

Full Length Research Paper

Impact of a community pharmacist-based diabetes management program on clinical outcomes measures

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This is a prospective pre-post study which was carried out to assess the impact of a community pharmacist-based diabetes management program on clinical outcomes measures. Forty seven outpatients from the Government polyclinic were initially enrolled for this study but only 30 stayed on till the end of the program which was for duration of 3 months. Subjects were followed-up on 4 visits, whereby the community pharmacist provided a structured, standardized diabetes education program which involved counseling and education. Each session lasted about 1 hour on a one to one basis. Lifestyle behaviours such as physical activities, smoking and alcohol consumption were also evaluated. Compliance, awareness and also their knowledge on diabetes were assessed. A Likert-type patient satisfaction survey was also conducted. At the end of the study, HbA1c was significantly reduced by 1.2% ($p < 0.001$), post-prandial 2 hours blood glucose reduced by 3.34mmol/l ($p < 0.001$), total cholesterol decreased by 0.37mmol/l ($p < 0.016$), systolic blood pressure decreased by 9.1mmHg ($p < 0.001$), diastolic blood pressure decreased by 4.8mmHg ($p < 0.001$). Weight, BMI and waist circumference did not change significantly. There was a significant improvement in the compliance score and the patients were satisfied with the outcome of the program which showed better control of their diabetes. In conclusion, the community pharmacist has made an impact on the clinical outcome measures of the diabetic patient who participated in the program.

Keywords: Diabetes, Disease Management, Pharmaceutical Care, Community Pharmacy

INTRODUCTION

An estimated 190 million people are affected by diabetes mellitus world-wide, with over 330 million predicted to have the condition by 2025 (IDF 2004).

These figures, however, may significantly underestimate the extent of the problem, since up to 50 % of the population with diabetes are thought to remain undiagnosed and therefore untreated (Gonzalez-Clemente, 2003). The prevalence of type 2 diabetes varies considerably in regions, from 1% in Vietnam to 30 % in Nauru. A significant observation is that

prevalence (and incidence) of this chronic disease is on the increase. In Malaysia, the National Health Morbidity Survey (NHMS) done in 1986 showed that the prevalence of diabetes was 6.3%. The prevalence increased to 8.3% in 1996 (NHMS 1996). In 2003, the International Diabetes Federation (IDF) estimated the prevalence of diabetes mellitus in Malaysia for adults 20 -79 years of age as 9.4% which is equivalent to 1.25 million diabetics. Estimates for the year 2025 for the same age group is 12.1% or 2.6 million (Sicree, 2003).

Type 2 diabetes is a major cause of premature morbidity and mortality, particularly from cardiovascular diseases (CVDs), blindness, amputations and renal failure. Thus, the management of type 2 diabetes must

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not only address the control of hyperglycaemia but also the other CVD risk factors such as hyperlipidemia, hyperinsulinaemia, hypertension and obesity. Poor glycaemic control manifests in costly, lifelong morbidities, including blindness, kidney failure, amputations and cardiovascular diseases. The economic burden of treating long-term diabetes complications is well documented (Hogan, 2002; Wagner, 2001).

The involvement of community pharmacists in the management of the diabetes patient has been shown to be beneficial to the patient outcomes (Cranor, 2003). The expertise of the pharmacist in monitoring therapeutic outcomes in chronic diseases such as diabetes is under-utilized. In Malaysia, patients are not routinely referred to the community pharmacists for therapeutic monitoring, counseling and education as pharmacists are still not widely recognized as part of a multi-disciplined healthcare team.

The aim of this study was to assess short-term clinical outcomes of diabetes patients being provided with a diabetic care program by a dedicated community pharmacist in a community pharmacist set-up. It may be used as ground work to start a pharmacist-managed diabetes care clinic in the polyclinics or government hospitals.

