



Pharmaceutical Services Division
Ministry of Health Malaysia

PROTOCOL
Medication Therapy
Adherence Clinic:
Diabetes
Second Edition 2014

Second Edition 2014
Pharmaceutical Services Division
Ministry of Health, Malaysia

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Perpustakaan Negara Malaysia
Cataloguing-in-Publication Data

ISBN: 9789675570544



9 789675 570544

PREFACE



Medication Therapy Adherence Clinic (MTAC) was introduced in 2004 as part of the clinical pharmacy services in the Ambulatory Clinic System which emphasizes on medication management to improve on quality, safety and cost-effectiveness of patient care. The first Diabetes Medication Therapy Adherence Clinic (DMTAC) service was initiated in Penang General Hospital. Over the time span of a decade, this service has expanded and extended throughout the nation and has remained as one of the major MTACs in the Ministry of Health (MOH) facilities. To date, majority of the hospitals and health clinics are currently providing MTAC Diabetes services to patients.

Adherence level to Diabetes Mellitus medications was chosen as one of the Key Performance Indicators (KPI) for the honorable Minister of Health. Therefore, it is timely to review and publish this second edition of DMTAC Protocol. This protocol comprises outlines of the procedures and documentations during MTAC Diabetes sessions. It serves as a guide for pharmacists in the course of managing diabetic patients during MTAC Diabetes sessions. The availability of this protocol will enable the standardization of practice and establishment of MTAC Diabetes services throughout MOH's facilities.

I would like to applaud the Clinical Pharmacy Working Committee (Endocrine-Diabetes Mellitus Subspecialty), Pharmaceutical Services Division, MOH for their contributions and commitment to the publication of this protocol.

Thank you

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A. INTRODUCTION

Diabetes Mellitus (DM) has become a major healthcare burden in almost all countries in the world. According to the National Health and Morbidity Survey (2011) conducted by the Ministry of Health Malaysia, the prevalence of diabetes among Malaysian adults of over 30 years has continued to rise from 8.3% (NHMS II - 1996), to 14.9% (NHMS III - 2006) and peaked at 20.8% (NHMS 2011). This alarming finding urges us to manage and educate patients with diabetes aggressively in order to prevent further increasing trend in DM prevalence.

The findings of the United Kingdom Prospective Diabetes Study (UKPDS) showed that with every 1% reduction in HbA1c, there was a 21% reduction in death related to diabetes, a 14% reduction in the incidence of myocardial infarction and a 37% reduction in the incidence of micro-vascular complications (Stratton et al 2008). Adherence to medication regimen is one of the vital parts of diabetes management. Several studies have shown that poor adherence to medication therapy was associated with poor glycemic control. Among the factors that contribute to low medication adherence included demographic, psychological, social, healthcare provider and disease related as well as treatment related factors (Delamater 2006).



Diabetes Medication Therapy Adherence Clinic (DMTAC) is an ambulatory care service offered by pharmacists in collaboration with physicians with the aim of helping diabetic patients to achieve better medication adherence level and glycemic control. Patients enrolled will be follow-up for a minimum of 8 visits where they will receive medication adherence assessment, identification and management of drug related problems, medication counseling, monitoring of clinical outcomes and diabetes education by the pharmacist.

Many studies have been carried out to assess the outcomes of pharmacist led diabetes clinics, and have reported significant reduction in HbA1c, which is an outcome measure of glycemic control. A randomized clinical trial involving 217 Type 2 diabetes patients who received pharmacist care for a period of 12 months in the United States showed a 2.5% significant reduction in HbA1c (Rothman et al 2005). A similar study in Australia also showed a significant 0.9% reduction in HbA1c after a 6 months follow-up (Krass et al 2006). Patients who underwent a pharmacist managed diabetes clinic in Thailand showed a reduction of 0.8% in HbA1c after 8 months of follow-up as well as improvement in medication adherence level (Phumipamorna et al 2008).

