

# Unity in Diversity and the Standardisation of Clinical Pharmacy Services

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## Unity in Diversity and the Standardisation of Clinical Pharmacy Services

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## A strategic approach to increase the compliance of patients with type 2 diabetes mellitus

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**ABSTRACT:** High levels of noncompliance of some patients with Diabetes Mellitus (DM) are still being found. The aim of this study was to assess the effectiveness of public counseling and booklet handouts to increase compliance of patients with type 2 DM. This study was a prospective quasi-experimental pretest–posttest study. The glycated hemoglobin (HbA1c) test was conducted and the *Morisky Medication Adherence Scale* (MMAS-8) questionnaire was administered before and 12 weeks after intervention. The interventions were public counseling and educational booklets, which were made thrice during the study period. The study was conducted at Makasar and Kebon Pala primary healthcare centers in East Jakarta. Among 30 respondents with type 2 DM who completed the interventions, 63.3% of patients had HbA1C level > 7% and 53.4% had a MMAS-8 score > 2, which was considered as low compliance. However, after the interventions, the percentages declined significantly ( $p < 0.05$ ) to 23.3% and 33.3%, respectively. In conclusion, the public counseling and booklet handouts were effective to improve the compliance of patients with type 2 DM.

### 1 INTRODUCTION

Diabetes mellitus (DM) is a group of chronic metabolic disorders characterized by hyperglycemia and abnormalities in carbohydrate, fat, and protein metabolism. However, type 2 DM is characterized by a combination of some degrees of insulin resistance and relative insulin deficiency. Insulin resistance is manifested by increased lipolysis and free fatty acid production, increased hepatic glucose production, and decreased skeletal muscle uptake of glucose (DiPiro et al. 2015). If not handled well, this metabolic disorder can cause microvascular and macrovascular complications, which would increase the treatment cost of the patients (Koda-Kimble et al. 2009).

DM is a worldwide health problem, whose global prevalence was estimated to be 6.4%, affecting 285 million adults in 2010 and is projected to increase to 7.7%, affecting 439 million adults in 2030. It was estimated that between 2010 and 2030, there will be an increase of 69% of the number of adults with DM in developing countries and 20% in developed countries (Shaw, Sicree, & Zimmet 2010). Data from the International Diabetes Federation (IDF) in 2015 showed that the prevalence of DM in adults (20–79 years) in Indonesia was 6.2%. The highest prevalence of DM was found in the spatial regions of Yogyakarta (2.6%) and Jakarta (2.5%) (Balitbangkes, 2013).

One of the causes of the failure of patients' blood glucose control in DM is nonadherence of patients to their treatment. The poor adherence to the treatment of DM patients is still a matter of considerable importance in the management of DM. Several studies have reported that compliance of patients with type 1 DM ranged between 70 and 83%, whereas that of patients with type 2 DM was approximately 64–78%. The level of compliance of patients with type 2 DM is lower than that of patients with type 1 DM, which can be due to the fact that treatment regimens in type 2 DM are generally more complex and polypharmacy and adverse drug reactions arise more frequently during treatment (Kocurek 2009).

One way to improve adherence to treatment can be through the provision of education. Education can be realized in various ways, including counseling and providing educational booklet for the patients, by pharmacists as one form of pharmaceutical services to improve the knowledge and understanding of patients (Malathy et al. 2011). In one study, educational programs were also known to be effective in improving HbA1c, fasting glucose, cholesterol, BMI, and triglycerides tests (Rashed et al. 2016).

Education every patient individually through methods such as personal counseling is difficult, especially in primary healthcare in Indonesia. This is because the number of pharmacists who work in primary healthcare centers is generally limited. Therefore, there is a need to find an alternative provision of education that enhances the knowledge and understanding of DM patients on the diseases and treatment, such as the public counseling and delivering educational booklets for the DM patients. These can be simpler methods that can provide information to patients when they visit primary healthcare centers as well as when they are at home. Nevertheless, the effectiveness is still questioned. Thus, the researcher found it interesting to assess the effectiveness of public counseling and booklet handouts.

