

Comparative-Effectiveness Research/HTA

Impact of a Collaborative Pharmaceutical Care Service Among Patients With Diabetes in an Ambulatory Care Setting in Qatar: A Multiple Time Series Study



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ABSTRACT

Background: Diabetes mellitus is highly prevalent in the Middle East and the burden associated with it is dramatically increasing. Pharmacists working in collaborative healthcare teams have an important role to improve outcomes in the primary care of diabetes. **Objectives:** To evaluate the impact of a collaborative pharmaceutical care service (CPCS) on improving outcomes among patients with diabetes in a primary care setting. **Methods:** This was a retrospective, multiple time series study involving patients attending an ambulatory diabetes clinic at Qatar Petroleum Healthcare Center in Dukhan, Qatar. Patients' glycated hemoglobin A_{1c}, fasting plasma glucose, body mass index, systolic blood pressure, diastolic blood pressure, and lipid profile were obtained at baseline, 6 months, and 12 months of receiving CPCS through a retrospective chart review. A repeatedmeasures analysis of variance test was used to determine the impact of the intervention on clinical outcomes. **Results:** Ninety-six patients with diabetes were included in the analyses. There was a statistically significant reduction (ie, improvement) in glycated hemoglobin A_{1c} by 1.4%, fasting plasma glucose by 41.3 mg/dL, body mass index by 1 kg/m², systolic blood pressure by 14.9 mm Hg, and diastolic blood pressure by 8.7 mm Hg from baseline to 12 months (P<.001 for all). Nevertheless, no significant reductions were observed in the lipid profile. **Conclusions:** CPCS provision improves clinical outcomes in patients with diabetes over a 12-month follow-up period in a primary healthcare setting. Future studies should determine the long-term impact of a collaborative care model in this setting. **Keywords:** clinical outcomes, collaborative care, diabetes mellitus, multidisciplinary, pharmaceutical care, primary healthcare, Qatar

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Introduction

Diabetes mellitus affects many people worldwide, and its prevalence has reached epidemic proportions.¹ Diabetes affected 8.8% of people between the age of 20 and 79 years in 2017 globally.² The number of individuals with diabetes is expected to rise by 55% to 592 million by 2035.^{3,4} Diabetes-related complications, including nephropathy, retinopathy, neuropathy, stroke, and cardiovascular diseases, are increasing in parallel with high rates of uncontrolled diabetes.⁵ This increase results in huge economic burden on healthcare systems globally. Overall, the risk of mortality among patients with diabetes is almost twice that of people of a similar age who do not have diabetes.⁶ Almost half of all deaths attributable to diabetes occur before the age of 70 years.⁷ In the Middle East and North Africa region, 0.3 million people aged 20 to 79 years died because of diabetes in 2017,² and it will be the seventh cause of death by 2030.⁸ Similarly, the prevalence of diabetes and the mortality associated with it are high in Qatar.

Managing diabetes is among the top priorities in Qatar's National Health Strategy.⁹ The prevalence of diabetes among adults in Qatar is 14.1%,¹⁰ which is projected to rise to 29.7% by 2035.⁴ The prevalence of diabetes-related complications, particularly,

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nephropathy, retinopathy, and neuropathy, among Qataris with diabetes between 2011 and 2013was 12.4%, 12.5%, and 9.5%, respectively.¹¹ Regarding cause-specific mortality, diabetes was responsible for 9.03% of deaths in Qatar.¹² In an unpublished study conducted in a primary healthcare center in Qatar, approximately 86% of patients with diabetes had uncontrolled diabetes (glycated hemoglobin A_{1c} [Hb A_{1c}] >7.5%). In another study among patients with uncontrolled diabetes in a primary care setting in Qatar, 73% of the patients were nonadherent to their medications.¹³ Therefore, the high prevalence of diabetes and its complications, along with the increased prevalence of uncontrolled diabetes management service.

