

Original Article

Pharmacist Interventions in Improving Clinical Outcomes in Patients with Type 2 Diabetes Mellitus Among the Underrepresented Population: A Collaborative Ambulatory Care Pharmacy Practice (CAPP) Approach

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ABSTRACT

Objective: The objective of this study was to evaluate the impact of pharmacist's interventions through a collaborative ambulatory care pharmacy practice (CAPP) model in patients with type 2 diabetes mellitus (T2DM) among the underrepresented population. **Methods:** Eligible patients were 18 years and older with a diagnosis of T2DM with or without comorbid cardiovascular disease risk factors. Patients were enrolled through routine primary care provider referrals. During a one-on-one, face-to-face scheduled clinic visit, the pharmacist provided a comprehensive medication management by reviewing vital signs and laboratory values, provided medication reconciliation and management, followed by medication counseling through a CAPP approach in a primary care setting. The pharmacist worked in close collaboration with the primary care provider to intervene on medication therapy through recommendations to initiate, adjust, modify, or discontinue drug therapy and order laboratory tests and drug concentration levels as appropriate. Each visit was documented as a "PharmD Progress Note" in the patient's electronic medical record. Follow-up visits were scheduled until patients' targeted treatment goals were achieved. Primary and secondary outcome data were collected and then analyzed. **Findings:** A pharmacist saw 47 patients over 12 months. Sixty-four percent of the participating patients were able to achieve targeted treatment goals. A statistically significant decrease in the mean change in hemoglobin A1c, diastolic blood pressure, fasting blood glucose, and triglyceride levels was observed from the baseline which was -2.3%, -7.75 mmHg, -76.1 mg/dL, and -55.5 mg/dL, respectively. No significant changes in other clinical outcomes were observed. **Conclusion:** The CAPP model demonstrated a significant reduction in clinical endpoints in patients with T2DM among the high-risk underrepresented population.

KEYWORDS: Ambulatory care, clinical outcomes, collaborative ambulatory care pharmacy practice, diabetes mellitus, medication adherence

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INTRODUCTION

The United States health-care system is currently placing a strong emphasis on the effectiveness of clinical outcomes from treatment regimens of chronic diseases. The prevalence of multiple chronic health conditions is increasing and will continue to grow as the population age. About 44% of the US population has \geq one chronic condition(s), and one-third has \geq three chronic conditions. Patients with multiple chronic health conditions usually require complex medical management

and are likely to be subjected to taking numerous medications to manage their chronic health conditions. Challenges found around effective clinical outcomes of achieving the optimal treatment goals and preventing long-term complications. Besides, worsening of the

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disease severity and uncontrolled clinical outcomes may potentially increase health-care costs from higher hospital admission rates.

Diabetes mellitus is a prototype for this problem. People with diabetes mellitus must attain their glycemic control and the ability to manage their comorbidities related to cardiovascular disease risk factors such as high blood pressure and elevated cholesterol.^[1,2] A report released by the American Association of Colleges of Pharmacy^[3-5] Standing Committees and Argus Commission (AACP Report) in 2010 states that the increasing complexity of patients and their treatment regimens in primary health-care settings requires access to providers who can manage patients' medication therapy, identify adverse events, and manage drug-related problems. Thus, pharmacists are trained and qualified to provide the required care around medication management in the primary or ambulatory care setting and have demonstrated their abilities to improve clinical- and patient-related outcomes. This report also eludes that pharmacists will have new opportunities to provide direct delivery of primary or ambulatory care services to the patients collectively and collaboratively with other primary care providers. The pharmacists' efforts will be complementary to those of other health professions and not competitive. Therefore, an interprofessional effort will be required to meet the primary care needs of all Americans now and for the coming decades.

With the introduction of the Patient Protection and Affordable Care Act, which emphasizes the safety and quality of medication use, there is an incredible opportunity for pharmacists to take a leadership role in direct patient care.^[6] Pharmacists are accountable for ensuring that a patient's drug therapy is appropriate, effective, and safe and that the patient is compliant with the treatment plan. In lieu, the Medicare Modernization Act of 2003 requires that Medicare Part D insurers should provide medication therapy management (MTM) services to selected beneficiaries,^[7] with the goals of providing education, improving adherence, or detecting adverse drug events and medication misuse.^[8] In a consensus definition, MTM has been defined as "a distinct service or group of services that optimize therapeutic outcomes for individual patients that are independent of, but can occur in conjunction with, the provision of drug product." A detailed framework and the core elements of an MTM service model can be found in a statement released by the American Pharmacists Association and the National Association of Chain Drug Stores Foundation.^[9-12] Unlike MTM, comprehensive medication management (CMM)^[13] is conducted in a collaborative setting where pharmacist assesses each patient's

medications including prescription and nonprescription items and individualizes the care with appropriate follow-up to determine the targeted patient-related outcomes. By virtue of pharmacist's knowledge and training in pharmacy education puts them into a suitable position to perform CMM. Therefore, pharmacists are, more than anyone, qualified and trained to work onsite in a primary care practice settings or in an ambulatory environment,^[14-16] either at an integrated health system or at a physician's office based^[17] or at a community clinic site, to optimize patient's complex medication regimens.

