



# Evaluation of a Pharmacist-Managed Medication Adjustment Clinic Within an Academic Endocrinology Practice

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Diabetes, which affects 34.2 million Americans, is a complex, chronic, progressive condition that requires consistent follow-up to properly manage (1). Despite clinical practice guidelines identifying steps for aggressive escalation of antihyperglycemic therapies, implementation of these changes is often delayed. For many patients, this phenomenon, known as clinical inertia, leads to an extended median time to treatment intensification of >1 year after an A1C test result above target (2,3).

A diverse team of health care professionals with synergistic expertise, including medication management and education, diabetes technology support, prevention of complications, dietary intervention, and alleviation of social barriers, facilitates an interdisciplinary approach to combat clinical inertia and reduce barriers to optimal diabetes management (4). One study quantifying the benefits of an interdisciplinary treatment approach identified a 1% greater A1C lowering and decreased hospitalization rates (5).

Skilled pharmacists contribute their expertise in areas such as medication management, technology support, and alleviation of social barriers to the interdisciplinary diabetes care team. Pharmacists working collaboratively with primary care physicians have consistently achieved optimization of chronic disease management. When pharmacists are involved in interdisciplinary diabetes management teams within the primary care setting, studies have demonstrated 0.5–2% greater A1C lowering compared with interdisciplinary teams without a clinical pharmacist (6–10).

In contrast to the wealth of evidence supporting pharmacists' impact within primary care settings, there is minimal literature describing the outcomes of pharmacists working within specialty endocrinology clinics. Patients seen within an endocrinology clinic often have more complex forms of diabetes, significant comorbidities, complicated insulin regimens, a need for insulin pump therapy and/or continuous glucose

monitoring, and an increased incidence of adverse events, including frequent and severe hypoglycemia (11). A pharmacist's skill set is needed within the interprofessional team managing this level of complexity in diabetes treatment.

In February 2019, University of Kentucky HealthCare (UKHC) added a pharmacist-managed medication adjustment clinic to support patients requiring closer follow-up within the Barnstable Brown Diabetes Center (BBDC) adult endocrinology clinic. Usual endocrinology care within the BBDC includes diabetes care provided by an endocrinology provider, diabetes education team (registered nurse and dietitian), social worker, and other support staff. Within the adult endocrinology clinic, there are 10 physicians and 6 advanced practice providers who see approximately 300 patients per week. Endocrinology providers make referrals to the pharmacist-led medication adjustment clinic for patients who would benefit from more frequent interactions to optimize their medications between provider appointments. Within the medication adjustment clinic, one pharmacist, who is a certified diabetes care and education specialist (0.9 full-time equivalent status), provides comprehensive medication management services and education in accordance with the credentialing and privileging process at UKHC, with supervision by the clinic's medical director. Within the privileging process, the pharmacist independently adjusts medications as clinically indicated, based on current practice guidelines. Patients meet with the pharmacist in person, via telehealth, or via telephone on two half-days per week, in visits scheduled for 30 minutes each.

At the time this clinic was initiated, it was theorized that the addition of a pharmacist to this endocrinology interdisciplinary care team to support timely optimization of diabetes medication regimens would improve patients' glycemic control, as assessed by A1C testing. The purpose of this study was to evaluate change in A1C between patients who were enrolled

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in the pharmacist-led medication adjustment clinic compared with usual endocrinology care within this academic medical center.

### Research Design and Methods

This was a retrospective observational cohort study evaluating patients with diabetes seen by the pharmacist-led medication adjustment clinic versus those who received usual care at the BBDC adult endocrinology clinic. The study was approved by the University of Kentucky Institutional Review Board.

The cohort seen in the medication adjustment clinic included patients who were 18–99 years of age with diabetes, an A1C >7% at initial (or index) visit, and at least one repeat A1C result measured 1–6 months after the index visit who were referred to and seen within the medication adjustment clinic between 1 February 2019 and 29 February 2020. Any patients seen in the medication adjustment clinic for a nondiabetes-related visit were excluded. The cohort receiving usual endocrinology care included matched patients based on *International Classification of Diseases*, 10th edition, diabetes code; age ( $\pm 5$  years); and pre-visit A1C ( $\pm 0.5\%$ ) who had at least one repeat A1C 1–6 months after the index visit and saw an adult endocrinology provider between 1 February 2018 and 29 February 2020. Patients referred to or seen by the medication adjustment clinic were excluded from the usual endocrinology care cohort.

