visit by HMR Pharmacist	Name of medications (Oral tabs/Caps only)	Dose	Date of supply	Quantity of medicine supplied	No. of Medicine Left	No. of Medicine should be Left	Percentage of different
Mean							

Appendix 10: HMR-CP 10 Activities Checklist.

ACTIVITIES CHECKLIST

ACTIVITY 1: RECEIVING OF REFEREAL PATIENTS

☐	Receive referral memo with patient's new prescription (HMR-CP1)*
☐	Obtain patient's agreement for HMR programme by completing the HMR consent form (HMR-CP2)
☐	Record patient's particulars in HMR Review Appointment Record (HMR-CP3)
☐	Obtain and completed patient's initial data (Part 1-3 HMR-CP6)

Data set for home visit after referral is received

Activity 2 : Pharmacist Home Visit To Patient's Home

Pre-visit

1. Patient Folder

☐ Partial Complete HMR-CP6 (Part 1-3)

☐ Patient Health Record

☐ Pamphlets for patients

2. Bag

☐ Electronic BP set (optional)

☐ Alcohol Swab and Lancet (optional)

☐ Glucometer & Strip (optional)

☐ Calculator

☐ Disposable rubber glove

☐ Tablet Counting Tray

☐ Spatula

3. Phone call Reminder

☐ Reminder through telephone to patient/caregiver to inform the details of the home visit (e.g: day, time)*

During Visit

	Introduce yourself and explain the objective of the home visit
	Verified information on patient's demography, current medical status and other issues that may influence medication administration (Part 1-3 of HMR-CP6,)
	Reconcile patient's mediation including OTCs, traditional preparation and health supplements (Part 4, HMR-CP6, HMR-CP7)
	Interview patient on medication storage, concomitant medication and other related issues (Part4, HMR-CP6, HMR-CP7)
	Assess patient's adherence using Pill Count Data (HMR-CP9)
	Screen patient for any medication or medical related problem (Part5, HMR-CP6, 7)
	Identify pharmaceutical issues (Part 6, HMR-CP6, HMR-CP7)
	Counsel patient on pharmaceutical care issues (Part 6 of HMR-CP6, HMR-CP7)
	Reassess patient's understanding after counselling
	Remind patient to attend the clinic on the appointment date with medical officer/physician
	Distribute related pamphlet/leaflet to patient/caregiver
	HMR-CP 13 and 14 have been fill-up.

Remind patient/caregiver to bring all the balance medication on next appointment with medical officer and return to pharmacy unit to get new supply based on new   prescription

Post Visit

	Complete HMR-CP6 Form (Reminder: HMR-CP7 shall be used for subsequent visit)
	Conduct a simple and early assessment on patient after first visit
	Discuss with prescriber pertaining any change of regimen or other suggested intervention
	Record all intervention and prepare report, HMR-CP8

Community Pharmacy Agreement for the research title "**Economic evaluation and clinical impact of home medication review (HMR) by community pharmacists among patients with type 2 diabetes mellitus (T2DM)**".

General Terms and Conditions

Prepared by:

Mohd Rozaini Rosli

Uitm PhD Student, Clinical Pharmacy

1. **Agreement**

In completing of this project, you as Full Registered Pharmacist and Community Pharmacist agree to the following terms and condition

2. **Definition**

Full Registered Pharmacist means a pharmacist who has fully registered under Section 6B, Registration of Pharmacist Act 1951.

Agreement means you agree to this terms and conditions and relevant programme specific research working flow.

Community Pharmacy means a premise with at least one pharmacist holding a Type A license issued under the Poisons Act 1952 who can supply/sell poison either by retail only or by both retail and wholesale.

Community Pharmacist means a pharmacist holding a Type A license issued under the Poisons Act 1952 who can supply/sell poison either by retail only or by both retail and wholesale.

Confidential Information means any information that;

a) Is by its nature confidential
b) Is designated by Malaysian Government through Personal Data Protection Act 2010
c) You know or ought to know is confidential

Review area means an identifiable area within patient's home that allow for conversation with patients to talk at normal speaking volume.

Law means any applicable statute, regulation, by-law, ordinance or subordinate legislation in force in Malaysia

Patient Consent means consent by patient who is receiving HMR-CP.

3. **Your Obligation**

   3.1 **You must during the term of Agreement:**
      a. Ensure that you are at all times an eligible community pharmacist

b. Ensured that a Full Registered Pharmacist is involve in the delivery of services

c. Participate as required by the researcher in any evaluation process

d. Comply with all requirement notified in writing to you by researcher.

e. Fill up all the document provided by the researcher

f. Maintained the patient's confidential information.