A study conducted by Chong^[18] in the Micronesian community in Hawai'i with diabetes mellitus discovered that the minority populations are more vulnerable to long-term complications of uncontrolled diabetes and medication nonadherence. One of the reasons that had been identified for the Micronesian community for opting out from the treatment regimen was the misconceptions around westernized medicine due to diverse language, cultural, social, and economic influence. Therefore, the study was designed to incorporate diabetes education on the clinical outcomes of Micronesian patients with diabetes mellitus. The results demonstrated positive outcomes in achieving the targeted treatment goals, enhancing medication compliance, improving clinical outcomes, and preventing rapid progression of long-term complications. The diabetes education program proposed in the study had customized weekly diabetes education classes that were administered by a team of health-care professionals, including pharmacists, nurses, family care physicians, dietitians, social workers, physician assistants, and others. The program helped to develop an amicable and family atmosphere by creating successful care and learning environment to build trust and the lasting patient-provider relationship. Direct patient care was provided readily with easy access through collaborative care on a continual weekly basis as well as any follow-up visits. Such collaborative effort in providing patient care had proven clinical outcomes in the patient community, especially in patients who are at high risk for treatment failures. Based on the result of the Micronesian study, the current study was sought to evaluate the impact of implementing an ambulatory care pharmacy practice model to improve clinical outcomes in patients with diabetes mellitus among the underrepresented population in Lawndale, California.

METHODS

This is a prospective, non-crossover, pre- and post-intervention study design conducted in a primary care setting located in the city of Lawndale over 18 months. The purpose of this study was to evaluate the impact of a collaborative ambulatory

care pharmacy practice (CAPP) model to improve clinical outcomes in patients with type 2 diabetes mellitus (T2DM) in the high-risk underrepresented patient population. Enrolled patients were referred by the primary care providers (nurse practitioner, physician assistant, or primary care physician) during regular clinic visits from June 1, 2015, to January 31, 2017. Patient consent forms and institutional review board approval were attained before the start of the study. The study was advertised using word-of-mouth by the participating patients. Eligibility criteria for study enrollment include: (i) patients aged 18 years and older at the time of study enrollment, (ii) history of attending clinic on a regular basis, (iii) had been diagnosed with T2DM, with or without hypertension and/or dyslipidemia, (iv) medication treatments were not at goals during regular clinic visit, (v) experienced adverse drug events from the medications, (vi) had provided written informed consent before participating in the study, and (viii) were likely to reside in the East Los Angeles or surrounding area for at least 12 months. Patients were ineligible if they had: (i) a severely debilitating condition such as cancer, AIDS, psychiatric disorder, or substance abuse which might limit full participation in the study, (ii) inability to complete study forms or questionnaires, (iii) foreseen difficulty in coming for regular clinic visits, or (iv) had a diagnosis of pregnancy during the study period.

The overall framework of the study started with selecting the patients using eligibility criteria, as discussed earlier. After patients were identified, they were then scheduled for one-on-one and face-to-face clinic visit appointments with the pharmacist to have their medication optimized based on targeted therapeutic goals through a CMM using the CAPP model. The involved pharmacist in this study had a Doctor of Pharmacy degree in addition to having extensive training in diabetes care management. Under the CAPP model, the pharmacist was given full autonomy to order laboratory tests, drug concentration levels, and provide recommendations to initiate, adjust, modify, or discontinue drug therapy. Pharmacist interventions were then documented as “PharmD Progress Notes” in the electronic medical records for other health-care providers to follow. Finally, follow-up appointments with the pharmacist were scheduled on a continual regular basis until targeted treatment goals were achieved. Through this collaborative team effort, all measurable clinical outcomes were identified and evaluated. The sampling area for this study was located at Lawndale Medical and Mental Health Services (LMMHS) in Lawndale, California. At the time of research, the population of Lawndale was about 34,000. The population at Lawndale comprised of

61.0% Hispanic or Latino, 16.2% White, 10.1% African American, 10.0% Asian, and the rest were Native American, Pacific Islanders, and other races. LMMHS is one of the 17 clinics, which belongs to Eldorado Community Service Centers that spreads over to the greater metropolitan of Los Angeles region to provide both medical and mental health services. Patients who were coming to LMMHS primary care service were mostly underrepresented and low-income populations, including Hispanic, African American, Asian, and Pacific Islanders, and had Medical or Medicare medical benefits.