METHODS

Study Design and Setting

This was a prospective study, using a single-group, pre-post design from systemic randomly selected out-patients (sixty seven patients who met the inclusion criteria and were willing to participate in this study) from 2 Government Polyclinics in Kuala Lumpur. These patients agreed to participate in this program voluntarily. They were followed up with 4 visits within a period of 3 months at the study site which was a community pharmacy. On their monthly visits, a specially designed diabetes managed care program for the community pharmacy was adhered to. Ethical clearance was made by Ministry of Health Malaysia (NIH) and Clinical Research Committee (CRC).

Sampling

Participants were informed about the aims and objectives of the study, its contents and consented to the study (written consent).

The inclusion criteria for the participants were:

- i. Patients with Type II Diabetes Mellitus currently on oral hypoglycaemic agents with or without insulin
- ii. Age group 40 – 64 years old

- iii. Men and women, irrespective of their race
- iv. Current levels of HbA_{1c} > 6.5 % or FBS > 8 mmol/L or PP-2 hours > 10.0mmol/L (based on patient's diabetic record book)
- iv. May also have other cardiovascular risk factors such as hypertension, hyperlipidaemia, overweight/obese

A secluded corner at the dispensing counter was used for the individualized diabetes education and counseling, clinical measurements, monitoring and pharmacotherapy assessment

Program Contents

The programs of the visits were as listed below:

- i. The patient's profile which included personal data, medical history and current medication (based on the green record book that was given to diabetes patients from the polyclinic) was taken.
- ii. A patient's visits record was created for the patient for the documentation of all the visits and parameters monitored for the duration of this study.
- iii. Clinical measurements for the HbA_{1c}, post prandial 2 hours blood glucose, total cholesterol, blood pressure reading, body weight, body mass index and waist circumference were done by the pharmacist..
- iv. A series of related questions to assess the patient's general awareness, understanding and knowledge of diabetes was asked.
- v. Counseling on topics such as understanding diabetes, preventing complications, importance of timings of dosing and compliance, importance of blood glucose monitoring, understanding the difference between the HbA_{1c}, fasting and post-prandial glucose levels was given to the patient during the monthly visits.
- vi. A daily dietary record form was given to the patients to have them record their daily food intake for at least 3 different days and this was evaluated by the pharmacist. Other nutritional and dietary advice based on the Medicinal Nutritional Therapy Guidelines were given.
- vii. Cardiovascular risk factors associated with diabetes such as high blood pressure, hyperlipidemia and obesity were explained and their significance and target levels emphasized.
- viii. Weight management was emphasized based on the weight, body mass index and waist circumference measurements taken at every visit. This was with reference to the Malaysian Clinical Practice Guidelines on the Management of Obesity 2004.
- ix. Evaluation of lifestyle behaviors such as smoking, alcohol intake and physical activities was done and changes were recommended accordingly based on the Malaysian Clinical Practice Guidelines on the Management of Type 2 Diabetes Mellitus 2004.

Table 1: Distribution of patients based on ethnicity

	Initial (%) n=47	Dropout (%) n=17	Final (%) n=30
Malay	23 (49)	12 (70)	11 (37)
Chinese	16 (34)	3 (18)	13 (43)
Indian	8 (17)	2 (12)	6 (20)

X A compliance measurement interview questionnaire described by (Morisky, 1986) was conducted once during the first visit and repeated on the final visit.

There were

4 questions that were asked in this questionnaire. For every “yes”, 1 point was allocated and zero points for a “no”. The total score was a maximum of 4 points. Higher scores would indicate poor compliance whereas lower scores, better compliance

xi. The participants were asked to fill up a patient awareness and satisfaction questionnaire at the end of the study. They were given a choice to complete it on the spot after the end of the final visit or they could take it home to fill it up. The results were judged by a 5-point Likert scale type (Strongly Agree- 4 points, Agree- 3 points, Undecided- 2 points, Disagree- 1 point, Strongly Disagree- 0 point). Assessment was done on the consensus of individual questions as well as the overall survey. The higher the score, the more satisfied they were about the program. The survey also solicited free-response feedback.

