

Provision of Medication Therapy Management by Pharmacists to Patients With Type-2 Diabetes Mellitus in a Federally Qualified Health Center

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ABSTRACT

Background: Type-2 diabetes mellitus is a complex condition for which pharmacists are well suited to improve patient outcomes by delivering medication therapy management (MTM) services. When diabetes is well controlled, patients can avoid its long-term complications, such as cardiovascular and renal diseases. This article describes an MTM pilot program that was implemented at a federally qualified health center (FQHC).

Methods: This program was implemented at three clinics involving patients with uncontrolled diabetes, defined as hemoglobin A1c (HbA_{1c}) greater than 8%. The primary endpoint assessed was HbA_{1c}. Secondary endpoints included knowledge scores, medication adherence, and patient satisfaction. Outcomes were compared with a group of patients from the same clinics who did not receive MTM.

Results: Fifty-seven patients met the established criteria and were enrolled in the six-month program. Thirty-seven patients completed the program and had an average 15% reduction in HbA_{1c} ($P < 0.05$). Their average knowledge scores and medication adherence scores also increased from baseline.

Conclusion: MTM provided by pharmacists as part of a health care team at an FQHC led to significant reductions in HbA_{1c}.

Keywords: medication therapy management (MTM), federally qualified health center (FQHC), type-2 diabetes mellitus

INTRODUCTION

Type-2 diabetes mellitus is a chronic condition that may have serious implications for a person's health if not managed properly. Sustained elevated blood glucose levels can lead to complications such as nephropathy, neuropathy, retinopathy, and most importantly, atherosclerotic cardiovascular disease.¹⁻³ According to the Centers for Disease Control and Prevention,

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more than 29 million people have diabetes in the United States, with one out of every four being undiagnosed.⁴⁻⁵ Lowering hemoglobin A1c (HbA_{1c}) to less than 7% has been shown to reduce microvascular and macrovascular complications.² Table 1 shows the benefits of diabetes control based on HbA_{1c} reduction.

Type-2 diabetes is a complex condition that requires treatment with a combination of modalities, including lifestyle modifications, medical nutrition therapy, oral antihyperglycemic agents, noninsulin injectable agents, and insulin. Several studies have provided evidence of the value to and improvement of patient outcomes in diabetes care through provision of medication therapy management (MTM) services by pharmacists. A meta-analysis of 44 studies was conducted in 2014 to assess the effectiveness of interventions made as a result of MTM services in patients with chronic conditions; the analysis showed that MTM improved appropriate medication prescribing, use, and adherence.⁶ The long-term clinical and economic benefits described by The Asheville Project investigators include more than 50% of patients presenting with decreased HbA_{1c} in addition to an increased number of patients with optimal HbA_{1c} values of less than 7% at each follow-up assessment.⁷ Clinical pharmacists' efforts to work with patients to achieve positive quality outcome measures

Table 1 Benefits of Diabetes Control²

Complications of Diabetes	Decrease in Risk per 1% HbA _{1c} Reduction	P value
Stroke	12%	0.035
All-cause mortality	14%	< 0.0001
Myocardial infarction	14%	< 0.0001
Heart failure	16%	0.021
Cataract extraction	19%	< 0.0001
Any diabetes-related endpoint	21%	< 0.0001
Diabetes-related death	21%	< 0.0001
Microvascular endpoints	37%	< 0.0001
Amputation or death from peripheral vascular disease	43%	< 0.0001

HbA_{1c} = hemoglobin A1c

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in diabetes management have also been well studied. Joseph Manganelli, PharmD, MPA, described the various roles clinical pharmacists fulfill in providing MTM services for patients with type-2 diabetes who are in need of transitions of care, engaged in polypharmacy, experiencing financial issues, and in need of patient education in the Montefiore Health System, a large accountable care organization.⁸ The author highlights decreased morbidity and mortality and increased quality of life for the patients, as well as increased cost-savings for the health system due to decreased inpatient readmissions and increased quality outcomes.⁸