Several small scale studies have been conducted locally to evaluate the impact of pharmacists' involvement in MTAC-Diabetes. A prospective study was conducted among 85 MTAC-Diabetes patients in Kuala Lumpur Hospital from February 2008 to August 2009 with a follow up period of 9 months, showed significant improvements with HbA1c reduction of 1.7% compared to 0.6% in Standard Care group (Loganadan et al, 2011). In addition to this, a retrospective evaluation of MTAC-Diabetes in Penang Hospital revealed that patients who attended MTAC-Diabetes had managed to achieve 1.2% HbA1c reduction after 8 months (Lim et al, 2010). A larger scale of retrospective study, involving nine (9) centers from Ministry of Health and 170 patients, also demonstrated an improvement of diabetic control (1.1% HbA1c reduction) after 6 months of follow up with the pharmacist (Noraini.M et al 2010).

B. OBJECTIVES

1. To improve patients' knowledge towards medications and disease.
2. To increase patients' adherence towards diabetes medications.
3. To reduce adverse effects and complications resulting from multiple drug regimens.
4. To educate patients about diabetes complications, proper self-management, use of medications and self-care devices.
5. Assist physicians in monitoring patient's drug therapy and medical conditions, particularly their responses to therapy in-between doctor's visits.

C. SCOPE OF SERVICE

1. The DMTAC Service will operate in the clinic area during the clinic day. Subsequent visits shall be carried out in Pharmacy/Clinic area.
2. The DMTAC pharmacist will perform duties including assessing patients for pharmaceutical care issues, documenting actions and plans, providing appropriate education to patients, and completing follow-ups.
3. Activities at the clinic will be carried out according to the suggested workflow (**Refer Appendix I and II**).

D. MANPOWER REQUIREMENT

DMTAC services can only be provided by trained pharmacist(s).

E. APPOINTMENT

All appointments will be scheduled by DMTAC pharmacists.

F. OUTCOME MEASUREMENTS

Every patient should be monitored and assessed during each DMTAC visit. All facilities providing DMTAC services shall monitor the following indicators as outcome measurements for the service.

- (i) Compliance of DMTAC patients towards diabetic medications
- (ii) Glycaemic control, eg HbA1c, FBS, 2HPP etc
- (iii) Knowledge of medication eg DFIT score
- (iv) Other lab parameters eg lipid profile, blood pressure etc

G. PROCEDURE

1. PATIENT SELECTION

- 1.1 Diabetic patients currently managed in the hospital or health clinic.
- 1.2 Patients with uncontrolled Diabetes despite optimum medications has been prescribed.
- 1.3 Patients non-compliant to medications.
- 1.4 Patients with HbA1c > 8.0%.
- 1.5 Patients with co-morbidities/multiple medications.
- 1.6 Patients with complications (macro-vascular and micro-vascular).

2. INITIAL ASSESSMENT BY THE DMTAC PHARMACIST

- 2.1 During the initial visit, the pharmacist will perform an initial assessment of the patient. The initial evaluation will involve:
 - 2.1.1 Review of patient medical/medication history
 - 2.1.2 Conducting a baseline assessment of:
 - a) Past medical/medication history
 - b) Social/family history
 - c) Occupational history (eg shift work, office work, student etc)
 - d) Medication knowledge

- e) Medication adherence
 - f) Diet and lifestyle
 - g) Allergies (drug and food etc.)
- 2.1.3 Review of vital signs and laboratory parameters
 - 2.1.4 Determination of medication-related problems and issues
 - 2.1.5 Patient (and/or caregiver) interview
 - 2.1.6 Diabetes knowledge assessment
- 2.2 During the initial interview, the following will be reviewed with the patient:
 - 2.2.1 DMTAC mission
 - 2.2.2 Anticipated benefits to the patients or care givers
 - 2.2.3 Goals for patient
 - 2.2.4 Patient's specific drug therapy related needs
 - 2.2.5 Patient's rights and responsibilities in the program
 - 2.3 Upon agreeing to enroll into the program, the patient will sign an informed consent form (DMTAC/F1), allowing their information to be released or shared with other healthcare providers involved in their care for the sole purpose of providing critical information needed for coordination of their care, unless they advise otherwise.
 - 2.4 Patient's appointment book or prescription could be tagged as identification.
 - 2.5 The pharmacist will then proceed with the **Education Modules** (*Appendix III*). The modules will be delivered at the pace based on patient's understanding and knowledge assessment at every visit, to be completed before visit 8.

