# Evaluation of Diabetes Education and Pharmacist Interventions in a Rural, Primary Care Setting

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Americans, or 9.3% of the U.S. population, and is associated with significant costs to the health care system (1). The estimated total cost of diabetes increased from \$132 billion in 2002 to \$245 billion in 2012. Average medical expenditures are 2.3 times higher in patients with diabetes compared to those without diabetes (1). Diabetes self-management education (DSME) is the ongoing process

iabetes affects 29.1 million

tion (DSME) is the ongoing process of facilitating the knowledge, skills, and ability necessary for diabetes self-care (2). Patients with diabetes make multiple decisions every day about their health management. The literature supports the effectiveness of diabetes education to improve clinical outcomes and quality of life in this complicated patient population (3).

General practice providers have limited time to spend with patients for diabetes education (4). To overcome this barrier, an interprofessional approach to care has been used to give patients the tools they need to achieve glycemic targets. Because of their medication expertise in a variety of chronic disease states, pharmacists are well positioned to provide comprehensive diabetes services, including basic education and counseling on diabetes topics such as blood glucose management, diet, and exercise. Pharmacists also have the ability to monitor patients' laboratory testing values and to recommend therapies for hypertension, dyslipidemia, cardiovascular disease,

and microvascular complications, which are often seen with advanced diabetes (5).

Diabetes regimens have become more involved as multiple new therapies have become available within the past several years (6). Patient counseling is imperative regarding new medications such as glucagon-like peptide-1 (GLP-1) receptor agonists, sodium-glucose cotransporter 2 inhibitors, and concentrated insulins. With multidrug regimens that include new agents, the risk of adverse effects and hypoglycemia increases. Pharmacists can draw on their training and expertise to improve both clinical and economic outcomes related to diabetes medications (5).

Because of the versatility of pharmacists, the use of this profession in disease state management continues to expand. The U.S. Department of Veterans Affairs and other federal agencies, managed care organizations, and, more recently, organizations adopting the patient-centered medical home have incorporated the skills of pharmacists to enhance patient care (5). In a systematic review, Wubben and Vivian (7) evaluated 21 studies of pharmacist delivery of diabetes education in the outpatient setting; 13 of the studies documented A1C reductions of  $\geq 0.5\%$  (7). Of the studies that included blood pressure as an endpoint, one-third reported significant reductions in both systolic and diastolic blood pressure in the intervention groups. Nearly all of the studies documented reductions in

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blood pressure and cholesterol levels when a pharmacist was involved in patient care, but these reductions were not statistically significant between study groups. The authors concluded that pharmacists serve as a bridge between patients and other health care providers (HCPs) (7).

Kaiser Permanente, a large health maintenance organization, has used pharmacists to improve outcomes related to diabetes and other chronic diseases for years. In a 2013 Northern California study, Ip et al. (8) showed that pharmacist inclusion on a primary care team decreased patients' A1C when compared to a control group of patients who did not have a pharmacist on their team. Those in the enhanced care group that included pharmacists were also more likely to reach their A1C goal and demonstrated improvement in long-term cardiovascular risk (10year risk of coronary heart disease). Additionally, these participants showed improvements in LDL cholesterol and blood pressure, similar to the findings of the systematic review by Wubben and Vivian (7,8).

Current guidelines recommend a patient-centered approach to care with a focus on patients' needs and preferences (2). Primary care providers (PCPs) have expertise in a wide variety of conditions, but they also have time constraints that may pose barriers to providing comprehensive diabetes education (4). Their limited time with patients may help to explain why adherence remains low to recommendations that all patients receive diabetes education at the time of their diagnosis.

According to the Centers for Disease Control and Prevention (9), 57.4% of newly diagnosed patients reported attending a diabetes class in 2010. Other sources estimate that only 30% of patients receive some sort of formal diabetes education (10). Rural residents are even less likely to participate in diabetes education because of documented barriers including lower income, poorer perception of overall health, higher proportion of elderly, and limited access to specialty care (4). In rural communities, participation in DSME is lower when the closest education program may be miles away (11).

In 2006, diabetes education was initiated in this rural, hospitalowned, family medicine clinic in the southeastern United States. The office includes three physicians and one physician's assistant. It is part of a network of 18 outpatient clinics and is located the furthest distance from its ownership hospital. In the past, patients referred to education classes at the closest hospital-based diabetes center often did not attend because of the perceived long distance from the clinic (15-20 miles). Initially, a pharmacist provided diabetes education at the clinic for a half day weekly for 6 months. The clinic was then transitioned to pharmacy services for one full day every other week. Additional clinic days were added based on patient volume. The objective of this study was to determine the effect of pharmacist interventions and education on A1C in this rural family medicine clinic and to evaluate patient participation and the services provided to patients.