MEDICATION ADHERENCE

Current treatment success rates are lower than what is thought to be possible based on the medical literature.⁹ One explanation for this gap is poor medication adherence; up to 50% of adult patients with chronic conditions are nonadherent to their prescribed medication regimens.⁹ Social and economic factors that affect medication adherence include burdensome schedules, medication cost, and inability/difficulty in accessing a pharmacy.^{10–12} Even with the convenience of electronic prescribing, which eliminates the need for patients to take a physical prescription to the pharmacy, about 22% of all electronic prescriptions and 28% of electronic prescriptions for new medications were still not filled, according to one study.¹⁰ In addition to social and economic factors, low health literacy compounds this issue tremendously. According to the Agency for Healthcare Research and Quality, 71% of older adults have difficulty using print materials, 80% have difficulty using documents such as forms and charts, and 68% have difficulty interpreting numbers and performing calculations. The agency also found that two-thirds of older patients lack the ability to understand information presented to them regarding their prescription medications.¹¹ The Department of Health and Human Services conducted the first-ever National Assessment of Adult Literacy and determined that disparities exist in health literacy among racial/ethnic groups.¹² In 2003, the survey results revealed that 77 million adults had basic or below-basic health literacy; when compared by race, white adults had the lowest share (28%) in the basic and below-basic category, while African-American and Hispanic adults had the largest share (65% combined) in the basic and below-basic category.¹² Low health literacy combined with social and economic factors, polypharmacy, and adverse drug events have all been implicated as contributing factors to medication nonadherence in adult patients with chronic conditions. Medication nonadherence leads to decreased treatment efficacy, reduced patient safety, and increased health care costs.^{13,14}

MEDICATION THERAPY MANAGEMENT

MTM is defined by the American Pharmacists Association as a “service or group of services that optimize therapeutic outcomes for individual patients.”¹⁵ The pharmacist plays an integral role in helping patients manage their disease states. By delivering MTM, pharmacists provide individualized medication therapy reviews to prevent or resolve drug-related problems, in addition to health and wellness education that can help to preserve or improve a patient’s health. MTM sessions may be conducted in a variety of care settings and may be done over the

telephone as well.¹⁶ There is growing evidence that supports implementing MTM in the ambulatory care setting to help improve clinical outcomes and quality of care for patients with chronic diseases.^{17,18} A study evaluating the health outcomes of hypertensive patients after provision of care by a community pharmacist in a rural setting found that in an experimental group of 25 patients compared with a control group of 26 patients, systolic blood pressure remained significantly reduced from an average of 151 mm Hg to 140 mm Hg after six months ($P < 0.001$), and diastolic pressure was found to be significantly lower at the second-, fourth-, and fifth-month intervals as well; study group patients also reported consistently higher quality-of-life and program satisfaction scores at the conclusion of the study.¹⁹ A meta-analysis was conducted to determine if the aim of MTM services to reduce the effects of medication-related problems could be proven beneficial. The analysis revealed that MTM interventions significantly improved medication appropriateness ($P < 0.001$) and medication adherence (4.6% of patients achieved threshold adherence levels); reduced health plan expenditures and costs (mean difference, \$363–\$399); and reduced the odds of hospitalization for patients with diabetes (odds ratio, 0.91–0.93) or heart failure (adjusted hazard ratio, 0.55; 95% confidence interval, 0.39–0.77).⁶ Patients with chronic diseases, such as diabetes, and complex medication regimens often require special attention and care to ensure that their disease state is managed comprehensively to achieve targeted health outcomes.²⁰

OBJECTIVES

In this article, we describe an MTM pilot program at a federally qualified health center (FQHC) that consists of three clinics in the greater Houston area. The purpose of this program was to improve the management of diabetes among patients with uncontrolled type-2 diabetes (defined as HbA_{1c} greater than 8%) through a pharmacist-led MTM intervention. Along with improving HbA_{1c} levels, other objectives of the MTM program were to improve medication adherence and patient diabetes self-care knowledge and to evaluate patient satisfaction with the pharmacist-run program.

METHODS

Pilot Site Description

Spring Branch Community Health Center (SBCHC) is an FQHC that serves a primarily low-income Hispanic population. Physicians, physician assistants, and nurse practitioners serve as the primary care providers (PCPs) for patients. Prior to the start of this pilot MTM effort, SBCHC did not have a pharmacist on site or an MTM protocol in place. For the pilot program, SBCHC adapted the Managing Your Medications (MyRx) program.