### 2 METHODS

This was an interventional prospective study conducted from September 2016 to January 2017 at Makasar and Kebon Pala primary healthcare centers in East Jakarta, Indonesia. A quasi-experimental pretest–posttest was designed to assess the effectiveness of interventions, which were public counseling and booklet handouts, given during the period of the study. The public counseling was performed as a public lecture for DM patients, while the booklets provided information about diabetes treatment. The interventions were given three times during the 12-week study period. The collected data were glycated hemoglobin (HbA1c) levels and *Morisky Medication Adherence Scale* (MMAS-8) scores from pretest and posttest performed before and 12 weeks after interventions.

The study participants were patients with type 2 DM.

Inclusion criteria:

- Patients aged > 18 years
- Patient had diabetes for more than 1 year
- Patients speak and understand Indonesian
- Patients used oral antidiabetic oral (OAD)
- Patients with fasting glucose test > 126 mg/dl
- Patients who came regularly to the two primary healthcare centers for the routine checkup

Exclusion criteria:

- a. Patients cannot answer the questionnaire independently due to mental illness, dementia, or other comorbid medical conditions, which were not stable
- b. Patients with hearing or vision problems
- c. Pregnant women

The tools used to collect data in this study were the HbA1C level gauges i-Chroma™ and MMAS-8 questionnaires. The questionnaire contained a list of statements or questions structured so that the respondent had the ease of completing them by providing check mark (✓) in the answer choices or writing a brief answer (Morisky & DiMatteo 2011).

Descriptive analysis was used to obtain a distribution frequency as well as the proportion of various variables of the study. These variables were divided into three groups of different characteristics, namely sociodemographic, clinical, and lifestyle characteristics. Paired t-test was used to determine the changes in HbA1c levels, whereas Wilcoxon's *t*-test was performed to determine the changes in MMAS-8 scores. Statistical significance was set at  $p < 0.05$ . All statistical analyses were performed using Statistical Package for Social Sciences software for Windows version 22.0 (SPSS Inc., Chicago, USA).

### 3 RESULTS AND DISCUSSION

From September 2016 to January 2017, 44 patients were selected as respondents, but only 30 patients completed the interventions as the study requirement.

#### 3.1 Patient characteristics

Distribution of the patients based on their sociodemographic characteristics is shown in Table 1.

The majority of respondents were females (73.3%). A similar study conducted by Yuniarti (2013) showed similar results with higher prevalence of type 2 DM patients. Most of the respondents (56.7%) aged  $\geq 60$  years. This is reasonable because the risk of disease progression of type 2 DM increases with age (Perkeni 2006). In terms of level of education and occupation, they were mostly in middle (46.77%) and unemployed (83.3%), respectively. These were because most of the respondents were housewives and some of them were retired due to their age.

Table 1. Sociodemographic characteristics.

Characteristic	<i>n</i> (%)
Sex	
Male	8 (26.7)
Female	22 (73.3)
Total	30 (100.0)
Age (years)	
< 60	13 (43.3)
$\geq 60$	17 (56.7)
Total	30 (100.0)
Level of education	
Low	11 (36.7)
Middle	14 (46.7)
High	5 (16.7)
Total	30 (100.0)
Occupation	
Unemployed	25 (83.3)
Employed	5 (16.7)
Total	30 (100.0)

Clinical characteristics of the respondents are shown in Table 2. Respondents with type 2 DM for < 5 years were 63.3%, and 83.3% of them had comorbidity, particularly hypertension. The prevalence of DM patients with hypertension depends on the type of diabetes, age, obesity, and ethnicity. Hypertension is a major risk factor for both cardiovascular and microvascular diseases (American Diabetes Association 2012).

Most of the patients (66.7%) received combination of two OADs, namely the sulfonylurea class (glibenclamide or glimepiride) and the class of biguanide (metformin). *Perkumpulan Endokrinologi Indonesia* (2011) had recommended to use two to three types of ADOs when monotherapy could not stabilize blood glucose levels after 2–3 months (with HbA1c level > 7%).

