PROTOCOL

MEDICATION THERAPY
ADHERENCE CLINIC:
DIABETES

PHARMACEUTICAL SERVICES DIVISION
MINISTRY OF HEALTH MALAYSIA
PREFACE

Pharmacy practice which was traditionally product centered has now shifted towards patient care. Pharmaceutical care, which is comprehensive and patient focused is vital in ensuring that patients receive rational, safe and effective treatment.

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. MTAC is operated by pharmacists who provide drug therapy monitoring and patient’s education in improving their ability to successfully manage disease condition and preventing debilitating symptoms together with reducing the likelihood of medication errors. The service also includes clinical pharmacokinetic consultation, laboratory monitoring and dosage adjustment of relevant medications.

This protocol is meant for clinical pharmacists involved in the management of diabetes therapy which comprises outlines on the activity and documentations in handling MTAC Diabetes. The availability of this protocol will enable the standardisation of practice and expansion of MTAC Diabetes services throughout Ministry of Health (MOH) facilities.

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

Thank you

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CONTENTS

A. INTRODUCTION .......................................................................................... 1
B. OBJECTIVES ............................................................................................... 2
C. SCOPE OF SERVICE .................................................................................... 2
D. MANPOWER REQUIREMENT ....................................................................... 2
E. APPOINTMENT ............................................................................................. 2
F. PROCEDURE
   1. Patient Selection ..................................................................................... 3
   2. Initial Assessment By The DMTAC Pharmacist ....................................... 3
   3. Second And Subsequent Visits ............................................................... 4
   4. Missed Visits ......................................................................................... 4
   5. Pharmaceutical Review .......................................................................... 5
   6. Medication Dispensing And Counselling ............................................. 5
   7. Documentation ....................................................................................... 5
G. REFERENCES ................................................................................................. 6
H. APPENDICES
   Appendix I : MTAC (Diabetes) Workflow ................................................. 7
   Appendix II : MTAC (Diabetes) Workflow- Subsequent Visits.............. 8
   Appendix III : Education Outline For Diabetes Patients...................... 9
   Appendix IV : MTAC (Diabetes) Pharmacotherapy Review Form... 10
A. INTRODUCTION

Diabetes has become a major healthcare burden in almost all countries in the world. According to the Third National Health and Morbidity Survey (2006) conducted by the Ministry of Health Malaysia, the prevalence of diabetes among Malaysian adults of over 30 years has almost doubled from 8.3% in 1996 to 14.9% in 2006 within a short span of a decade. The findings of the United Kingdom Prospective Diabetes Study (UKPDS) showed that with every 1% reduction in HbA1c, there is a 21% reduction in death related to diabetes, 14% reduction in the incidence of myocardial infarction and 37% reduction in the incidence of microvascular complications (Stratton et al 2008). Adherence to medication regimen is one of the vital part 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 include demographic, psychological, social, health care provider and disease related as well as treatment related factors (Delamater 2006).

Pharmacists can play a significant role in improving diabetic patients’ medication adherence level as well as their glycemic control. Many studies on the outcomes of pharmacist led diabetes clinics 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 significant reduction in HbA1c of 2.5% (Rothman et al 2005). A similar pharmacist led diabetes clinic in Australia also showed a significant 0.9% reduction in HbA1c after a 6 month 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 (Phumipamorn et al 2008).

Diabetes Medication Therapy Adherence Clinic (DMTAC) is an ambulatory care service conducted by pharmacists in collaboration with physicians with the aim of helping diabetic patients improve their medication adherence level and glycemic control. The patients enrolled in this clinic will be followed up for a minimum of 8 visits where they will receive medication adherence assessment, identification and management of drug related problems, medication counselling, monitoring of clinical outcomes and diabetes education by the pharmacist.
B. OBJECTIVES

1. To maximize the benefits of medication therapy in diabetic patients.
2. To reduce adverse effects and complications resulting from multiple drug regimens.
3. To assist clinicians in the management of patients placed on anti-diabetic therapy.
5. To provide consultative services to healthcare providers on diabetes medications and related issues.
6. To reduce emergency room visits of patients and decrease total healthcare costs of diabetes.
7. To serve as information resource for patients enrolled in the DMTAC.