The MyRx program included a bundle of four components: pharmacist medication reviews, health education, health counseling using motivational interviewing, and follow-up calls at scheduled intervals. This program targeted racial and ethnic minorities older than 55 years of age living in city-owned residential facilities. Pharmacists visited patients’ homes and performed MTM with the components mentioned above.²² After each session, the pharmacist called patients to follow up and to answer any questions the patients may have had.

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Table 2 Patient Characteristics

Age in years, average	53
Gender, n (%)	
Male	23 (40)
Female	34 (60)
Race, n (%)	
Hispanic	45 (79.0)
Black/African-American	6 (10.5)
White	3 (5.3)
Not specified	3 (5.3)
Education level, n (%)	
Middle school or lower	20 (35)
High school	17 (30)
Technical school	4 (7)
Associate's degree	5 (9)
College or university	7 (12)
Not specified	4 (7)

In this program, two Spanish-speaking pharmacists were recruited for the SBCHC pilot, which equated to 0.25 full-time equivalents at the clinic. The implementation protocol included integrating the pharmacist into the primary care team, modifying clinical workflow so that the pharmacist's visit would be scheduled following the PCP visit, and facilitating interprofessional communications by scheduling "huddles" at intervals during each work day when the pharmacist and the PCP could discuss patient care concerns and recommendations.

Patients

A total of 57 patients participated in the pilot MTM program, 37 of whom completed the MyRx protocol. Participants were recruited via phone calls placed by clinic staff or by referral from their physician if they met the following criteria: Patients had to be 18 years of age or older, have a confirmed diagnosis of type-2 diabetes (with an average duration of diabetes of eight years), and have an HbA_{1c} greater than 8% (Table 2). An HbA_{1c} greater than 8% was utilized to remain consistent with the clinic's definition of a patient with uncontrolled diabetes.

The participants received no incentive to participate in this program. Clinic staff scheduled patient visits to the clinic that aligned with the pharmacists' part-time schedules.

Patient Visits

Patient visits occurred at all three locations of SBCHC. Patients were initially scheduled for a 30-minute baseline consultation visit with the pharmacist. This time allocation was extended to 45 minutes at the request of the pharmacist to allow enough time to complete the sessions. Baseline data recorded during each appointment included HbA_{1c}, weight, height, medication use, and personal history of diabetes. The pharmacist also assessed the patients' knowledge, attitudes, and beliefs about diabetes prior to the comprehensive medication review. Diabetes knowledge was assessed using a questionnaire

developed during the MyRx study (Appendix 1), and a modified Morisky scale was used to assess adherence (Appendix 2). Objective measures of adherence could not be obtained due to patients receiving their medication through various avenues because SBCHC does not have in-house pharmacies.

Upon completion of the review, the pharmacist discussed recommendations regarding the current drug therapy with the PCP while the patient was still present so that the pharmacist could review any changes made to the patient's therapy with the patient. The pharmacist then documented any interventions made during the visit. After the initial visit, the pharmacist (or pharmacist interns under the supervision of a pharmacist) made follow-up telephone calls to patients from the clinic. The pharmacist interns who assisted with the calls were Spanish-speaking advanced pharmacy practice experience or fourth-year students. If an intervention was required during the follow-up calls, the intern and the pharmacist would consult the PCP or the physician on duty. At the pharmacists' discretion, an additional face-to-face consultation was added for 14 patients who needed further advice to assist with their diabetes management.

The pharmacist conducted a post-intervention visit during which medication knowledge and adherence were reassessed and a patient satisfaction survey was completed. Table 3 depicts the overall timeline of the MTM intervention. The pharmacists and pharmacist interns documented their interventions on paper forms that were scanned into the patients' electronic charts at the conclusion of each visit.