3. SECOND AND SUBSEQUENT VISITS

- 3.1 The subsequent visits shall be scheduled every 1-3 months, based on patients' need, their current health status, other clinic visits and medication refills appointments.
- 3.2 Assessment at every visit shall include:
 - i. Therapeutic goals
 - ii. Glycemic control
 - iii. Medication adherence
 - iv. Discussion of disease progression and complications
 - v. Discussion of laboratory parameters
 - vi. Medication knowledge (DM drugs & others)
 - vii. Adverse reaction
 - viii. Review and discussion of SMBG (insulin dose adjustment)
- 3.3 To provide education on insulin adjustment during each visit. Discussion with the physician should be done if any concern arises.
- 3.4 Target glucose need to be individualized as per current management. Discussion with physician might be necessary.
- 3.5 To provide health advice and education when appropriate and make referral to other healthcare providers for interventions.
- 3.6 Review appointments until glycaemic control and other laboratory parameters achieve target goals.

4. REGISTRATION OF DMTAC PATIENT

A registry of all DMTAC patients must be maintained.

5. MISSED VISITS

Patients will be contacted and appointment will be rescheduled.

6. PHARMACEUTICAL REVIEW

- 6.1 Identifying pharmaceutical care issues
 - a) Carefully assess the patient and obtain all information required to ascertain if any intervention or recommendation has to be made.
 - b) Identify patient-specific health or drug related problems.
- 6.2 Solving pharmaceutical care issues
 - a) Identify the most suitable therapeutic alternatives for the patient.
 - b) Formulate a patient-specific action plan with the patient, including identifying specific health outcomes and the means (drug or non-drug) to achieve them.
 - c) Take a holistic approach to patient care (i.e. consider patient's medical, social, and financial needs) in establishing the action plan.
 - d) Consider whether non-pharmacological therapy may help to prevent or solve the health or drug related problem.
- 6.3 Drug therapy monitoring
 - a) Monitor patient's adherence to the plan.
 - b) Follow up on patient's progress to ensure the achievement of desired outcomes, making modifications to the existing plan if necessary.
- 6.4 Pharmacist's recommendations
 - a) All interventions must be documented and discussed with prescriber.

7. MEDICATION DISPENSING

7.1 DMTAC pharmacist shall dispense the medications.

8. DOCUMENTATION

8.1 All relevant data are to be recorded using designated forms, and stored in the patient's profile and/or case notes.

- a. DMTAC/F1 – Patient informed consent form
- b. DMTAC/F2 – Patients' pharmacotherapy review form
- c. DMTAC/F3 – Diabetes knowledge assessment