Clinical Data Collection

For the first visit, a baseline level of HbA1c and total cholesterol levels were taken. Measurements of these two parameters were taken again on the fourth and final visits.

Also on the first and every other subsequent visit, 2 hour post prandial blood glucose levels, blood pressure measurements, body weight, body mass index and waist circumference were taken. This served as a guide to the progress of the patient and to further encourage and motivate the patient on his participation in managing his diabetes. All the clinical measurements: the HbA1c, post prandial 2 hours blood glucose, total cholesterol and blood pressure were done by the pharmacist. Measurement of body weight, body mass index and waist circumference were taken by the pharmacy assistants.

Instrumentation

The instruments or diagnostic tools used for measurements of the outcome parameters were:

i. DCA 2000+ Analyzer (Bayer) which measured the HbA1c levels. The test linearity ranges from 2.5-14.0.

Values outside the range are reported as less than 2.5 or greater than 14.0.

ii. Optium Xceed Diabetes Monitoring System (Abbott Medisense) – measured the post prandial blood glucose. Measurement range was from 1.1 mmol/L – 27.8mmol/L. The test results are calibrated close to the plasma blood samples.

iii. Omron HEM 907 Digital Automatic Blood Pressure Monitor– measured the blood pressure by the oscillometric method. Measurement range was from 0 – 299 mmHg; accuracy is within ± 4 mmHg.

iv. Accutrend GCT (Roche Diagnostics) – measured the total cholesterol levels by the reflection photometry method. Measurement range was from 3.88 mmol/L – 7.76 mmol/L.

v. Omron Karada Scan – measured the body weight and calculated Body Mass Index. Measurement range was from 0 – 135 kg.

vi. Waist circumference was taken with a measuring tape measured to the nearest 0.1cm. It was taken midway between the inferior margin of the last rib and the crest of the ilium in a horizontal plane (WHO 1995).

Data Analysis and Statistical Methods

The data were analyzed using SPSS version 12.0. Numeric data were expressed as mean \pm SD or SEM depending on the barriers. Paired T-test was conducted to compare paired data with a significance level of $p < 0.05$. The statistical significance was performed with median and mean variables, 95 % confidence interval and odd ratios.

RESULTS

Patient Demographics and Characteristics

Of the 67 patients that consented and signed up to participate in the study, only 46 of them turned out for the initial visit. Drop-out of patients at follow-ups resulted in 30 patients remaining at the end of the study of which 27 came for 4 visits, 2 came for 3 visits and 1 patient for 2 visits. As such, all the data that were analyzed will be based on these 30 patients who completed the 3 months study period. Of the 30 patients, there were 17 males (56.7 %) and 13 females

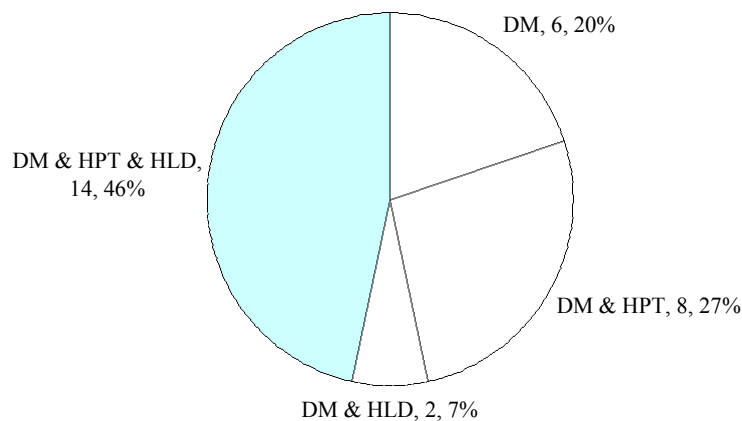


Figure 1 Pattern of Co-Morbidities DM – Diabetes Mellitus, HPT – Hypertension, HLD – Hyperlipidemia