In this study, the enrolled patients were selected, identified, and had been attended by a primary care provider under the supervision of a chief medical officer during routine clinic visits. For the interventions, the pharmacist worked collaboratively with the primary care provider during the clinic visits, where the patients participated in providing the CMM under the CAPP model, as shown in Figure 1. The clinic opened from Monday to Friday, from 8 am to 5 pm. For the study, the scheduled clinic visits were on Wednesdays and Fridays from 9 am to 1 pm. The daily number of patient visits planned for the study ranged between two and four patients per day. During the CMM, the patients were checked in by a medical assistant who took the vitals, followed by attending the pharmacist as a scheduled new patient visit for 45 min. The pharmacist reviewed all the medications in terms of appropriateness, including herbal supplements, over-the-counter medications, and complementary medicines. The pharmacist also reviewed laboratory values and provided patient counseling and/or education on the proper and safe use of drugs.

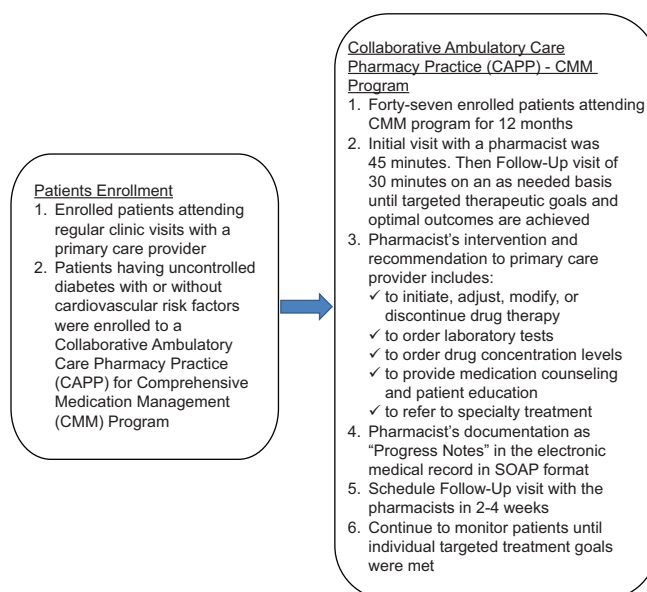


Figure 1: Conceptual framework and protocol of the study design

The pharmacist also interacted with the primary care provider concerning all the interventions recommended for the patients aside from writing the “PharmD Progress Notes.” The interventions provided by the pharmacist included the recommendation to initiate, adjust, modify, and discontinue drug therapy. The pharmacist also ordered and reviewed laboratory results and drug concentration levels as necessary to monitor drug treatment outcomes. Through this program, follow-up visits of 30 min were scheduled with the pharmacist on an as-needed basis until targeted treatment goals were achieved or met. Targeted treatment goals were determined and individualized according to the extent and severity of the disease of each patient. Typically, patients returned for follow-up visits every 2–4 weeks; however, they were determined based on the severity of the illnesses or level of patient educations needed. The duration of this CMM for the enrolled patient as new or follow-up visits was up to 12 months long, different from the study period. The conceptual framework of the proposed study design is shown in Figure 1.

Primary and secondary clinical endpoints were collected prospectively on the 1st day of the visit or at enrollment as a baseline, then during the scheduled clinic visits, and at 12 months. Hemoglobin A1c (HbA1c) was the primary endpoint evaluated. The secondary endpoints included fasting plasma glucose, systolic blood pressure (SBP), diastolic blood pressure (DBP), total cholesterol (TC), low-density lipoprotein (LDL), high-density lipoprotein (HDL), triglycerides (TGs), and microalbumin testing.

All data were collected and analyzed. Continuous variables were compared by the Student’s *t*-test. An alpha of 0.05 would be used to determine statistical significance.

RESULTS

During the study period, 47 ($n = 47$) patients were eligible to be enrolled in the study. Through the CAPP approach, 64% ($n = 30$) of the participating patients were able to achieve targeted treatment goals within 12 months. Table 1 shows the demographic data and medical conditions of the study participants. A total of 81% of the patients were found to have more than 2–3 comorbid conditions, namely diabetes, and/or hypertension, and/or dyslipidemia. The majority of the patients were female (73%), with a mean age of 54 years. The average weight was 196 pounds (89 kg), with a mean body mass index (BMI) of 33.61 kg/m², which revealed that most of the patients were obese. The number of patients using tobacco was 17%, and pulmonary diseases (e.g., asthma, chronic obstructive pulmonary disease, and emphysema) were found in 21%

of the enrolled patients. Neuropathy and nephropathy were also found in some patients.