Four patients (13.3%) experienced side effects such as fatigue, dizziness, limp, and shaking after using glibenclamide as well as nausea after taking metformin. Fatigue, dizziness, limp, and shaking are symptoms of hypoglycemia that may occur after using antidiabetic sulfonylureas such as glibenclamide (Lacy et al. 2011). Symptoms of hypoglycemia usually occur when the blood glucose level is <60 mg/dl. This can be handled by the intake of sweets (sweet tea, syrup, etc.) but not with artificial sweeteners or carbohydrate such as rice (Soegondo et al. 2011). Digestive tract disorders are the major side effects that often occur in the use of metformin. The percentages of side effects on the digestive tract disorders due to metformin were 10–53% for diarrhea and 7–26% for nausea or vomiting. Although side effects of metformin can be reduced by taking metformin concurrently or after the meal and dose titration, some patients still cannot tolerate the side effects (Lacy et al. 2011).

Table 2. Clinical characteristics.

Characteristic	n (%)
<b>Duration of type 2 DM</b>	
< 5 years	19 (63.3)
≥ 5 years	11 (36.7)
Total	30 (100.0)
<b>Comorbidity</b>	
No	5 (16.7)
Yes	25 (83.3)
Total	30 (100.0)
<b>No. of OAD</b>	
1	7 (23.3)
2	20 (66.7)
3	3 (10.0)
Total	30 (100.0)
<b>Adverse drug reactions</b>	
No	26 (86.7)
Yes	4 (13.3)
Total	30 (100.0)

Lifestyle characteristics of the respondents are presented in Table 3. Respondents who use herbs in addition to their medication were 16.67%. Herbs used by the respondents such as insulin leaf, bay leaves, bitter leaf, and mangosteen peel were believed to blood glucose levels. The respondents drank the water after boiling such plants as a medicine decoction. More than 400 different plants and extracts were believed to be beneficial for patients with diabetes. Most of these plants have been reported to have hypoglycemic properties, but there is no sufficient evidence to conclude about the efficacy of medicinal plants against diabetes (Yeh et al. 2003).

A proportion of 63.3% of the respondents confessed that they adjusted their diet with restriction of sugar and carbohydrates (rice), and 56.7% of the respondents exercised regularly. Weight loss and diet (in patients who are obese) may improve short-term blood glucose levels and have the potential to improve long-term metabolic control. Meal planning should be at sufficient nutrient content and accompanied by a reduction in total fat, especially saturated fat (Soegondo et al. 2011). In terms of physical activity, "The Canadian Diabetes Association (CDA) 2003 Clinical Practice Guidelines" has recommended patients with type 2 DM to do moderate-intensity physical activities such as fast walking and cycling for at least 150 min per week for at least 3 days, but not consecutively (Plotnikoff 2004).

### 3.2 Effectiveness of education

This study used HbA1c levels to assess compliance of patients with type 2 DM because HbA1C measurement results are not much affected by variations in daily plasma glucose levels as a result of diet, exercise, and medication. However, compared to other blood glucose tests, the cost of HbA1C examination is higher (WHO 2011). HbA1C is the gold standard for monitoring long-term blood glucose control in order to describe the level of patient compliance. Patient compliance has a positive correlation with a decrease in HbA1C. HbA1C value ≥ 7% showed a low-level compliance to their treatment (Chua & Chan 2011). Patients with a low glucose control together with poor adherence to treatment have a high possibility of ineffectiveness of the therapy. Every 25% increase in medication adherence is associated with decreased HbA1c (Rumsfeld 2006).

Table 3. Lifestyle characteristics.

Characteristic	n (%)
<b>Herbs</b>	
No	25 (83.3)
Yes	5 (16.7)
Total	30 (100.0)

Dietary habit	
Not adjusted	11 (36.7)
Adjusted	19 (63.3)
Total	30 (100.0)
Exercise	
No	24 (80.0)
Yes	6 (20.0)
Total	30 (100.0)

HbA1c measurement in this study was conducted at the Indonesian Center for Health Laboratory Ministry of Health that has been accredited to ISO/IEC 17025: 2005. The analytical method used for the measurement refers to the methods used in the DCCT (The Diabetes Control and Complications Trial), that is, HPLC method (high-performance liquid chromatography) (Sacks 2011). Mean HbA1C levels before and after interventions are provided in Table 4.