3.2 You must Immediately notify the researcher in writing if:

a. You cannot perform the service

b. You have any problem with service or patients

I am …………………………………………………. with I/C
No ………………..…………
      (as full name in identity card)
agree to participate in the Home Medication Review by Community Pharmacy (HMR-CP) Programme as a Medication Reviewer. I will give full cooperation for this project. Full explanation about the programme has already been explained by researcher and I understand it well.

Sign: ………………………………………………….

Name: …………………………………….

I/C No : …………………………………………..

Date : …………………………..

Company Stamp:

Researcher,

……………………………………………………………

Name :

Stamp:

Date :

Appendix 12: HMR-CP Consent for Focus Group from participant

Participants Consent Form

HOME MEDICATION REVIEW PROGRAMME

I am……………………………………………. with I/C No …………………………………………………

          (as full name in identity card)

agree to participate in the focus group discussion related Home Medication Review by Community Pharmacists (HMR-CP). The Programme will be conducted by qualified pharmacist and I will give full cooperation. Full explanation about the programme has already been explained by pharmacist in-charge and I understand it well. I agree and will join the close group discussion.

Name of Participants : ………………………………………………….

I/C No : …………………………………………………

Date : … …………………………………………………

Pharmacist in-charge,

…………………………………………………………

Name :

Stamp:

Date :

(Fill in two copies: original copy will be kept by pharmacist, second copy will be kept by patient)

Appendix 12: HMR-CP Persetujuan menyertai perbincangan tertutup berkumpulan oleh peserta

BORANG KEBENARAN MENJADI PESERTA

PROGRAM 'HOME MEDICATION REVIEW'

Saya   ……………………………………   bernombor   kad pengenalan ……………………………………....   (nama seperti kad pengenalan)

bersetuju untuk mengikuti program perbincangan tertutup berkumpulan berkaitan Home Medication Review by Community Pharmacists (HMR-CP). Perbincangan tersebut akan di ketuai oleh pegawai farmasi yang berkelayakan dan saya akan memberikan kerjasama sepenuhnya. Saya telah diberi penerangan berkaitan program ini dan faham penjelasan yang telah diberikan. Saya bersetuju dan akan menyertai perbincangan tertutup berkumpulan tersebut.

…………………………………………………………

Nama Peserta : ………………………………………………….

No.KP : ………………………………………………….

Tarikh : …………………………………

Pegawai Farmasi yang bertangungjawab

  …………………………………………………..

Nama :

Cop Jawatan :

Tarikh :

(Di isi di dalam dua salinan: asal-disimpan oleh Pegawai Farmasi, pendua-diserah kepada peserta)

Appendix 13: HMR-CP for Quality of life tools (EQ-5D-5L)

Under each heading, please tick the **ONE** box that best describes your health
TODAY

MOBILITY

I have no problems in walking about ❑

I have slight problems in walking about ❑

I have moderate problems in walking about ❑

I have severe problems in walking about ❑

I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑

I have slight problems washing or dressing myself ❑

I have moderate problems washing or dressing myself ❑

I have severe problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑

I have slight problems doing my usual activities ❑

I have moderate problems doing my usual activities ❑

I have severe problems doing my usual activities ❑

I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑

I have slight pain or discomfort ❑

I have moderate pain or discomfort ❑

I have severe pain or discomfort ❑

I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑

I am slightly anxious or depressed ❑

I am moderately anxious or depressed ❑

I am severely anxious or depressed ❑

I am extremely anxious or depressed ❑

We would like to know how good or bad your health is **TODAY**.

☐ This scale is numbered from **0** to **100**.

☐ **100** means the <u>best</u> health you can imagine.
   0 means the <u>worst</u> health you can imagine.

☐ Mark an **X** on the scale to indicate how your health is **TODAY**.

☐ Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

Best
imaginable
health state

100

9 0

8 0

7 0

6 0

5 0

4 0

3 0

2 0

1 0

0

Worst
imaginable
health state

Appendix 14: HMR-CP for Patients' Knowledge about Diabetes (14-1tems MDKT)

UNTUK SOALAN NOMBOR 1-14, SILA **BULATKAN** PADA JAWAPAN YANG SESUAI.