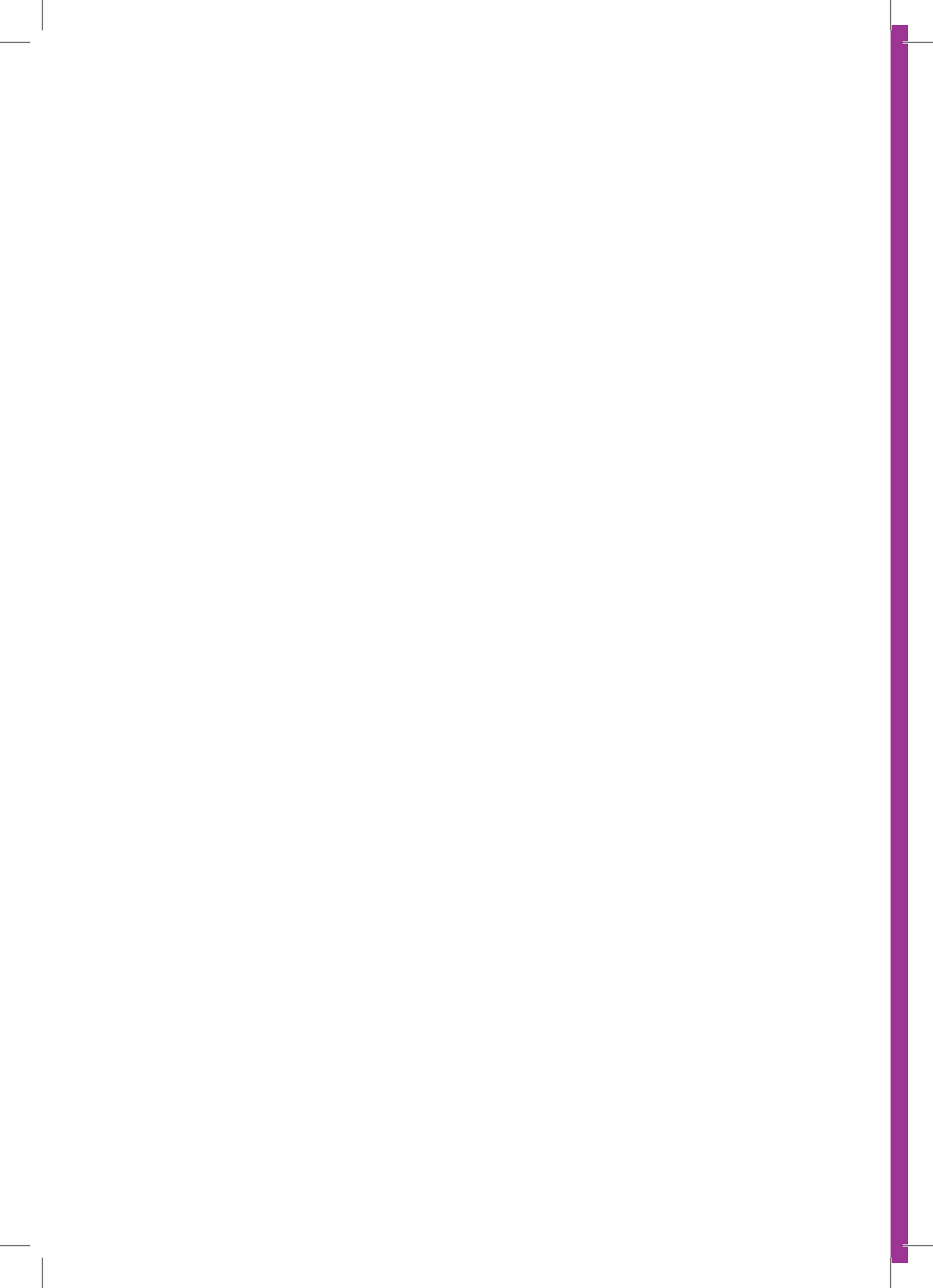
9. DISCHARGE CRITERIA

DMTAC pharmacist can discharge patient who fulfill any one (1) of the following criteria:

- a) Achieve HbA1c **7%** or **7.5%** (Target need to be individualized) for at least **2** consecutive readings,
- b) Completed a minimum of **eight (8) visits**, with good medication knowledge score (DFIT) 100% and **good adherence**,
- c) Defaulted **six (6)** months or **two (2)** consecutive DMTAC visits, **whichever** is longer,
- d) Patient discharged/transferred to other facilities for follow-up.