Diabetes management is not only restricted to medications but rather requires a multidimensional approach, including lifestyle-related aspects, medication-related aspects, selfmonitoring, and continuous follow-up.¹⁴ This approach increases the need for specialized services and a multidisciplinary collaborative care model in managing diabetes to help improve clinical outcomes and reduce the risk of complications. Pharmacist-led services have been shown to be effective in managing many noncommunicable diseases including hypertension, asthma, arthritis, and others.^{15–17} This service generally includes, but is not limited to, medication review, patient education and counseling, self-care empowerment, and lifestyle adjustment.¹⁸ Furthermore, pharmacist-led interventions were shown to have a positive impact on patients with diabetes in terms of improved clinical outcomes, such as HbA_{1c} , blood pressure (BP), medication adherence, and increased quality of life.^{19–23} Continuous improvements in health outcomes and cost savings were also evident when patients with diabetes received ongoing pharmaceutical care services from a community pharmacy diabetes care program.24 In addition, several systematic reviews clearly support the impact of such services on reducing hospitalizations, risk of diabetes-related complications, and mortality.^{25–28}

Although global evidence supports the positive impact of pharmaceutical care interventions among patients with diabetes, it is unknown whether such interventions would improve patient outcomes in a primary healthcare setting in Qatar. Pharmacists' roles are largely limited to traditional dispensing and medication reconciliation upon limited physician referrals within the primary care sector in Qatar. In addition, pharmacist-led services and collaborative care models vary among different countries and settings. To our knowledge, there were no studies conducted in Qatar to document and assess the impact of a pharmacist's care in the context of a collaborative pharmaceutical care service (CPCS) on the outcomes of diabetes.

Thus, the purpose of this study was to assess the impact of a CPCS on clinical outcomes among patients with diabetes receiving care in a primary care setting in Qatar. The study was conducted as per the international guidelines for conducting research in human subjects. Qatar Petroleum (QP) and Qatar University Institutional Review Board approved the research protocol and data collection instruments. Patient confidentiality was maintained, and their identifiers were not disclosed. As in most retrospective data collection studies, no patient consent was required for this study.

Methods

Study Design

This was a multiple time series, retrospective study involving patients with diabetes attending a diabetes care clinic in Qatar.

Study Setting

This study was conducted at the diabetes clinic of QP Healthcare Center in Dukhan. The center provides various high-quality services including pharmacy, pathology, x-ray, ultrasound, and dental services to QP employees and their families, as well as other members of the community, including Qatar nationals and residents. The diabetes clinic has been providing pharmaceutical care to patients with diabetes and other chronic diseases in Qatar since 2007. Nevertheless, comprehensive documentation of the service through the Medical Information Management System was recently implemented in 2016.

Study Population and Participants

The study includes all adult patients previously or newly diagnosed with diabetes receiving care for diabetes at the QP Healthcare Center only. Patients were eligible to be included if they were 18 years or older, diagnosed with diabetes type 1 or type 2, and referred by the physician to the CPCS.

Sample Size and Sampling Technique

The sample size of 82 was estimated using G-Power 3.1 software (Heinrich-Heine University, Düsseldorf, Germany)²⁹ with the following inputs: (1) tails, 2; (2) effect size, $0.4^{24,30}$; (3) α error probability, 0.05; and (4) power, 0.9. The effect size of HbA_{1c} obtained from the literature was used in the power analysis. After accounting for 20% missing or incomplete data, the total sample size needed was approximately 100 patients. Because the service documentation was introduced in 2016, it was expected that the population would be small. Therefore, universal sampling technique was applied to include all eligible patients who received the service and had complete documentation (n = 96).

Description of the CPCS

Under the CPCS, the pharmacist in collaboration with a nurse educator undertakes medication reconciliation, drug therapy assessment, and patient and family education with the aid of audiovisuals, pictograms, and scheduled telephone follow-ups. The pharmacist also communicates with physicians to resolve any identified drug-related problems (DRPs) and documents the interventions using a specific intervention form. The intervention form is a modified version of pharmacist's workup of drug therapy documentation, which comprised the pharmacist's patient database, assessment of drug therapy, desired therapeutic outcomes, therapeutic alternatives, patient-specific recommendation, and monitoring and follow-up plan. The pharmacist and the nurse educator have full access to patients' electronic medical records. Each patient interaction lasts approximately 30 to 40 minutes. The frequency of follow-up varied according to each patient's need, but majorly done on a monthly basis. Regular face-to-face and telephone follow-ups are individualized on the basis of each patient's case. Moreover, patients can call the pharmacist at any time to inquire about or report any adverse event experienced. So far, only 1 pharmacist and 1 nurse educator are involved in the CPCS. The pharmacist has more than 10 years of experience in diabetes education in primary care settings. The pharmacist focuses on drug-related issues and monitoring, whereas the nurse educator focuses on non-drug-related issues such as lifestyle, psychosocial support, and self-care.