RESULTS

The 37 patients who completed the intervention had an average baseline HbA_{1c} of 10.06%. After 16 weeks, the average HbA_{1c} was 8.53%, a 1.53 percentage-point average reduction ($P < 0.05$). The pharmacists made an average of four interventions per patient at the first visit. These interventions included recommendations for lifestyle modifications, drug therapy changes, additional testing, and other measures. There were 24 medication-related interventions, all of which were accepted by the patients' PCPs. The patients' average knowledge score increased from 8.47 of 10 (84.7%) to 9.57 of 10 (95.7%). The average medication adherence score increased from 28.33 of 30 (94.4%) to 29.22 of 30 (97.4%). At the conclusion of the final pharmacist visit, patients completed a program satisfaction survey; the average score on the patient satisfaction survey was 77.35 of 80 possible points (97%). The patient satisfaction survey provided statements and asked participants to rate how much they agreed or disagreed with each one on a Likert scale ranging from "strongly agree" to "strongly disagree" and included statements such as: "I am putting what I learned from this program into practice" and "I see positive changes in myself already from being in this program."

A convenience sample was established to help determine the efficacy of the pilot MTM program. These patients were selected from the same clinics after the commencement of the program and retrospectively reviewed. For each cohort that started the program in a particular month, a control group of the same number that met the inclusion criteria was identified and monitored for changes in HbA_{1c}. Among 37 patients who had an average baseline of 10.32%, their average HbA_{1c} after 16 weeks of standard care (no pharmacist intervention)

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Table 3 MyRX Ambulatory Care Pilot Timeline

Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 12	Week 16
Enrollment	First onsite consultation with pharmacist	Telephone follow-up	Telephone follow-up	Midpoint visit with pharmacist (optional): Held only at discretion of pharmacist for patients requiring additional assistance or with significant knowledge deficits	Telephone follow-up	Telephone follow-up	Last onsite consultation with pharmacist
Patients identified and screened for eligibility	Knowledge assessment: disease, medications, and medication adherence; blood drawn and anthropometric measures taken	Knowledge assessment: long-term complications	Knowledge assessment: healthy eating and food choices		Knowledge assessment: hypoglycemia and hyperglycemia	Knowledge assessment: exercise, stress management, and medication adherence	Knowledge assessment: disease and medications; blood drawn and anthropometric measures taken
Appointment made for patient to see pharmacist	Patient education: process initiated	Patient education: medication adherence and self-care/prevention of long-term complications	Patient education: medication adherence and appropriate food choices		Patient education: medication adherence and self-care/prevention of hypo- and hyperglycemia	Patient education: medication adherence and self-care/exercise and stress management	—

was 10.06% (a 0.26% absolute decrease). Diabetes knowledge and medication adherence were not assessed for this group.

DISCUSSION

Pharmacists in the ambulatory care setting often encounter patients both newly diagnosed with type-2 diabetes and patients who have had this chronic disease for years. All patients require proper education and disease monitoring. Patients face barriers in managing their disease state, specifically in understanding how to take their medications appropriately and become actively engaged in self-management of their diabetes.

Two pharmacists were charged with meeting with patients for visits, with each pharmacist allocating four hours per week for these meetings. Pharmacy students served as interns, which reduced program costs and provided students with valuable practice experience. Only 37 of 57 patients completed the program, which equates to 20 patients (35%) being lost to follow-up. Reasons for this loss to follow-up include scheduling the patients' visits around the pharmacists' four-hours-a-week schedules. The patients who were served were mostly indigent with limited means of transportation. There was no incentive for patients to participate in the intervention. Patients also had to pay out-of-pocket costs for HbA_{1c} tests, which meant that some patients were unable to complete their follow-up. In addition, the population was highly transient, and many had relocated prior to their follow-up visit.

Despite the challenges with follow-up and adherence to the program, the pharmacists made a significant impact on the patients who participated in the intervention. We hypothesize that part of the reason the pharmacists were successful was the competency of the pharmacists in addressing cultural nuances. Seventy-nine percent of the patients were Hispanic, as were both of the pharmacists and the pharmacists' interns. A study

that evaluated pharmacists' provision of information to Spanish-speaking patients showed that having Spanish-speaking staff significantly impacted the provision of information to these patients.²¹ If a Spanish-speaking pharmacist is not readily available, moderate success has been achieved by pairing pharmacists with Spanish-speaking health promoters.²²