H. REFERENCES

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APPENDICES

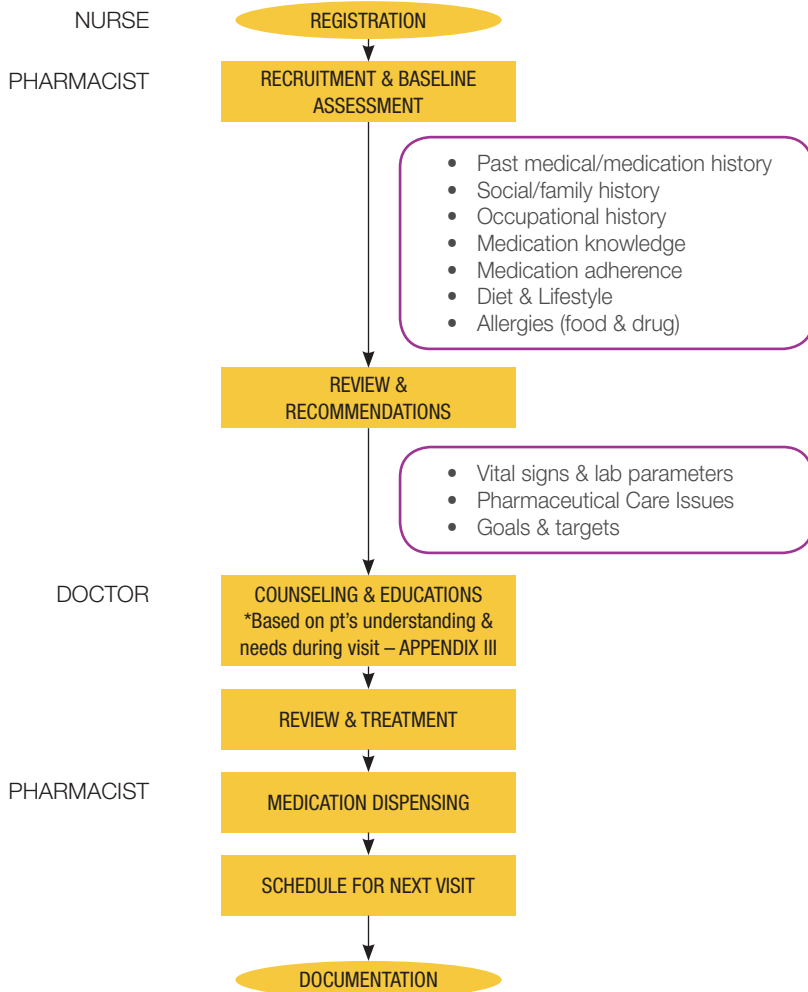
I. APPENDIX

APPENDIX 1

MEDICATION THERAPY ADHERENCE CLINIC (DIABETES) WORKFLOW

FIRST DMTAC VISIT

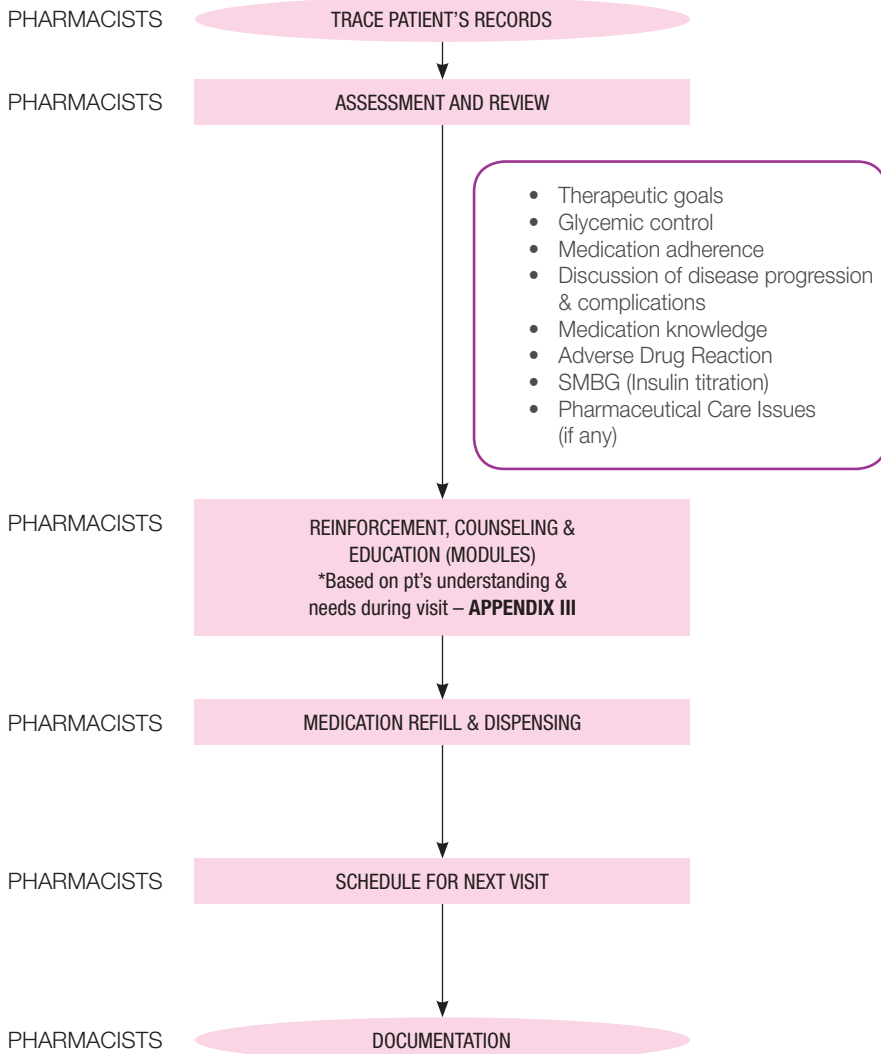
Location: Diabetes Clinic



MEDICATION THERAPY ADHERENCE CLINIC (DIABETES) WORKFLOW

SUBSEQUENT VISIT (Every 1–2 months)