With regard to the primary endpoint, a CMM led by the pharmacist demonstrated a significant reduction in HbA1c for those patients who participated, 9.85% (mean) at baseline to 7.55% (mean) 12 months as shown in Table 2. The mean reduction in HbA1c levels was 2.3%. Similarly, mean fasting blood glucose (FBG)

Table 1: Patient demographic data, medical conditions, and comorbidities^[21,22]

Variables	Number of patients ($n=47$)
Demographic data	
Age, mean±SD	54±9.3
Gender, n (%)	
Male	13 (28)
Female	34 (72)
Weight (pounds), mean±SD ^a	196±62.2
BMI, mean years±SD	33.61±10.0
Use of tobacco, n (%)	8 (17)
Medical conditions, n (%)	
Atrial fibrillation	3 (6)
Cardiovascular disease ^b	31 (66)
Diabetes mellitus	47 (100)
Dyslipidemia	25 (53)
Neuropathy	10 (21)
Nephropathy	25 (53)
Pulmonary disease ^c	10 (21)
Thyroid disease	3 (6)
Comorbidities	
1 comorbidity	9 (19)
2 comorbidities	25 (53)
≥3 comorbidities	13 (28)

^aPound or lb, ^bCardiovascular disease includes hypertension, myocardial infarction, angina pectoris, and heart failure, ^cPulmonary disease includes asthma, chronic obstructive pulmonary disease, and emphysema. BMI=Body mass index, SD=Standard deviation

Table 2: Primary and secondary endpoints on day 1 and 12 months later

Clinical outcomes	Mean±SD		<i>P</i>
	Day 1 on enrollment	12 months after the program	
HbA1c (%)	9.85±2.94	7.55±1.79	<0.05
FBG (mg/dl)	218.50±100.50	142.40±23.48	<0.05
TG (mg/dl)	203.40±37.13	147.90±30.21	<0.05
TC (mg/dl)	188.40±56.99	149.10±41.35	NS
LDL (mg/dl)	138.90±31.13	95.86±23.13	NS
HDL (mg/dl)	48.57±17.15	46.00±11.60	NS
SBP (mmHg)	144.50±17.46	130.80±13.35	NS
DBP (mmHg)	79.00±11.41	71.25±3.53	<0.05

NS=Not significant. SD=Standard deviation, HbA1c=Hemoglobin A1c, FBG=Fasting blood glucose, TG=Triglyceride, TC=Total cholesterol, LDL=Low-density lipoprotein, HDL=High-density lipoprotein, SBP=Systolic blood pressure, DBP=Diastolic blood pressure

levels decreased from 218 mg/dL to 142 mg/dL, which also showed a significant difference. The mean TG levels decreased from 203 mg/dL to 147 mg/dL, and DBP decreased from 79 mmHg to 70 mmHg at 12 months later ($P < 0.05$). However, no significant changes were observed in other secondary outcomes, as shown in the table during the study time intervals.

Under the CAPP approach, the CMM also impacted on the appropriateness and adherence to other drug therapies in patients with diabetes based on the contemporary clinical practice guidelines. As shown in Table 3, through the CAPP approach, 100% ($n=47$) of the patients were taking low-dose aspirin, 78% ($n=37$) of the patients were taking either an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB), and a lipid-lowering agent was taken by 76% ($n=36$) of the patients. From the study, about one-third of the patients attending the CMM were receiving basal or long-acting insulin injection plus an oral medication or insulin injection only [Table 3]. Forty percent (40%) of the patients received a flu vaccination, and fifty-three percent (53%) of the patients received pneumonia vaccination through pharmacist interventions.

DISCUSSION

The main objective of this study was to evaluate the impact of a CAPP model to help improve clinical outcomes of diabetes through appropriate pharmacist interventions. In this practice model, the collaborative team was able to provide optimal drug therapy to the patients for treatment and prevention of long-term complications secondary to uncontrolled hyperglycemia.