C. SCOPE OF SERVICE

1. The DMTAC Service will operate in the clinic area during clinic day.
2. The DMTAC pharmacist will perform a multitude of duties throughout the day: assessing patients and addressing their needs, documenting actions and plans, providing appropriate education to patients, and completing follow-ups.
3. Activities at the clinic should be structured according to the suggested workflow (Refer Appendix I and II)

D. MANPOWER REQUIREMENT

On a typical DMTAC day, at least one (1) pharmacist should be placed in the clinic. The DMTAC has an average of 3-5 patient visits per day, with a range of 3-5 scheduled visits.

E. APPOINTMENT

All appointments will be scheduled by pharmacists or other health care providers participating in the clinic.
F. PROCEDURE

1. PATIENT SELECTION
   1.1 Diabetic patients currently managed in the hospital or health clinic
   1.2 Patients with uncontrolled diabetes
      • HbA1c > 8.0%
      • Fasting Blood Sugar (FBS) > 6.1 mmol/L
      • 2 Hours Post Prandial (2HPP) sugar level > 8.0 mmol/L
   1.3 Diabetics with co-morbidities/ multiple medications
   1.4 Diabetics with complications (macrovascular and microvascular)

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) Diet and lifestyle
         d) Allergies (drug and food etc.)
         e) Medication knowledge
         f) Medication adherence
      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
   2.2 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
      2.2.3 Goals for patient or caregiver
      2.2.4 Patient specific drug therapy related needs and goals
      2.2.5 Patient’s rights and responsibilities in the programme
   2.3 Upon agreeing to enroll into the programme, the patient will sign an
      informed agreement, 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 advice otherwise.
   2.4 Identification of DMTAC patients such as tagging the appointment book
      or the prescription is an optional requirement.
2.5 After the initial interview, the pharmacist will schedule the patient’s next appointment based on the need of assessment after the initial visit, their current health status, or other clinic appointments and medication refills. The majority of patients will be seen monthly.

2.6 The pharmacist can also proceed with the first visit module depending on the suitability of the clinic setting/time.

2.7 Patient’s visit frequency will be based on multiple issues and scheduled accordingly:
   2.7.1 Need for refills (30 or 60 days or 14-28 days if pill boxes are used)
   2.7.2 Change in medication
   2.7.3 Patient’s ability to handle one month or more of medication supply
   2.7.4 Visit schedule at diabetes clinic
   2.7.5 Miscellaneous reasons as determined by the pharmacist that warrants a visit

2.8 Patient education (Refer to Appendix III)

3. SECOND AND SUBSEQUENT VISITS
   3.1 To take place one to two months later. Assessment of glycaemic control and discussion of clinical results will be done. Therapeutic goals shall be clearly stated.
   3.2 Adherence to the therapeutic plan shall be assessed at each visit (reassurance and reinforcement).
   3.3 Every visit shall include interviewing and educating patients regarding disease control, signs and symptoms of adverse reactions and disease progression or development of new complications.
   3.4 Every visit shall have appropriate objective information documented such as laboratory or Self Monitoring of Blood Glucose (SMBG) results as point of care for disease state management.
   3.5 To provide health advice and education (Refer to Appendix III) when appropriate and make referral to specialist clinic for interventions.
   3.6 Review appointments until glycaemic control and other clinical parameters achieve target goals.

4. MISSED VISITS
   Patients will be contacted by telephone the day after a missed appointment to reschedule appointments
5. PHARMACEUTICAL REVIEW

5.1 To be done by DMTAC pharmacists at the earliest opportunity based on patient selection criteria, or after referral of patient by doctors / other healthcare professionals.

5.2 Identifying Drug-related problem
   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.

5.3 Solving Drug-related problem
   a) Identify the most suitable therapeutic alternatives for the patient.
   b) Consider whether non-pharmacological therapy may help to prevent or solve the health or drug related problem.
   c) Formulate a patient-specific action plan with the patient, including identifying specific health outcomes and the means (drug or non-drug) to achieve them.
   d) Take a holistic approach to patient care (i.e. consider patient’s medical, social, and financial needs) in establishing the action plan.

5.4 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

5.5 Pharmacist’s recommendations
   a) Offer feedback to the patient’s clinician and discuss the patient’s progress according to the action plan and outcome.