Table 2: Clinical Measures for Mean Scores and Standard Deviations (n=30)

		Mean	Std. Deviation	Std. Error Mean
Pair 1	HbA1c PRE %	9.13	1.74	0.32
	HbA1c POST %	7.86	1.61	0.29
Pair 2	PP 2-HRS PRE (mmol/L)	13.02	4.24	0.77
	PP- 2-HRS POST (mmol/L)	9.68	3.52	0.64
Pair 3	TC PRE (mmol/L)	5.02	0.93	0.17
	TC POST (mmol/L)	4.65	0.79	0.14
Pair 4	SBP PRE(mmHg)	135.93	14.26	2.60
	SBP POST(mmHg)	126.87	13.53	2.47
Pair 5	DBP PRE (mmHg)	82.83	10.57	1.93
	DBP POST (mmHg)	78.00	10.07	1.84
Pair 6	WT IN kg PRE	74.20	14.48	2.64
	WT IN kg POST	74.04	14.20	2.59
Pair 7	BMI PRE kg/m ²	28.41	4.80	0.88
	BMI POST kg/m ²	28.32	4.76	0.87
Pair 8	WST PRE (cm)	95.01	11.22	2.05
	WST POST (cm)	93.82	10.89	1.99

PP-2 = Post prandial 2 hours; TC = total cholesterol; SBP = systolic blood pressure; DBP = diastolic blood pressure; WT = weight; BMI = body mass index; WST = waist circumference

(43.3 %). The mean age of the participants was 54.8 ± 5.6 years old. The minimum age was 44 years while the maximum was 64 years. The average age for the female participants was slightly higher at 55.0 ± 5.7 years as compared to the male participants which was 54.6 ± 5.7 . (Table 1)

History of Diabetes Mellitus

As for the breakdown of the number of years of having

been diagnosed with diabetes mellitus, 3 (10 %) patients have diabetes for less than a year, 18 (60 %) patients have diabetes for between 1 to 5 years, 7 (23.3 %) patients have diabetes for 5 – 10 years and only 2 (6.7 %) patients have diabetes for more than 10 years.

Pattern of Co-Morbidity

The breakdown of co-morbidities of the patients is summarized in Figure 1. In short, more than 80 % of

Table 3: Paired Samples Test for Clinical Outcome Measures

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	HbA1c pre % - HbA1c post %	1.27	1.17	0.21	0.83	1.70	5.94	29	0.000
Pair 2	PP 2- pre – PP 2- post (mmol/L)	3.34	5.20	0.95	1.40	5.28	3.52	29	0.001
Pair 3	TC pre – TC post (mmol/L)	0.37	0.78	0.14	0.07	0.66	2.56	29	0.016
Pair 4	SBP pre – SBP post (mmHg)	9.07	10.67	1.95	5.08	13.05	4.65	29	0.000
Pair 5	DBP pre – DBP post (mmHg)	4.83	5.36	0.98	2.83	6.84	4.94	29	0.000
Pair 6	WT in pre – WT in post (kg)	0.16	1.97	0.36	-0.58	0.89	0.44	29	0.667
Pair 7	BMI pre – BMI post kg/m ²	0.09	0.75	0.14	-0.19	0.37	0.63	29	0.534
Pair 8	WST pre – WST post (cm)	1.20	3.43	0.63	-0.09	2.47	1.91	29	0.066

the patients had more than one co-morbidity besides diabetes mellitus.

Pattern of Prescribed Anti-Diabetic Agents

The patients were prescribed an average of 1.97 oral hypoglycemic agents (OHAs) and/or insulin per patient. The common OHAs used were glibenclamide, gliclazide, metformin and acarbose. Only 1 patient was prescribed with insulin (Mixtard). 10 patients (33.3 %) were on 1 OHA, 12 patients (40 %) on 2 OHAs, 7 patients (23.3 %) on 3 OHAs and 1 patient (3.3 %) was on 4 OHAs. It must be noted that the 4th OHA (rosiglitazone) for this patient was added on by a private physician that this patient was also seeing

Clinical outcomes

A summary of the results of the clinical measures and its statistics is presented in Table 2 and Table 3. Based on the Clinical Practice Guidelines for Diabetes Mellitus

(2004), the summary of comparisons between outcome measures and target values are shown in Table 4. adherence and intervention for the patients is presented in Figure 3.