Data Collection Instrument

We developed a data collection instrument to retrieve relevant data from the medical records. The form included the following sections: patient's sociodemographic information, clinical data, and diabetes-related outcomes. The instrument was reviewed by 2 experts in the research field (1 professor of clinical pharmacy and 1 practitioner from the hospital setting). The practicing pharmacist and nurse piloted the instrument by collecting data recorded from 2 randomly selected patients' medical records to ensure feasibility and efficiency of the data collection.

Outcome Measures

The primary outcome measures were clinical outcomes (ie, HbA_{1c} , fasting plasma glucose [FPG], BP, body mass index [BMI], and lipid profile). These outcomes were extracted for each patient at baseline (defined as the outcome measures at the beginning of the previous 12 months) and at 6 and 12 months of follow-up. The secondary outcome measure was DRPs identified by the pharmacist during the same follow-up period of 12 months.

Statistical Analysis

Data were analyzed descriptively and inferentially as appropriate using Statistical Package for Social Sciences software version 23.0 (IBM Corp, Armonk, NY) and Microsoft Excel. Frequencies and percentages were used to describe the patients' demographic and clinical characteristics at baseline. Repeated-measures analysis of variance test was used to compare the primary outcomes at baseline and after receiving the CPCS for 12 months. Comparisons were carried out using a significance level of .050 or less (2-sided P value).

Results

Baseline Sociodemographic Characteristics of the Study Patients

Ninety-six eligible patients with a mean age of 49.8 ± 9.2 years (range 34-84 years) were included in the analyses. Only 1 patient was excluded because of incomplete profile data. Most (67.7%) were male and of Qatari (32.3%) or Indian (34.4%) nationality. Table 1 presents the baseline sociodemographic characteristics of the patients.

Baseline Clinical Characteristics of the Study Patients

As presented in Table 2, all patients had type 2 diabetes mellitus, with an average BMI of 29 \pm 5.4 kg/m². Diabetes-related

Table 1 – Sociodemographic characteristics of patients with diabetes attending an ambulatory diabetes clinic in Qatar (n = 96).

Variable	n (%)
Age (y), mean ± SD	49.8 ± 9.2
Sex	
Male	65 (67.7)
Female	31 (32.3)
Nationality	
Indian	33 (34.4)
Qatari	31 (32.3)
Sudanese	4 (4.2)
Others	28 (29.2)
Smoking status	
Never smoked	46 (47.9)
Ex-smoker	18 (18.8)
Current smoker	32 (33.3)
SD indicates standard deviation.	

Table 2 – Baseline clinical characteristics of patients with diabetes attending an ambulatory diabetes clinic in Qatar (n = 96).

	(01)
Variable	n (%)
Diabetes mellitus	
Туре 1	0 (0.0)
Туре 2	96 (100.0)
Weight (kg), mean ± SD	79.9 ± 16.6
Height (m), mean \pm SD	1.7 ± 0.1
BMI (kg/m²), mean ± SD	29.1 ± 5.4
Comorbidities	
Hypertension	94 (97.9)
Coronary heart disease	0 (0.0)
Dyslipidemia	95 (99.0)
Obesity	30 (31.3)
Asthma	3 (3.1)
Diabetes-related complications	
Macrovascular complications	
Ischemic heart disease	2 (2.1)
Peripheral vascular disease	2 (2.1)
Cerebrovascular disease	0 (0.0)
Microvascular complications	
Diabetic nephropathy	52 (54.2)
Diabetic neuropathy	88 (91.7)
Diabetic retinopathy	1 (1.0)

BMI indicates body mass index; SD, standard deviation.

microvascular complications, namely, neuropathy and nephropathy, were prevalent in 91.7% and 54.2% of the patients, respectively. Nevertheless, a very small percentage of the patients experienced diabetes-related macrovascular complications such as ischemic heart disease (2.1%) and peripheral vascular disease (2.1%) (Table 2).