Location: Diabetes Clinic



DMTAC

EDUCATION MODULES FOR DIABETES PATIENTS

First Module

- ❑ Brief overview on diabetes (symptoms, complications, etc)
- ❑ Therapeutic goals, specifically blood glucose (HbA1c, FBG etc.)
- ❑ Specific discussion on medication use/adverse effects with the patient (insulin and hypoglycaemic agents)
- ❑ Self monitoring of blood glucose (SMBG) - how, when, why etc. (if applicable)
- ❑ Signs and symptoms of hypo/hyperglycaemia, sick day management and course of action to be taken
- ❑ Medication storage at home
- ❑ Patient's concerns

Second Module

- ❑ Cardiovascular education (Lipids, blood pressure, peripheral vascular disease, and goals)
- ❑ Benefits, risks and options for improving blood glucose controls
- ❑ Discussion on medication use/adverse effects with the patients (anti-hypertensives, anti-platelets, and anti-cholesterol)
- ❑ Patient's concerns

Third Module

- ❑ Benefits of exercise
- ❑ Hypoglycaemic reactions (reminder)
- ❑ Basic nutrition
- ❑ Introduction to benefits of quit smoking
- ❑ Patient's concerns

Fourth Module

- ❑ In-depth discussion on diabetes complications (macro & micro complications, etc.)
- ❑ Prevention, detection, and treatment of complications
- ❑ Foot care
- ❑ Patient's concerns



DIABETES MEDICATION THERAPY ADHERENCE CLINIC (DMTAC)

Jabatan Farmasi

Persetujuan untuk menyertai MTAC Diabetes

Saya, yang beralamat di
.....
.....
dengan ini bersetuju untuk menyertai program MTAC Diabetes yang dianjurkan oleh
Jabatan ini, yang akan berlanjutan sekurang-kurangnya 8 lawatan. Saya berjanji
akan

Mematuhi tarikh-tarikh lawatan & masa temujanji yang diberikan,

Membawa bersama kesemua ubat-ubatan yang diambil semasa temujanji

Dan bersetuju bahawa informasi saya akan digunapakai antara pegawai kesihatan
untuk tujuan perbincangan rawatan saya

Tarikh:

Tandatangan:.....

Nama:

No. K/P:

No. Tel.:

Pegawai Farmasi :

.....

Nama :

Tarikh:

MEDICATION THERAPY ADHERENCE CLINIC (DIABETES) PHARMACOTHERAPY REVIEW

Pharmacy Department:

Name: I/C:

Age: Gender: M / F Race:

Date of visits:/...../...../...../...../.....

Past Medical History (summary):

Social/Family History: Smoking:
Alcohol:

Drug Allergies:

Diet and Lifestyle

Medications List (Before enrolment)

1.	8.
2.	9.
3.	10.
4.	11.
5.	12.
6.	13.
7.	14.

LABORATORY RESULTS

Parameters	Normal Value	Date											
GLYCEMIC CONTROL													
FBS (mmol/L)	4.4-6.0												
2HPP (mmol/L)	4.4-8.0												
RBS (mmol/L)	<10.0												
HbA1c (%)	<6.5%												
PHYSICAL PARAMETERS													
Blood Pressure (mmHg)	<140/80												
Weight (kg)													
Height (cm)													
Waist circum.	M <90cm, F < 85cm												
BMI	<23												
RENAL PROFILE													
Na (mmol/L)	135-145												
K (mmol/L)	3.5-5.0												
SrCreatinine (µmol/L)	57-130												
GFR (ml/min)													
Urine Prot													

Parameters	Normal Value	Date									
LIVER FUNCTION											
T Protein (g/L)	66-87										
Albumin (g/L)	35-52										
Globulin (g/L)	20-36										
T.Bilirubin (µmol/L)	0-24										
ALT (IU/L)	0-42										
ALP (IU/L)											
>15yrs	34-104										
(3-15yrs)	98-369										
LIPID PROFILE											
T.Chl (mmol/L)	3.5-5.7										
TGL (mmol/L)	≤1.7										
LDL (mmol/L)	≤2.6 or ≤1.8										
HDL (mmol/L)	≤1.1										
OTHERS											

Date:

Visit:

PHARMACEUTICAL CARE ISSUES	INTERVENTION	OUTCOME

BORANG PENILAIAN PENGETAHUAN DIABETES PESAKIT

Diabetes - Medication Therapy Adherence Clinic (MTAC)

NAMA:

MRN:

Sila jawab SEMUA soalan dan tandakan (/) untuk jawapan.