Compliance interview questionnaire analysis

The mean compliance score was 2.13 ± 0.90 at baseline and 1.63 ± 0.96 at the study end. The mean score for difference between the pre and post results was 0.5 ± 0.82 ($p < 0.002$).

Patients' satisfaction and feedback survey

The maximum points that can be scored by each patient were 44 points and minimum 0 point. The mean value for the overall satisfaction of the patients towards this program was 39.2 ± 4.6 . The minimum score was 29 points while the maximum score was 44 points. This would translate to an 89 % patient satisfaction rate for this diabetes management program.

Table 4 Summary of patients achieving target values and lifestyle changes

Target values*	Baseline (%) n=30	Study end n=30 (%)	Difference n
HbA1c % ≤6.5%	1 (3.3)	4 (13.3)	+ 3
Post prandial 2 hours < 8.0 mmol/L	3 (10)	12 (40)	+9
Blood Pressure < 130/80 mmHg	9 (30)	13 (43.3)	+4
Total Cholesterol < 4.5 mmol/L	12 (40)	15 (50)	+3
Waist circumference < 90 cm for men < 80 cm for women	3 (10)	4 (13.3)	+1
Body Mass Index ≤ 22.9 kg/m ²	0	1 (3.3)	+1
Exercise 150min/week	9 (30)	20(66.7)	+11
Smoker	5 (16.7)	4 (13.3)	-1
Alcohol	2 (6.7)	3 (10)	+1