Figure 1 presents antidiabetic medication regimens received by the patients at baseline and at 12 months of follow-up. At baseline, most of the patients received 1 (25%), 2 (28.1%), or 3 (29.2%) oral hypoglycemic agents (OHAs). Nevertheless, more patients were switched to 1 OHA, 2 OHAs, or 1 OHA plus insulin (32.3%, 32.3%, and 21.9%, respectively) at 12 months of follow-up compared with the baseline. Moreover, the proportion of patients who were following only dietary restrictions with no antidiabetic medications increased from 1% to 6.3% at 12 months of the intervention.

Clinical Outcome Measures

The changes in clinical outcomes from baseline to 12 months of receiving CPCS are presented in Table 3. Upon initiation of the intervention, each outcome was measured at baseline, 6 months, and 12 months. HbA1c consistently and significantly decreased from baseline to 12 months (8.5% \pm 1.4% vs 7.1% \pm 1.1%) with a difference of 1.4% (P<.001). Similarly, FPG also significantly decreased from baseline to 12 months of the CPCS intervention by 2.3 mmol/L (8.6 \pm 2.1 mmol/L vs 6.3 \pm 0.6 mmol/L; P<.001). HbA_{1c} and FPG consistently and significantly decreased from baseline to 12 months (HbA_{1c}: 8.5% vs 7.1%; P<.001; FPG: 8.6 \pm 2.1 mmol/L vs 6.3 ± 0.6 mmol/L; P<.001). Both systolic blood pressure (SBP) and diastolic blood pressure (DBP) significantly dropped by 14.9 and 8.7 mm Hg, respectively (P<.001), after 12 months of receiving CPCS. Furthermore, the weight and BMI of patients were significantly reduced by 3 kg and 1 kg/m², respectively (P<.001 for both). Nevertheless, patients' lipid profiles (low-density lipoprotein

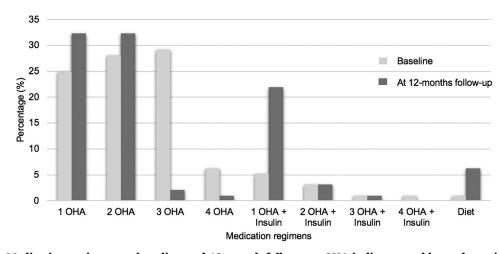


Fig. 1 - Medication regimens at baseline and 12-month follow-up. OHA indicates oral hypoglycemic agent.

cholesterol, high-density lipoprotein cholesterol, triglycerides, and total cholesterol) did not significantly change throughout the 12-month follow-up period.

Pharmacist-Identified DRPs

Table 4 presents the types of DRPs identified by the pharmacists who provided the CPCS at QP Healthcare Center during 2016. The American Society of Hospital Pharmacists classification 1996³¹ was used to classify the DRPs. A total of 133 DRPs were identified. The most frequently identified DRPs were lack of understanding of the medication (39.8%), inappropriate dose, dosage

Table 3 – Clinical outcome measures in patients with diabetes attending an ambulatory diabetes clinic in Qatar ($n = 96$).					
Outcome	Mean <u>+</u> SD			Р	
measure	Baseline	6 months	12 months	value*	
Glycemic contro	1				
HbA _{1c} (%)	8.5 ± 1.4	7.4 ± 1.2	7.1 ± 1.1	<.001	
FPG (mmol/L)	8.6 ± 2.1	6.4 ± 1.2	6.3 ± 0.6	<.001	
Anthropometry					
Weight (kg)	79.9 ± 16.6	78.3 ± 15.8	76.9 ± 15.4	<.001	
BMI (kg/m²)	29.1 ± 5.4	28.5 ± 5.1	28.1 ± 5.1	<.001	
BP (mm Hg)					
Systolic	140.2 ± 15.7	129.1 ± 14.7	125.3 ± 11.3	<.001	
Diastolic	84.7 ± 9.5	79.5 ± 8.5	76.0 ± 6.7	<.001	
Lipid profile (mmol/L)					
LDL-C	2.7 ± 0.8	2.8 ± 0.9	2.7 ± 0.9	.702	
HDL-C	1.2 ± 0.5	1.2 ± 0.5	1.3 ± 0.7	.551	
TG	1.6 ± 0.9	1.7 ± 0.9	1.7 ± 0.9	.728	
TC	4.3 ± 0.1	4.3 ± 1.1	4.1 ± 0.9	.101	

BMI indicates body mass index; BP, blood pressure; FPG, fasting plasma glucose; HbA_{1c}, glycated hemoglobin A_{1c}; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; SD, standard deviation; TC, total cholesterol; TG, triglycerides.