6. MEDICATION DISPENSING AND COUNSELLING

6.1 Pharmacist shall dispense the medication and counsel the patient

6.2 Follow-up counselling: during part-supply medication collection or during scheduled appointment

7. DOCUMENTATION

7.1 All relevant data to be recorded using designated forms, and stored in the patient’s profile and/or case notes

7.2 Documentation shall include the following: (Appendix IV)
   a) Patient demography and medical/medication history.
   b) Laboratory values
   c) Assessment of patient’s medication knowledge
   d) Assessment of patient’s adherence
   e) Pharmaceutical care issues and pharmacist’s plans.
7.3 After each visit, update patient’s progress in the DMTAC form which include patient’s current status, identified drug related problems and monitoring results, current medication list as needed, allergies, adverse drug reactions, medication adherence, any interventions, and action/plan for each medical condition addressed.

7.4 Any intervention and recommendations to clinicians shall be documented in the patient’s profile and/or case notes.

G. REFERENCES


MEDICATION THERAPY ADHERENCE CLINIC (DIABETES) WORKFLOW

Location: Diabetes Clinic

Nurses → Registration

Pharmacist → Pharmacist review
- Drug knowledge assessment
- Compliance assessment
- Pharmaceutical care issues
- Signs & symptoms assessment
- Medication Review

Doctor → Review & treatment

Pharmacist → Medication dispensing & counseling

Pharmacist → Schedule for next visit/appointment

Pharmacist → Documentation
MEDICATION THERAPY ADHERENCE CLINIC (DIABETES) WORKFLOW
- SUBSEQUENT VISITS

**Location**: Pharmacy Department/ Diabetes Clinic

1. **Pharmacist**
   - Trace patient’s record

2. **Pharmacist**
   - Assessment and review
     - Glycaemic control (SMBG)
     - Laboratory results if available

3. **Pharmacist**
   - Medication refill

4. **Pharmacist**
   - Reinforcement, counseling and education
     - Refer to *Appendix III* for scheduled education

5. **Pharmacist**
   - Schedule for next visit/appointment

6. **Pharmacist**
   - Documentation
EDUCATION OUTLINE FOR DIABETES PATIENTS

First Visit
- Brief overview on diabetes
- 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
- Patient concerns

Visit 2
- Other therapeutic goals (Blood pressure, Lipid etc.)
- Benefits, risks and options for improving blood glucose controls
- Foot care
- Specific drug counselling
- Patient’s concerns

Visit 3
- Benefits of exercise
- Hypoglycaemic reactions (reminder)
- Basic nutrition
- Patient’s concerns

Visit 4
- In-depth discussion on diabetes (macro & micro complications, etc.)
- Cardiovascular education (Lipids, blood pressure, peripheral vascular disease, set goals)
- Prevention, detection, and treatment of complications
- Patient’s concerns

Visit 5
- Health benefits of good glucose control
- Smoking cessation (if applicable)
- Alcohol reduction (if applicable)
- How to continue goals, long term plans.

Subsequent follow-ups
- Revision of treatment goals
- Specific drug counselling
- Patient’s concerns
Medication Therapy Adherence Clinic (Diabetes)
Pharmacotherapy Review
Pharmacy Department, Hospital / Health Clinic

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. 15.
2. 9. 16.
3. 10. 17.
4. 11. 18.
5. 12. 19.
6. 13. 20.
7. 14.
### Review of patient's understanding (medication), Indicator: Yes = 1, No = 0

<table>
<thead>
<tr>
<th>Medication</th>
<th>Visit</th>
<th>Visit</th>
<th>Visit</th>
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<tbody>
<tr>
<td>Date:</td>
<td>Date:</td>
<td>Date:</td>
<td>Date:</td>
<td>Date:</td>
</tr>
<tr>
<td>D</td>
<td>F</td>
<td>I</td>
<td>T</td>
<td>D</td>
</tr>
</tbody>
</table>

Score (%) = \( \frac{\text{No. of "Yes"}}{\text{No. Of Questions}} \) \times 100%

### Key:
- D=Dose
- F=Frequency
- I=Indication
- T=Method of Administration

### Pharmacist's Notes:
MTAC PROTOCOL - DIABETES

### Modified Morisky Medication Adherence Scale

<table>
<thead>
<tr>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
<td>Date:</td>
<td>Date:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