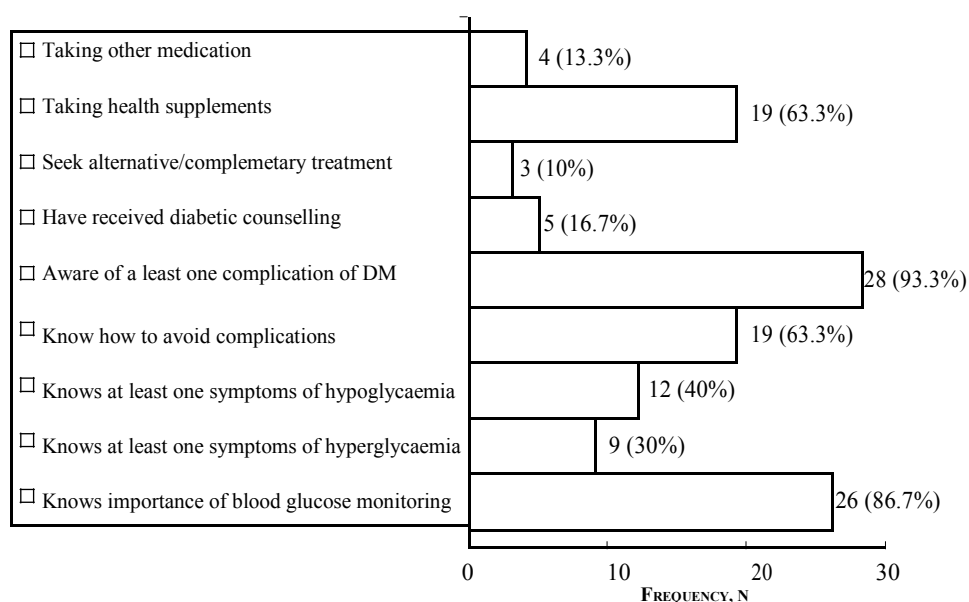


Figure 3 Analysis of therapy adherence and intervention

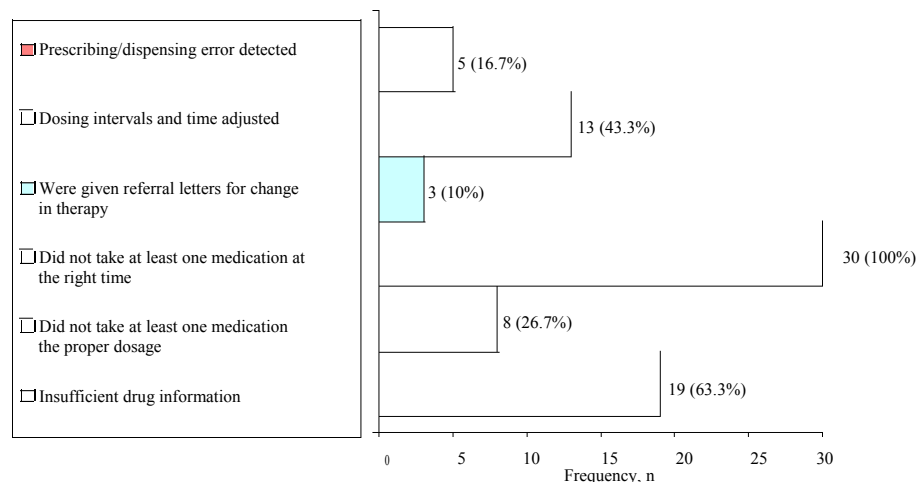


Figure 3 Analysis of therapy adherence and intervention

DISCUSSION

Based on the 30 patients that followed through the program for 3 months, a diabetes care program managed by a community pharmacist has shown significant reductions in the HbA1c levels, total cholesterol levels, systolic and diastolic blood pressure and post prandial blood glucose levels. The results are consistent and similar to the numerous studies done in other pharmacist-managed diabetic clinics in

ambulatory and community pharmacy models when pharmacists are involved in the care of patients with diabetes. The similar findings also obtained by various workers (Shane-McWhorter 2005; Garrett 2005; Leal 2004; Morello 2006; Cioffi, 2004; Cranor, 2003).

The mean reduction of 1.2 % for the value of HbA1c at the study end (baseline 9.1 ± 1.7 %, study end 7.9 ± 1.6) would translate into the reduction of diabetic related complications. A 1 % decrease in serum HbA1c corresponds to a significant decreased risk of complications. This includes 43% reduction in amputation or fatal peripheral blood vessel disease, 37 % reduction in microvascular complications eg kidney disease and blindness, 21 % reduction in all deaths

The summary of the findings of the patients' healthcare practices and awareness is presented in Figure 2. The summary of the analysis of therap

related to diabetes, 14% reduction in heart attacks and 12 % reduction in strokes (Stratton, 2000). Even so, the Western Pacific Declaration on Diabetes 2005 states that all improvements or reductions are beneficial, whether or not a target is reached.

Significant reductions in the HbA1c and post prandial 2 hours blood glucose levels as well as the other measured outcomes such as the total cholesterol,

systolic and diastolic blood pressure is most likely due to better compliance and adherence to therapy by the patients. The patients have a better understanding of their disease and know the importance of maintaining their blood glucose levels to target to avoid complications. They have also made some lifestyle and dietary modifications such as increasing their physical activity to at least 150 min/week, reducing simple

Carbohydrates such as rice, sugar, white bread and increasing complex carbohydrates such as whole grains, fruits, legumes and nuts. Low glycaemic index foods were suggested and certain food substitutions were recommended. They were asked to modify their

eating habits such as eating more frequent meals with smaller portions and avoiding high calorie snacks.