^{*} P value was calculated using repeated-measures analysis of variance. Comparisons were made among all time points. No post hoc analysis was conducted. form, schedule, route of administration or method of administration (17.3%), and actual and potential adverse drug events (14.3%).

Discussion

This is the first study in Qatar to evaluate the impact of a CPCS on diabetes outcomes in a primary healthcare setting. A significant improvement in the HbA_{1c} was observed over the 12-month follow-up period (P<.001). Consistent with our findings, Cranor and Christensen³⁰ showed that 57% of patients with diabetes who received the community-based pharmaceutical care service had achieved the target HbA1c (<7.0%) at the end of 9 months of followup (P=.040). Other studies reported a similar reduction in HbA_{1c} from baseline by 0.8% to 1.19% after a shorter follow-up period than in our study.^{19,23,24} One study reported a decrease by 21% in the risk of any diabetes-related endpoint, 21% in diabetes-related deaths, 14% in myocardial infarction, and 37% in microvascular complications with each 1% decrease in HbA_{1c}.³² Nevertheless, Machado-Alba et al $^{\rm 33}$ reported no ${\rm HbA}_{\rm 1c}$ improvement after pharmaceutical care provision. In the present study, FPG significantly dropped from baseline to 6 and 12 months by 41.3 mg/dL (ie, 2.3 mmol/L) (P<.001) compared with 27.2 mg/dL as reported by Obreli-Neto et al.34

The intervention also led to a significant reduction in BMI (1 kg/ m^2 ; P<.001) and weight (3 kg; P<.001) over the 12 months of followup. A study reported a similar significant reduction in BMI in patients receiving pharmaceutical care compared with the control group (29.1 kg/m² vs 29.7 kg/m², respectively; P=.020).³⁵ Similarly, a randomized controlled trial reported BMI reduction by 1.05 kg/ m² after patients received pharmaceutical care services for 12 months.³⁶ There was no effect of pharmaceutical care on weight reduction within and between groups as reported by another randomized controlled trial.³⁷ Nevertheless, patients were followed up for only 4 months in the former study, which may be insufficient to show a significant reduction in weight.

Furthermore, SBP and DBP decreased by 14.9 and 8.7 mm Hg, respectively, at the 12-month follow-up. CPCS intervention led to a higher drop in BP compared with that in other studies with the same follow-up period. Pharmacists' interventions reduced SBP by 9 mm Hg over 12 months in 1 study.³⁸ Another study reported a decrease in SBP and DBP by 14 and 5 mm Hg, respectively, after pharmaceutical care provision.³⁹ One study, however, showed

Table 4 – Types of drug-related problems identified by pharmacists among patients with diabetes attending an ambulatory diabetes clinic in Qatar.			
Type of drug-related problem	n (%)		
Lack of understanding of the medication	53 (39.8)		
Inappropriate dose, dosage form, schedule, route of administration, or method of administration	23 (17.3)		
Actual and potential adverse drug events	19 (14.3)		
Failure to receive the full benefit of prescribed therapy	10 (7.5)		
Condition for which no drug is prescribed	7 (5.3)		
Failure of the patient to adhere to the regimen	7 (5.3)		
Medication prescribed inappropriately for a condition	5 (3.8)		
Medication with no indication	4 (3.0)		
Actual and potential drug-drug, drug-disease, drug-nutrient, and drug-laboratory test interactions	3 (2.3)		
Therapeutic duplication	2 (1.5)		
Interference with medical therapy by social or recreational drug use	0 (0.0)		
Prescribing of medication to which the patient is allergic	0 (0.0)		
Problems arising from the financial impact of therapy	0 (0.0)		