# **Design and Methods**

This descriptive study incorporated retrospective medical chart review methodology. The study sample (n = 275) was composed of patients diagnosed with type 1 or type 2 diabetes who were referred to the clinic's pharmacist for diabetes education. Patients who were  $\geq 18$  years of age and had had at least one appointment for education between February 2007 and August 2014 were included; clinic employees and outside endocrinology referrals were excluded from the study sample.

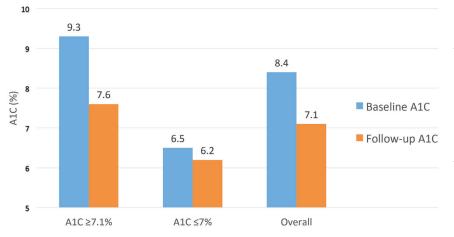
The pharmacist working at the clinic two to three times each month was credentialed as a certified diabetes educator. Patients were referred by their PCP, and baseline laboratory test values were reviewed before the initial visit.

The pharmacist documented patients' duration of diabetes, diabetes medications, diet, and exercise during the initial visit. Any patients who were not monitoring their blood glucose levels at home were provided a glucose meter and training on its use. Basic education included verbal and written information about reading food labels, carbohydrate recommendations for each meal, identification of high-carbohydrate foods, portion control, the benefits of exercise, and a review of A1C. Follow-up visits included reconciliation of diabetes medications, documentation of changes in diet and exercise, and review of patients' blood glucose monitoring values. Education regarding hypoglycemia was addressed when appropriate based on medications, blood glucose readings, or signs and symptoms reported by patients. The same basic diabetes educational materials were used for all patients. Therapy recommendations were made in collaboration with the providers. The pharmacist documented all encounters in each patient's electronic medical record at the time services were provided. Patients were referred back to their PCP when their glycemic goals were met or their diabetes was stable.

The primary outcome measure was change in A1C from baseline. A1C levels were collected at baseline and 3, 6, 9, and 12 months after the initial visit. For evaluation of the primary outcome, patients were included if a baseline and at least one follow-up A1C were available for them.

Secondary outcomes included change in A1C for patients not at goal (A1C  $\geq$ 7.1%) and the attainment of A1C  $\leq$ 7% for patients at goal. The type of diabetes education provided and the number of follow-up appointments were also examined. Service type data gathered in this study included basic education, assessment of blood glucose monitoring results, insulin initiation and

TABLE 1. Demographic Characteristics of the Study Population		
	Study Population (n = 275)	
Sex (n [%])		
Male	121 (44)	
Female	154 (56)	
Age		
Mean $\pm$ SD (years)	$60.0 \pm 12.8$	
Range (years)	19–86	
Elderly (≥65 years) (n [%])	117 (42.5)	
Diabetes type (n [%])		
Туре 1	5 (1.8)	
Туре 2	270 (98.2)	
Mean duration of diabetes (years)	11.2	



**FIGURE 1**. Reduction in A1C from baseline in patients having at least one follow-up A1C (n = 235).

titration, oral medication adjustment, teaching newly diagnosed patients, meter training, and GLP-1 receptor agonist initiation. All patients were included in the calculations for clinical services provided and follow-up appointments. To explore practice progression, the study interval was divided into two time periods based on the initial appointment: period one (2007–2010) and period two (2011–2014). The study was approved by the facility's institutional review board.

# **Statistical Analysis**

Two-tailed paired *t* tests were used to compare beginning and ending A1C values for the total sample and then

for patients at goal (A1C  $\leq$ 7%) and not at goal (A1C  $\geq$ 7.1%). Descriptive statistics were used to examine patient demographics and the type and number of clinical services provided.  $\chi^2$  Analysis was performed to analyze the difference in follow-up appointments between the clinic time periods. Statistical significance was established at  $P \leq 0.05$ . All analyses were performed using SYSTAT 13 (Systat Software, Inc., San Jose, Calif.).

# Results

A total of 275 charts were reviewed and analyzed for this study. One hundred and fifty-four patients (56%) were women; the average age was  $60 \pm$ 12.8 years; and 98.2% were diagnosed with type 2 diabetes. The average duration of the disease was  $11.2 \pm 7.7$  years (range 0–33 years). Table 1 depicts participants' characteristics.