As for the patient's healthcare practices and awareness, there were 4 patients (13.3 %) who were taking additional medications besides the ones

prescribed at the polyclinic. The reasons were due to unavailability of the medication that was previously prescribed by the private doctor at the polyclinic. There was one patient who actually added on an anti-hypertensive drug due to the recommendation from his friend. He was advised appropriately about the dangers of his action. Health supplements and herbal remedies were also taken by 19 patients (63.3 %). An observation among the patients' belief is that herbal remedies are safe and better to take in the long term as they do not have any side effects, whereas allopathic medicine will damage their liver and kidneys in the long run. Alternative/complementary therapy was also sought by 3 patients (10 %). The reason was that they wanted to try to cure their diabetes whereby allopathic treatment only controls the disease.

It is a known fact that although the number of patie-

nts

with diabetes is increasing at a staggering rate, only about one third of patients receive diabetes education (Harris 1996). In this study, only 5 patients (16.7 %) had received some diabetes education but without any follow-ups. In the course of this study, reinforcement of compliance and adherence to therapy was given to the patient at every visit as it was observed that the patient could not retain everything at initial visits. As such, a diabetes management program with routine follow-ups is important to ensure adherence and motivation in the maintenance of glycaemic control. The Compliance

Score based on the interview questionnaire was significantly reduced, indicating better compliance to therapy by the patients. Based on the awareness and knowledge feedback, most of them who had voluntarily omitted their medications or reduced their dosages earlier were now taking their medications as directed again. With the counseling given by the pharmacist on adjustment of dosage times and ways to reduce the side effects of the medications, the patients' drug tolerability and willingness to continue with "problematic" drugs were contributive in the overall improvement in their therapy adherence.

Based on the survey feedback analysis nearly all of the patients were agreeable that their understanding about diabetes in general has increased since joining the program. All participants agreed that they are more aware about the importance of medication compliance and dosing times since joining the program. Fairly all agreed that they are more conscious about the food that they eat and those they make an effort to avoid foods that may affect their blood glucose. 96.7 % have made an effort to start exercising or have increased or maintained the frequency of exercise. All of them agreed that they are more aware about the complications of diabetes that they may encounter if they do not control their blood glucose levels. Similarly all of them agreed that they are satisfied with the counseling, advice and guidance that they have received from the pharmacist. But 96.7 % found it easy to confide in the pharmacist about the obstacles that they face in controlling their blood glucose levels. 93.4% agreed that if they had not participated in this program, they would not be motivated to improve their uncontrolled or high glucose levels. Again all participants agreed that a diabetic program managed by pharmacists like this is beneficial to help create more awareness to diabetics like them. Nearly all agreed that a community set-up like this is appropriate to conduct a program like this. Again nearly all (96.7 %) agreed that they are determined to maintain the changes that they have made for the past 3 months after this study program is over.

The overall patient satisfaction score of is a valuab-

le indication that the patients were satisfied with this diabetic management care program. In short, the community pharmacist has made an impact on the patients to attain a high score like this.

From the interaction and communication between the pharmacist and the patient, some of the comments

were that they felt that there is no proper follow-up at the polyclinics as they were seen by different doctors at every visit. They were not told much about their conditions by their doctors, thus did not know exactly what to do to control their diabetes.

The patient's tolerability to the medications (side effects) was not asked. Language is a barrier to some of the Chinese patients as they do not understand the doctor's instruction in Malay.

They do not get proper guidance as to how to lower their blood glucose levels when their blood glucose is high. Instead they get scolded or accused of eating excessively. Also, proper instructions on the dosage timings of the diabetic medications in relation to meal times were not given clearly.

CONCLUSION

This study has demonstrated that community pharmacists can provide and conduct effective diabetic management programs with significant clinical outcome measures. Significant decrease in HbA1c translates to the reduction in the risk of diabetic complications. Significant reductions in total cholesterol and blood pressure were also relevant in the reduction of cardiovascular risk factors. The community pharmacist has also managed to influence more of the patients to start exercising more consistently. This study has also shown that the patients' compliance and adherence to therapy improved after following this program for 3 months. Based on the participants' feedback survey, they were very satisfied with the program and would like to see it as a regular and continuing program to benefit more diabetics like them

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