that SBP and DBP did not change significantly after the pharmacist's intervention compared with the control group³⁵ within only 5 months. Planas et \hat{al}^{40} reported a significant reduction in SBP (15.2 mm Hg; P=.010), but not in DBP (4.4 mm Hg; P<.050), after a 9-month follow-up. Conversely, the Pharmacist Assisted Medication Program Enhancing the Regulation of Diabetes study reported significant improvement in DBP (intervention: 73.4 mm Hg; control: 77.6 mm Hg; P<.050), but not in SBP, by the end of a 12-month follow-up period.¹⁸ A systematic review reported an SBP change between groups ranging between -3.3 and -23.05 mm Hg and a DBP change ranging between $-0.21 \mbox{ and } -9.1 \mbox{ mm}$ Hg.⁴¹ Tight BP control (<150/85 mm Hg) helps in reducing diabetes-associated macrovascular and microvascular complications and death according to the UK Prospective Diabetes Study 38.42

The lipid profile parameters (low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides, and total cholesterol) did not change significantly after the 12-month follow-up period (P=.702, .551, .728, and .101, respectively). Similarly, 2 studies reported a small, evident improvement in lipid profile that was not significant.^{24,30} The lipid profile parameters require a prolonged period of follow-up to show a clinically significant decrease compared with the baseline.

The collaborative aspect of the intervention helped in lowering multiple OHA use beyond 2 agents, but led to the addition of insulin to 1 OHA compared with the baseline. More patients were solely managed by diet after the 12-month follow-up. One study showed a significant improvement in the percentage of patients' medication understanding by 5.3% (P=.005) and medication adherence by 0.9% (P=.001) compared with the baseline.²³ Another study, however, showed no effect of pharmaceutical care on the mean number of medications used per patient $(P=.092)^{34}$ because authors reported only the mean number of drugs used in the last month of the 36-month study. This finding does not reflect the difference in medication use within the intervention group (preand postintervention) or the impact of the pharmacist's intervention in switching patients to more appropriate therapeutic regimens.

One hundred thirty-three DRPs were identified by the pharmacist and acted upon in collaboration with physicians. Jahangard-Rafsanjani et al³⁵ showed that pharmacist-delivered diabetes support program significantly increased the number of patients with drug therapy modification (21.3%) compared with the control group (7.5%) (P=.070). Another study reported that the most commonly identified DRPs were additional therapy needed and low dose.⁴³ Differences in DRP classification are attributed to differences in the settings and locations of practice.

There are several limitations to be considered when interpreting the results of the present study. We retrospectively evaluated the impact of CPCS on diabetes outcomes over time (baseline, 6 months, and 12 months) in the absence of a parallel control group. Future randomized controlled studies are needed to address this limitation. Furthermore, not all the patients included in the sample were new to the service; therefore, the baseline may not truly reflect the patients' values before receiving CPCS. Although the cohort may not be representative of the entire population with diabetes because of the absence of CPCS in other primary healthcare centers in Qatar, the results are of value because they provide evidence of the potential impact of CPCS on diabetes outcomes. Coincidently, all patients had type 2 diabetes, because the early incidence of type 1 diabetes in patients younger than 18 years was an exclusion criterion. The impact of comprehensive care may not necessarily be evident in young patients. In addition, the study followed patients for only 12 months, which may not be adequate to determine the longterm benefits of CPCS.

Conclusions

This is the first study in Qatar to evaluate the potential impact of CPCS on diabetes outcomes in a cohort of individuals with type 2 diabetes attending primary care clinics. Consistent with worldwide studies, this study confirms that in a primary healthcare center in Qatar, the implementation of an ambulatory, pharmacist-based intervention would potentially improve several clinical outcomes in patients with type 2 diabetes, including HbA_{1c}, FPG, weight, BMI, SBP, and DBP. Furthermore, this service promotes comprehensive identification of DRPs in patients with diabetes who are followed by the pharmacist in the primary healthcare setting for the purpose of optimizing patient therapeutic outcomes. Future studies should use more robust, randomized, controlled trial designs and measure both short- and long-term benefits of CPCSs in primary care settings.

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