For the primary outcome, 40 patients were excluded because of a lack of follow-up A1C levels. Baseline A1C ranged from 5.5 to 15.8%, with an average of  $8.4 \pm 1.9\%$ . The education and interventions provided by the pharmacist resulted in a mean A1C decrease of  $1.3 \pm 1.7\%$  (95% CI 1.04–1.47%, P <0.001) (Figure 1). Additional analysis included 159 patients with an A1C  $\geq$ 7.1% at baseline. A statistically significant mean reduction in A1C of  $1.7 \pm 1.8\%$ (95% CI 1.42-1.99%), representing a change from 9.3 to 7.6%, was found (P < 0.001). Patients with an A1C  $\leq$ 7% (*n* = 76) experienced a 0.3 ± 0.5% decrease in A1C (95% CI 0.19-0.42%, P <0.001). Based on baseline A1C levels, both groups (at goal and not at goal) improved after education (Table 2). More than half of the patients (59.2%) achieved an A1C goal of  $\leq 7.0\%$ .

Evaluation of clinic time period one (2007-2010) included 107 patients and clinic time period two (2011-2014) included 168 patients. A mean A1C decrease of  $2 \pm 2.9\%$  was observed in patients seen during the first time period, whereas those in time period two (2011–2014) experienced a decrease of  $1.2 \pm 2.5\%$ . There was no difference in baseline A1C levels for each time period; however, a significant difference was found in favor of time period one (95% CI 0.09-1.43, P = 0.026). A total of 410 follow-up appointments were made with the pharmacist averaging  $1.5 \pm$ 2.9 appointments per patient. A significant difference was not found between the two time periods in the number of follow-up appointments (95% CI - 1.19 to 0.19%, P = 0.157).The pharmacist did complete significantly more interventions during time period two than during time period one (379 and 233, respectively; P < 0.001). Total interventions, percentages of each intervention cat-

TABLE 2. A1C Improvement by Group							
Patient Population (n)	Mean Baseline A1C (% [SD])	Mean Follow- Up A1C (% [SD])	Mean A1C Difference (% [SD])	95% CI	t statistic (d.f.)	Р	
Total (235)	8.39 (1.91)	7.14 (1.43)	1.25 (1.65)	1.04–1.47	11.68 (234)	<0.001	
A1C ≥7.1% (159)	9.31 (1.62)	7.61 (1.49)	1.71 (1.80)	1.42–1.99	11.93 (158)	<0.001	
A1C ≤7.0% (76)	6.47 (0.37)	6.16 (0.50)	0.30 (0.49)	0.19–0.42	5.45 (75)	<0.001	

TABLE 3. Pharmacist-Led Interventions Provided ( $n = 612$ ) and
Patient Participation During the Study Period ( $n = 275$ )

Pharmacist Intervention	Patient Participation (n [%])	Percentage of Total Interventions
Basic education	275 (100)	39.4
Review of glucose readings	175 (63.6)	28.6
Insulin initiation and titrations	70 (25.5)	11.4
Oral medication adjustment	51 (18.5)	8.3
Education for newly diagnosed patients	38 (13.8)	6.2
Meter training	25 (9)	4.1
GLP-1 receptor agonist initiation	12 (4.4)	2.0

egory, and patient participation are displayed in Table 3. All patients received basic diabetes education and >63% received review of their blood glucose readings. The most common pharmacist clinical interventions were educational (45.6%), which included basic diabetes education (39.4%) and education of newly diagnosed patients (6.2%). Other frequently occurring interventions included review of blood glucose readings (28.6%), insulin initiations and titrations (11.4%), and adjustment of oral medications (8.3%).

# Discussion

This study documents pharmacistprovided diabetes education and the specific types of interventions offered. The clinical services provided represent all aspects of diabetes education, including disease process, nutrition, physical activity, medications, monitoring, and risk reduction. Pharmacist-led interventions in this rural primary care clinic were associated with the majority of patients experiencing an A1C reduction of  $\geq 1\%$ . As shown in the U.K. Prospective Diabetes Study, a 1% drop in A1C reduces the risk of microvascular complications (retinopathy, nephropathy, and neuropathy) by 35% (12). In addition to A1C lowering, patients had increased access to diabetes education and did not have to travel to a hospital-based diabetes center. The improved glycemic control and convenient access to education afforded by pharmacist-led interventions may diminish the risk of complications and decrease the costs associated with diabetes in these patients.

The greater decrease in A1C during time period one may be attributed to the lower number of patient appointments compared to time period two. This situation allowed for more educational instruction with each patient. However, it is important to note that there was no significant difference in the number of follow-up appointments between the two time periods, despite more patients being seen in time period two overall. Also, more patients with newly diagnosed diabetes or prediabetes were seen in time period two. The pharmacist completed significantly more interventions during time period two, which reflects greater collaboration

between the pharmacist and clinic HCPs.