- | | |
|---|---|
| <p>1. Kencing manis (Diabetes Mellitus) adalah penyakit:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Paras gula dalam darah tinggi <input type="checkbox"/> Kolesterol dalam darah tinggi <input type="checkbox"/> Tekanan Darah Tinggi <input type="checkbox"/> Tidak pasti <p>2. Fungsi gula (glukosa) di dalam badan adalah untuk:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Menghasilkan tenaga <input type="checkbox"/> Menghasilkan Oksigen <input type="checkbox"/> Membina tisu badan <input type="checkbox"/> Tidak pasti <p>3. Penyakit kencing manis disebabkan oleh factor berikut:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Berat badan berlebihan <input type="checkbox"/> Insulin dalam badan tidak mencukupi atau 'resistant' <input type="checkbox"/> Sejarah keluarga <input type="checkbox"/> Virus atau jangkitan kuman <input type="checkbox"/> Tidak pasti <p>4. Yang manakah antara berikut tanda-tanda paras gula di dalam darah tinggi (Hiperglisemia).</p> <ul style="list-style-type: none"> <input type="checkbox"/> Mulut kering dan dahaga <input type="checkbox"/> Turun berat badan <input type="checkbox"/> Kerap kencing <input type="checkbox"/> Kabur penglihatan <input type="checkbox"/> Lapar | <p>5. Yang manakah antara berikut tanda-tanda paras gula di dalam darah rendah (Hipoglysemia).</p> <ul style="list-style-type: none"> <input type="checkbox"/> Tangan menggigil <input type="checkbox"/> Berpeluh sejuk <input type="checkbox"/> Kerap kencing <input type="checkbox"/> Lapar <input type="checkbox"/> Letih dan tidak bertenaga <p>6. Paras gula didalam darah rendah juga boleh berlaku sekiranya anda,</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bersenam keterlaluhan <input type="checkbox"/> Tidak makan selepas mengambil ubat <input type="checkbox"/> Mengambil ubat atau insulin berlebihan <input type="checkbox"/> Makan berlebihan <p>7. Jika anda mengalami tanda-tanda hipoglysemia, apa yang patut dilakukan:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Minum jus atau ambil gula-gula <input type="checkbox"/> Periksa paras gula menggunakan glucometer <input type="checkbox"/> Baring dan rehat <input type="checkbox"/> Suntik insulin <input type="checkbox"/> Bersenam |
|---|---|

8. Apakah komplikasi (kesan buruk) penyakit kencing manis?
- Penglihatan kabur/katarak
 - Penyakit buah pinggang
 - Penyakit jantung
 - Penyakit saraf – kebas-kebas
 - Strok
 - Mudah dapat jangkitan kuman
 - Ulser
9. Apakah nama ubat kencing manis yang anda ambil?
- Metformin (Glucophage®)
 - Gliclazide (Diamicon®)
 - Gliclazide MR (Diamicon MR®)
 - Glibenclamide
 - Rosiglitazone (Avandia®)
 - Acarbose Repaglinide (Novonorm®)
 - Insulin _____
 - Tidak pasti
10. Bagaimana cara anda mengambil ubat-ubatan berkenaan?
- 30 minit sebelum makan
 - Bersama makanan
 - Sebaik selepas makan
 - Sebaik sebelum makan
 - Pada bila-bila masa
11. Adakah anda ada mengalami tanda-tanda berikut selepas mengambil ubat-ubatan kencing manis?
- Berat badan meningkat
 - Kembang perut
 - Loya/muntah
 - Cirit-birit/sembelit
 - Perut berasa pedih/tidak selesa
12. Sekiranya anda terlupa mengambil/makan ubat-ubatan kencing manis, apakah yang anda lakukan?
- Makan ubat sebaik teringat
 - Lupakan saja dos yang tertinggal
 - Gandakan dos ubat seterusnya
 - Memeriksa paras gula dalam darah
13. Apakah sasaran paras gula dalam darah yang perlu dicapai oleh setiap pesakit diabetes.
- HbA1c <7 %
 - Plasma glukosa (puasa) 4.4 – 6.1 mmol/L
 - 2 jam selepas makan/rambang 4.4 –8.0mmol/l
 - Plasma Glukosa >10.00mmol/l (puasa)

Sila jawab soalan berikut, sekiranya anda mengambil suntikan insulin.