The results of measurements performed using paired *t*-test show significant differences ( $p = 0.00$ ) between HbA1c levels before and after the intervention. At the beginning of the study, the mean level of compliance of respondents based on HbA1C was  $7.72 \pm 1.356\%$ , and 63.3% of respondents had HbA1C levels  $\geq 7\%$ . However, after the interventions, the mean declined to  $6.18 \pm 0.988$  with 23.3% respondents still having poor HbA1c levels. The decline in the mean of HbA1C levels showed that there was an increase of the compliance in patients with type 2 DM after being educated.

Measuring the level of compliance of the respondents in addition to using HbA1C levels was also conducted using questionnaires *Morisky Medication adherence Scale* (MMAS-8). MMAS is an assessment tool from WHO that has been validated and is often used to assess patients' adherence to treatment (Morisky & DiMatteo 2011).

MMAS-8 is the result of the revision of the MMAS-4, which has higher sensitivity and specificity, which were 93% and 53%, respectively. Sensitivity of 93% indicates that the scale is well used to identify patients with a low level of adherence, while specificity of 53% indicates that the scale could identify patients who do not have problems of treatment adherence (Krapek 2004).

Table 4. HbA1C levels before and after intervention.

	Before		After	
	n	%	n	%
HbA1c < 7	11	36.7	23	76.7
HbA1c $\geq 7$	19	63.3	7	23.3
Mean $\pm$ SD	$7.72 \pm 1.356$		$6.18 \pm 0.988$	
p	0.00			

The MMAS questionnaire was used because it was cheap and can be used easily in healthcare centers. MMAS-8 consists of eight questions with yes or no answers. MMAS-8 assessment scores were divided into three categories, namely low compliance with a score of more than 2, moderate compliance with a score of 1–2, and a high compliance with a score of 0 (Coppel et al. 2008). Mean MMAS-8 scores before and after interventions are summarized in Table 5.

The results of measurements performed using Wilcoxon's *t*-test shows that there was also a significant difference ( $p = 0.02$ ) between MMAS-8 scores before and after the interventions. It found that the mean of MMAS-8 score was  $2.83 \pm 2.086$  before the interventions, with 53.4% respondents having low compliance. The mean of the scores then declined to  $1.90 \pm 1.605$ , with low-compliance respondents becoming 33.3%, which also shows that the compliance of patients with type 2 DM had increased after the interventions.

A study conducted by Abdo & Mohamed (2010) who carried out a health education program for type 2 DM patients also shows that education was an effective tool that implicated change in knowledge and attitude of patients toward diabetes, random blood glucose levels, and HbA1C levels.

In 2006, the WHO declared that the pharmacist plays an important role to help overcome the problem of poor adherence to long-term therapy in chronic diseases such as diabetes mellitus. Patients with type 2 DM may be given medications that are manifold so that pharmacists are well positioned to provide education to patients about their treatment and explain the treatment regimen to improve the compliance (Farsaei et al. 2011). Various studies on educational interventions by pharmacy staff have been shown to improve control and compliance of patients with type 2 DM. A study by Lindenmeyer (2011) states that there were potential benefits of a given pharmaceutical intervention to improve the effectiveness of treatment, especially in education. Educational intervention provided by the pharmacy could also improve blood glucose control and compliance of patients with type 2 DM (Jennings et al. 2007).

Table 5. MMAS-8 scores before and after intervention.

	Before		After	
	n	%	n	%
High compliance	4	13.3	8	26.7
Middle compliance	10	33.3	12	40.0
Low compliance	16	53.4	10	33.3
Mean $\pm$ SD	$2.83 \pm 2.086$		$1.90 \pm 1.605$	
p	0.002			

Patient education is an important tool in the management of diabetes to optimize the treatment. If education can be implemented effectively, it would improve adherence to and self-management of the disease (Farsaei et al. 2011).

### 3.3 Limitation

The study sample is small, and the measurement level of compliance based on MMAS-8 questionnaire could be answered subjectively by respondents. Hence, further study with more respondents and involving their family needs to be conducted to know more about their compliance.

## 4 CONCLUSION

Public counseling and booklet handouts were effective to improve compliance in patients with type 2 DM.

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