Pharmacists are able to provide comprehensive medication management for diabetes, hypertension, and dyslipidemia. Previous studies examining pharmacists' impact on diabetes reflect different scopes of practice (7,8,13–16). The collaborative practice agreement is the most formal arrangement. Such an agreement allows pharmacists to perform patient care activities such as adjusting medications and ordering laboratory tests under a protocol with an HCP. Less formal agreements allow pharmacists to consult with HCPs during an office visit for medication changes and laboratory test orders. Finally, some pharmacists meet with patients, provide education, and then send pharmacotherapy recommendations back to HCPs (17). In the current study, all appointments were one on one, and medication adjustments were made at the time of the visit.

Pharmacist services can act as a bridge between appointments with HCPs, allowing for additional lifestyle counseling and medication adjustment. These services can also allow primary care providers the time they need to address other concerns not related to diabetes. Appointments with a pharmacist allow patients to have additional interactions with an HCP at the office. These additional encounters can increase compliance and accountability (5).

When reviewing the clinical services provided, it is important to note that patients in this study received two to three different services on average per appointment (e.g., meter training and basic education). In general, details of interventions used in other studies are reported in categories such as lifestyle counseling, DSME, and assessment of medication therapy (7,8,13–16). Several studies utilized goal-setting for exercise and weight loss and then reassessed those goals at each visit (13,14,16). Most studies did not offer details about the interventions or the education materials used.

The Steno-2 study in Denmark documented the success of intensive and continuous interventions (18). In that study, the intensive group received continuous lifestyle counseling and motivation with aggressive pharmacological treatment of type 2 diabetes, hypertension, and dyslipidemia. After almost 8 years, the intensive group showed a 50% reduction in the risk of cardiovascular and microvascular events. Although a pharmacist was not a member of the intensive care team, this study supports an interprofessional approach to patient care. It also highlights the importance of ongoing behavior modification and intensive medication management for patients with diabetes.

The roles of clinical pharmacists continue to expand. Results from previous studies showed positive results when pharmacists were involved with DSME (7,8,13–16). In Project IMPACT: Diabetes, Bluml et al. (13) reported that pharmacist participation in routine diabetes care lowered A1C by 0.8% in 25 underserved communities (13). Henry et al. (14) documented through a retrospective chart review that pharmacist interventions lowered A1C, LDL cholesterol, and systolic blood pressure. The A1C lowering was 0.99%, which was statistically and clinically significant. The study concluded that pharmacists can have a positive impact working within the health care team. Another retrospective chart review by Wallgren et al. (15) showed that, when managed by a pharmacy-operated clinic, military patients had a 1.6% reduction in A1C, and more patients met American Diabetes Association (ADA) treatment goals. The A1C lowering observed in the current study exceeds that seen in some previous studies and adds to the evidence in support of pharmacist participation in the clinical management of chronic diseases such as diabetes. Future research may evaluate the use of telemedicine in a similar practice setting.

One strength of the study was the inclusion of patients all along the diabetes spectrum, whereas other researchers have limited the study population to only patients with poorly controlled diabetes. All patients receiving education were included in the evaluation regardless of their baseline A1C level. Diabetes duration varied from newly diagnosed to longstanding diabetes of 33 years. The study population reflected what one would expect to see in a primary care setting, with the majority of the patients having type 2 diabetes.

Some limitations include the retrospective design and the lack of a control group for comparison. Retrospective studies are dependent on access to information, and some patients were excluded from this study because of a lack of follow-up documentation.

#### Conclusion

This study demonstrated a statistically and clinically significant reduction in A1C in patients treated at a rural primary care clinic and receiving diabetes education interventions from a pharmacist. This reduction in A1C has the potential to reduce the risk of complications and decrease costs related to diabetes.

The ADA recommends that all individuals receive diabetes education at the time of diagnosis and as needed thereafter. Pharmacist availability in the clinic encouraged participation in education and allowed for timely initial and follow-up appointments. The current model also meets the American Association of Diabetes Educators' recommendation that initial DSME be provided by an HCP (2).

With the increasing number and complexity of medications for diabetes, pharmacists are becoming vital members of the health care team. This study adds to the evidence supporting pharmacist involvement in diabetes management. Pharmacists bring to the team the specialized skill set needed to optimize medication therapy. Providing diabetes education in the rural primary care office also increases the opportunity for patients to have initial and ongoing education in a familiar setting.

#### **Duality of Interest**

No potential conflicts of interest relevant to this article were reported.

#### **Author Contributions**

L.T.M. researched the data, contributed to the discussion, and wrote, reviewed, and edited the manuscript. R.C.T. contributed to the discussion and reviewed and edited the manuscript. H.L.B. researched the data, contributed to the discussion, and wrote, reviewed, and edited the manuscript. L.T.M. is the guarantor of this work and, as such, had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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