1. Have you forgotten to take your medication in the past 3 months?
2. Are you sometimes neglectful in regard to your medication hours?
3. Do you skip your medicine hours when you are feeling well?
4. When you feel badly due to the medicine, do you skip it?
5. Have you ever forgotten your medication while traveling/going on a trip?
6. Do you have problems in remembering to take your medication?
7. Does the current treatment regime come across to you as troublesome?
8. Frequency of forgetting medication:
   a) 0-1 doses per week (0 marks)
   b) 2-3 doses per week (1 mark)
   c) >3 doses per week (2 marks)

**SCORE**

Yes = 1  No = 0

(0-2 Compliant  3-4 Average  5-9 Non-compliant)

---

### Modified Morisky Medication Adherence Scale

<table>
<thead>
<tr>
<th>Visit 5</th>
<th>Visit 6</th>
<th>Visit 7</th>
<th>Visit 8</th>
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<tbody>
<tr>
<td>Date:</td>
<td>Date:</td>
<td>Date:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

1. Have you forgotten to take your medication in the past 3 months?
2. Are you sometimes neglectful in regard to your medication hours?
3. Do you skip your medicine hours when you are feeling well?
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   a) 0-1 doses per week (0 marks)
   b) 2-3 doses per week (1 mark)
   c) >3 doses per week (2 marks)

**SCORE**

Yes = 1  No = 0

(0-2 Compliant  3-4 Average  5-9 Non-compliant)

---

**Notes on compliance**
# LABORATORY VALUES

<table>
<thead>
<tr>
<th>Laboratory Parameters</th>
<th>Normal Value</th>
<th>Date</th>
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<tr>
<td>Glycemic Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBS (mmol/L)</td>
<td>4.4 - 6.0</td>
<td></td>
</tr>
<tr>
<td>2HPP (mmol/L)</td>
<td>4.4 - 8.0</td>
<td></td>
</tr>
<tr>
<td>RBS (mmol/L)</td>
<td>&lt; 10.0</td>
<td></td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>&lt; 6.5%</td>
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<tr>
<td>Physical Parameters</td>
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<td></td>
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<tr>
<td>Blood Pressure (mmHg)</td>
<td>&lt; 130/80</td>
<td></td>
</tr>
<tr>
<td>Weight (kg)</td>
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<td></td>
</tr>
<tr>
<td>Height (cm)</td>
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</tr>
<tr>
<td>Waist circum.</td>
<td>M &lt; 90 cm</td>
<td>F &lt; 85 cm</td>
</tr>
<tr>
<td>BMI</td>
<td>&lt; 25</td>
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<tr>
<td>Renal Profile</td>
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</tr>
<tr>
<td>Na (mmol/L)</td>
<td>135 - 145</td>
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</tr>
<tr>
<td>K (mmol/L)</td>
<td>3.5 - 5.0</td>
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<tr>
<td>SrCreatinine (µmol/L)</td>
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<td>GFR (ml/min)</td>
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<tr>
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<tr>
<td>Liver Function</td>
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<td>Albumin (g/L)</td>
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<tr>
<td>Globulin (g/L)</td>
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<tr>
<td>T.Bilirubin (µmol/L)</td>
<td>3 - 21</td>
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</tr>
<tr>
<td>ALT (IU/L)</td>
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<td></td>
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<tr>
<td>ALP (IU/L)</td>
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</tr>
<tr>
<td>(&gt;15yrs)</td>
<td>34 - 104</td>
<td>98 - 369</td>
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<tr>
<td>Lipid Profile</td>
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<tr>
<td>T.Chl (mmol/L)</td>
<td>3.5 - 5.7</td>
<td></td>
</tr>
<tr>
<td>TGL (mmol/L)</td>
<td>0.6 - 1.6</td>
<td></td>
</tr>
<tr>
<td>LDL (mmol/L)</td>
<td>&lt; 2.5</td>
<td></td>
</tr>
<tr>
<td>HDL (mmol/L)</td>
<td>&gt; 1.5</td>
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</tr>
<tr>
<td>Others</td>
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**Notes**

- iv -
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<tr>
<th>Pharmaceutical Care Issues</th>
<th>Pharmacist intervention</th>
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