In this program, pharmacists as members of a primary care team showed added value to the multidisciplinary approach to outpatient care. This was evident by the 1.53 percentage-point average HbA_{1c} reduction ($P < 0.05$) in the intervention group compared with the 0.26 percentage-point reduction in the control group. The program provided organizational training to the pharmacists, which helped familiarize them with the workflow and operations of the institution. Pharmacists were involved in brief meetings with the PCP at the end of each workday and found that physicians were approaching them for other medication-related issues outside the diabetes program. One major key to the success of this program, we believe, was the structured process for addressing drug therapy problems that could coincide with existing workflows. This made it easier for the drug therapy problems to be resolved upon identification while the patient was still present. SBCHC expressed interest in continuing to have a pharmacist serve on its teams, but was unable to employ a pharmacist immediately due to the resources required to support the position. However, SBCHC is actively pursuing grant funding that will support a pharmacist on staff.

CONCLUSION

As a part of the health care team, pharmacists involved in MTM interventions take on the responsibility of educating the patient and monitoring the disease state along the way, especially between primary care visits. Pharmacists play a critical

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role in improving the quality of care that a patient receives. By reviewing medications with patients and educating them on their disease states and medications, pharmacists can help improve therapeutic outcomes. Monitoring the endpoints of the pilot with pharmacist follow-up has shown improved HbA_{1c} levels, which demonstrate better control of diabetes.

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APPENDIX 1

Diabetes Knowledge Assessment

1. **People with diabetes have a higher risk for heart disease and stroke, compared with people who do not have diabetes.**
 - True
 - False
2. **Warning signs of eye problems include which of the following:**
 - Having double vision
 - Seeing floating spots
 - Having trouble seeing
 - All of the above
3. **You can help lower your risk for kidney problems by making the efforts to reach your targeted blood glucose level and blood pressure level.**
 - True
 - False
4. **Exercise can lower your blood glucose, blood pressure, and cholesterol levels.**
 - True
 - False
5. **Carbohydrate counting is a method that helps you know what to eat and how much to eat.**
 - True
 - False
6. **These foods are high in carbohydrates:**
 - Bread, biscuits, cornbread, tortillas, and crackers
 - Corn, peas, potatoes, and sweet potatoes
 - All of the above are correct
7. **The A1C check:**
 - Tells you what your blood glucose has been over the last 2–3 months
 - Tells you how well your diabetes treatment plan is working
 - All of the above are correct
8. **If your A1C is 7 or higher:**
 - You may need a change in your treatment plan
 - Your diabetes plan is working well
 - All of the above are correct
9. **Blood glucose is too high when it is:**
 - Higher than 130 before meals
 - 180 and higher two hours after meals
 - All of the above are correct
10. **Blood glucose is too low when it's below 70.**
 - True
 - False

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APPENDIX 2

Medication Adherence Assessment

1. **How often have you forgotten to take your medicine for diabetes in the past week?**
 - Always
 - Very Often
 - Sometimes
 - Rarely
 - Never
2. **How often do you stop taking/injecting your medicine for diabetes because you were careless?**
 - Always
 - Very Often
 - Sometimes
 - Rarely
 - Never
3. **How often do you stop taking/injecting your medicine for diabetes because you feel better?**
 - Always
 - Very Often
 - Sometimes
 - Rarely
 - Never
4. **How often do you stop taking/injecting your medicine for diabetes when you experience side effects?**
 - Always
 - Very Often
 - Sometimes
 - Rarely
 - Never
5. **Please find the statement that best describes the way you feel right now about taking your diabetes medication as directed:**
 - A. No, I do not take, and right now I am not considering taking my diabetes medication as directed. (precontemplation)
 - B. No, I do not take, but right now I am considering taking my diabetes medication as directed. (contemplation)
 - C. No, I do not take, but I am planning to start taking my diabetes medication as directed. (preparation)
 - D. Yes, right now I consistently take my diabetes medication as directed.
6. **If the answer to question 5 is D, then ask: How long have you been taking your diabetes medication as directed?**
 - A. \leq 3 months
 - B. > 3–6 months
 - C. > 6–12 months
 - D. > 12 months