No.	Soalan	Jawapan
1	Penyakit kencing manis adalah disebabkan oleh	A Kandungan gula yang tinggi dalam darah B Kandungan kolesterol yang tinggi dalam darah C Kandungan lemak yang tinggi dalam darah D Tidak pasti
2	Pesakit kencing manis harus elakkan daripada memakan _____ dengan banyak.	A Ayam B Susu C Nasi D Kacang
3	Makanan yang manakah paling sesuai diambil oleh pesakit kencing manis?	A Coklat B Kentang goreng C Sayur hijau D Tidak pasti
4	Pesakit kencing manis boleh minum _____.	A Kopi yang dicampur susu pekat B Kopi '3 dalam 1' C Kopi yang dicampur gula D Kopi kosong
5	Ubat kencing manis tidak perlu diambil jika saya tidak makan makanan yang banyak.	A Ya B Tidak C Tidak pasti
6	Apakah sukatan paras gula darah diambil sebelum makan/puasa yang dikehendaki?	A Kurang daripada 6 mmol/L B Kurang daripada 8 mmol/L C Kurang daripada 10mmol/L D Kurang daripada 12 mmol/L
7	Apakah sukatan paras gula yang dikehendaki dalam darah yang diambil 2 jam selepas makan?	A Kurang daripada 10 mmol/L B Kurang daripada 12 mmol/L C Kurang daripada 15 mmol/L D Kurang daripada 20 mmol/L
8	Sekiranya paras gula dalam darah adalah tinggi, saya akan berasa	A Sakit dada B Kerap rasa dahaga dan kencing C Sakit telinga D Tidak pasti
9	Apakah tanda sekiranya paras gula dalam darah terlalu rendah?	A Pening B Cirit-birit C Sakit jantung D Tidak pasti
10	Jikalau saya rasa pening dan badan menggigil, (apabila paras gula dalam darah terlalu rendah). Saya harus makan /minum	A 1 biji gula-gula B 1 pinggan nasi lemak/mee C 1 gelas air 100ml dicampur 4 sudu besar gula pasir D 1 keping roti
11	Senaman boleh mengurangkan paras gula dalam darah.	A Ya B Tidak C Tidak pasti

12	Cara terbaik untuk penjagaan kaki saya adalah _____.	A Basuh dan keringkan kaki setiap hari B Urut dengan minyak setiap hari C Rendam kaki dalam air selama sejam setiap hari
13	Apakah kasut yang sesuai untuk dipakai oleh pesakit kencing manis?	A Selipar B Kasut kulit C Kasut kain
14	Penyakit kencing manis yang tidak terkawal boleh menyebabkan _____	A Masalah pendengaran B Masalah buah pinggang C Masalah paru-paru (contoh : sesak nafas) D Tidak pasti

TERIMA KASIH ATAS KERJASAMA ANDA

For question number 1-14, please **CIRCLE** the correct answer.

No.	Question	Answer
1	Diabetes is caused by _____.	A High blood sugar level B High blood cholesterol level C High blood lipid level D Not sure
2	Diabetic patient should avoid eating too much of _____.	A Chicken B Milk C Rice D Peanut
3	Which of the following is the most suitable food for diabetic patient?	A Chocolate B French fries C Green leaves vegetables D Not sure
4	Diabetic patient can drink	A Coffee with creamer B 3 in 1 coffee C Coffee with added sugar D Coffee without added sugar (Black coffee)
5	Diabetic medication does not need to be taken if I did not eat too much of food.	A Yes B No C Not sure
6	Which of the following is the most desirable blood sugar level taken before meal?	A Less than 6 mmol/L B Less than 8mmol/L C Less than 10 mmol/L D Less than 12mmol/L
7	Which of the following is the most desirable blood sugar level 2 hours after taking food?	A Less than 10 mmol/L B Less than 12 mmol/L C Less than 15 mmol/L D Less than 20 mmol/L
8	If my blood sugar level is high, I will	A Have chest pain B Feel thirsty and urinate frequently C Have pain in ears D Not sure
9	What is the symptom of low blood sugar level?	A Dizziness B Diarrhea C Chest pain
10	If I experience sudden dizziness and shivering due to low blood sugar, I should eat	A 1 sweets or hard candies B 1 plate of Nasi Lemak/ Mee C 1 glass of water 100ml with 4 tablespoons of sugar D 1 slice of bread
11	Exercise can decrease the blood sugar level.	A Yes B No C Not sure
12	The best way to take care of your feet is to:	A Wash and dry them everyday B Massage them with oil everyday C Soak them for one hour everyday

13	What kind of shoes is suitable for diabetic patient?	A Sandals B Leather shoes C Shoes made of fabric material
14	Uncontrolled Diabetes may lead to	A Hearing problems B Kidney problems C Lung problems (e.g. shortness of breath) D Not sure

THANK YOU FOR YOUR COOPERATION