14. Dimanakah anda menyimpan stok insulin?
- Dalam peti sejuk beku (0°C)
 - Dalam peti sejuk (2 –8 °C)
 - Atas peti sejuk
 - Dalam almari
15. Dimanakah anda menyimpan Novopen/Humapen yang mengandungi insulin atau insulin yang sedang digunakan?
- Di dalam almari berkunci
 - Di dalam peti sejuk
- Di dalam beg tangan
 - Pada suhu bilik
16. Berapa kerap anda menukar jarum untuk suntikan insulin?
- Setiap kali digunakan
 - Selepas 3–4 kali digunakan
 - Sehingga jarum tumpul
 - Sekali seminggu

SUMMARY OF DMTAC SESSION

No.	Aspect	Visit							
		1	2	3	4	5	6	7	8
1	Introduce yourself - purpose of DMTAC	✓							
2	Sign consent form (DMTAC/F1)	✓							
3	Disease and medication knowledge assessment (DMTAC/F3)	✓							
4	Brief overview regarding diabetes	✓	✓	✓	✓	✓	✓	✓	✓
5	Therapeutic goals (eg HbA1c, FBS, Lipid, BP)	✓	✓	✓	✓	✓	✓	✓	✓
6	Hyper and hypo symptoms	✓	✓	✓	✓	✓	✓	✓	✓
7	DM complications ~ kidney, eyes, CVS, peripheral wounds etc	✓	✓	✓	✓	✓	✓	✓	✓
8	Discussion of medication(s) used ~ either pills/insulin (Emphasize needs of insulin in future)	✓	✓	✓	✓	✓	✓	✓	✓
9	Discussion of any adverse effects with patients (with medication or insulin)	✓	✓	✓	✓	✓	✓	✓	✓
10	Diet and lifestyle ~ Food for breakfast/lunch/dinner, any extra? ~ Exercise/Smoking/Alcohol	✓	✓	✓	✓	✓	✓	✓	✓
		✓	✓	✓	✓	✓	✓	✓	✓
11	Self monitoring blood glucose - how, when, where ~ Give booklet, emphasize the need for SMBG								
		✓	✓	✓	✓	✓	✓	✓	✓
12	Sick day management & course of action to be taken	✓	✓	✓	✓	✓	✓	✓	✓

Assessment of Target Values									
13	Discuss laboratory parameters ~ FBS/HbA1c/Lipid profile/LFT/BP/SMBG/ Renal profile	✓	✓	✓	✓	✓	✓	✓	✓
Assessment of Insulin Issues									
14	Discuss dose/timing/technique/site of injection/ needle use	✓	✓	✓	✓	✓	✓	✓	✓
15	Discuss storage of insulin	✓	✓	✓	✓	✓	✓	✓	✓
16	Discuss frequency to change needles/disposal of needles	✓	✓	✓	✓	✓	✓	✓	✓
Other Assessments									
17	Assess adherence level	✓	✓	✓	✓	✓	✓	✓	✓
18	Assess understanding of medications - DFIT	✓	✓	✓	✓	✓	✓	✓	✓
Plans									
19	Review and set patient's targets	✓	✓	✓	✓	✓	✓	✓	✓
20	Discuss on insulin dose adjustment (if any)	✓	✓	✓	✓	✓	✓	✓	✓
21	Discuss on changes of medications (if any)	✓	✓	✓	✓	✓	✓	✓	✓
22	Other counseling (if any)	✓	✓	✓	✓	✓	✓	✓	✓
23	Get new TCA for pharmacist review	✓	✓	✓	✓	✓	✓	✓	✓

DMTAC – Mac 2014

Notes



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