Table 3: Types of medication taken by patients at the end of study period

Types of medications	Number of patients taking the medication ($n=47$)
Aspirin ^a	47
ACE inhibitors or ARB	37
Lipid-lowering drugs ^b	36
Anti-diabetics	
Number of oral medication(s)	
One Medication	9
Two Medications	18
Three Medications	4
Oral medication + insulin injection ^c	9
Insulin injection only	7
Vaccination	
Flu	19
Pneumonia	25

^aLow dose 81 mg aspirin, ^bLipid-lowering drugs include statins, fibrates, nicotinic acids, bile acid resins, and fish oil preparations,

^cBasal or long-acting insulin. ARB=Angiotensin receptor blocker, ACE=Angiotensin-converting enzyme

Besides, this model provided patients the opportunity to attend a CMM, as shown in Figure 1, where a pharmacist had the opportunity to work effectively with the patient to help to monitor drug therapy to ensure safe and proper use of medication over a specific period. By scheduling clinic visits continually, the patients had access to continuous health care and were able to adhere to the treatment regimen plan as prescribed by the primary care provider.

Table 1 shows the demographic characteristics and the medical conditions of underrepresented patients in the study. Through the CMM, it was found that drug treatments for the patients were not optimal, or patients lacked the understanding of their disease conditions before enrolled in the program. Table 1 also shows that a number of enrolled patients also had signs and symptoms of long-term complications such as neuropathy and nephropathy. The majority of the patients (67%) were found to have more than two comorbidities, which indicates the complexity of the treatment regimen to manage these conditions. Besides, most of the patients were found to be obese (mean BMI: 33.6 ± 10.0 kg/m²) which adds a significant burden to manage such patients and individualize their care. However, the CAPP model with the inclusion of CMM demonstrated a way to improve clinical outcomes in these vulnerable populations. Using such a program, the study showed that patients received optimal drug therapy, as evident by the improved clinical outcomes following interventions compared to prior enrollment to the program. Although it was not the primary focus of the study, the program also demonstrated a 100% conversion of enrolled patients taking low-dose aspirin, with many who were taking either an ACE or an ARB, and a lipid-lowering agent. It was noticed that one-fifth of the patients attending the CMM were treated with oral antidiabetic medications as well as insulin injections, including basal or long-acting insulin.

Based on our results, the underrepresented patients with T2DM who attended the CAPP program demonstrated improvement in HbA1c, FBG, DBP, and TG levels over 12 months. From Table 2, the mean HbA1c for the patients was 7.55% after attending the program for 12 months as compared to HbA1c on the average of 9.85% when enrolled in the program. Reducing HbA1c by 2.3% over the study period was considered a significant achievement by these patients to prevent further deterioration due to the long-term complications as demonstrated by the UKPDS^[19,20] studies.^[18,19] This CAPP model also served as a bridge to enable such patients to build trust and to feel comfortable with their health-care providers to receive individualized care. This program, in turn, had provided ample opportunities

and ease of accessibility to health care by the patients for immediate and sustainable individualized treatment intervention provided by the collaborative team. It was also noticed that the program affected lowering the TG level but not on TC and LDL cholesterol levels. No change in HDL cholesterol level over 12 months could indicate minimal physical activity probably due to obesity among the patients. However, there were no changes in SBP over 12 months.

As from the study, the patients improved in the clinical endpoints which were HbA1c, FBG, and TG levels over a noticeable period. A more significant impact on the clinical outcomes would result if the patients were to continue attending the program with appropriate support from the collaborative team and making continuous changes in a healthy lifestyle. It is hopeful that this program eventually will be able to use as a model to enhance medication and patient adherence and thus to improve quality of life, reduce health-care cost, and prevent further progression of short-term and long-term complications from these chronic diseases.

Our major limitation of the study was the small sample size ($n = 47$). In a continuous effort to promote awareness to prevent complications of chronic diseases among the underrepresented community, we projected that a community outreach program uniquely tailored to this patient population would be essential to promote continuity of care.^[18,21-23] Various studies showed that medication nonadherence consistently was a problem in the United States health-care system, which can result in an increase in healthcare cost, increased morbidity, increased mortality, and increase in 30-day hospital re admission rate.^[24-31] If the study was to be adjusted to a more extended period, lasting effects on the clinical outcomes and sustainable medication adherence could be achieved. In the future, our focus will be expanding the study period to 2–5 years.

The CAPP approach using the CMM program was vital for the success of helping underrepresented patients to achieve ultimate glycemic goals (HbA1c reduction by 2.3%), which may, in turn, help preventing long-term complications of chronic disease such as diabetes mellitus, hypertension, and dyslipidemia. Clinical outcomes impacted by this unique approach can help increase medication adherence, which ultimately optimizes the drug treatment regimen among this high-risk patient population.

AUTHORS' CONTRIBUTION

The author contributed to the design of the study, participated in data collection and analysis, writing of manuscript, and preparing of the final draft.

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Conflicts of interest

There are no conflicts of interest.

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