Cohorts were identified using billing data from Allscripts Patient Manager software. The University of Kentucky's Center for Clinical and Translational Science matched cohorts in a manner blinded to the authors. Chart review was completed via the Allscripts electronic health record, and data collection was organized within a secured REDCap file. All investigators and supporting staff involved were trained to ensure consistent data collection. The following patient data were collected: age, sex, ethnicity, race, insurance type, weight, height, baseline vital signs, baseline LDL cholesterol, baseline estimated glomerular filtration rate, baseline urine albumin-to-creatinine ratio, baseline comorbidities/complications, diabetes type, duration of diabetes, baseline diabetes medications, pre- and post-index A1C results ( $\pm 6$  months of index date), number of hypoglycemia episodes per week at baseline and 6 months after the index visit, total endocrinology visits during the 6 months after the index date, and hospital and emergency department (ED) visits at UKHC during the 6 months after index date. All baseline objective information included data closest to or on the index visit date and no more than 1 year before that date. Hypoglycemia occurrences were defined as

the frequency of glucose values <70 mg/dL per week based on provider documentation and/or glucose meter reports.

The primary outcome was change in A1C from before to after the index visit. All A1C results within 6 months of the index date were collected, but the A1C closest to 3 months post-index visit was used for the primary outcome if multiple A1C results were measured during this eligibility period. Secondary outcomes included change in A1C at 3 months (including results measured from 1 to 4 months) and 6 months (including results measured from 5 to 8 months) post-index visit; patients achieving an A1C of 7, 8, or 9%; patients with decrease  $\geq 1\%$  in post-index A1C; rates of decreased hypoglycemic frequency; and rates of diabetes-related hospital/ED visits within 6 months post-index visit. Prespecified subgroup analysis of the primary outcome was completed for diabetes type, diabetes duration, sex, insurance type, baseline A1C, and total number of visits within the BBDC.

The authors calculated that 92 patients per group would be needed to detect a 1% difference in A1C change between groups given an SD of 2.4% and using 80% power. Continuous variables were analyzed using independent samples *t* tests or independent samples difference of medians, as appropriate. Categorical (nominal) variables were analyzed using the Pearson  $\chi^2$  or Fisher exact statistic, as appropriate. Patients with missing data points were excluded from the primary and/or secondary outcomes analyses where data were missing. All statistical analyses were performed using IBM SPSS Statistics, v. 27, software. An independent statistician facilitated blinded analysis of data, as described above.

### Results

The BBDC medication adjustment clinic completed a total of 240 encounters with 163 unique patients between 1 February 2019 and 29 February 2020. Inclusion criteria were not met in 54 patients because of missing pre- and/or post-index A1C data ( $n = 33$ ), baseline A1C <7% ( $n = 13$ ), and nondiabetes-related reason for the visit ( $n = 9$ ). A total of 109 patients were included and matched, based on the previously described criteria, within both cohorts.

Baseline characteristics were similar between groups and are summarized in Table 1. The majority of patients had type 2 diabetes (69.7% within each cohort), and mean baseline A1C was 10.1% in medication adjustment cohort and 10.0% in the usual endocrinology care cohort ( $P = 0.984$ ). Additionally, the majority of patients had a duration of diabetes >20 years and experienced multiple diabetes complications and comorbidities. Baseline diabetes medication therapies were similar between groups, although insulin therapy was used in 100% of patients in the medication adjustment cohort compared

**TABLE 1** Baseline Characteristics

	Medication Adjustment Clinic Cohort (n = 109)	Usual Endocrinology Care Cohort (n = 109)	P
Age, years	52.5 ± 15.7	52.4 ± 15.7	0.941
Female sex	63 (57.8)	53 (48.6)	0.175
Weight, kg	94.8 ± 25.2	94.8 ± 24.7	0.983
Ethnicity			1.00
Non-Hispanic/Latino	105 (97.2)	105 (97.2)	
Hispanic/Latino	3 (2.8)	3 (2.8)	
Race			
White	93 (85.3)	86 (78.9)	
Black	15 (13.9)	21 (19.3)	
Asian	1 (0.9)	1 (0.9)	
Preferred language			0.582
English	105 (96.3)	103 (94.5)	
Spanish	2 (1.8)	5 (4.6)	
Other	2 (1.8)	1 (1.8)	
Insurance type			0.232
Medicare	42 (38.5)	32 (29.4)	
Medicaid	31 (28.4)	30 (27.5)	
Private	31 (28.4)	33 (30.3)	
Diabetes type			1.00
Type 1	31 (28.4)	31 (28.4)	
Type 2	76 (69.7)	76 (69.7)	
Diabetes duration, years			0.915
<10	26 (23.9)	30 (27.5)	
11–20	30 (27.5)	27 (24.8)	
>20	36 (39.1)	33 (36.7)	
A1C, %*	10.1 (2.0)	10.0 (2.0)	0.984
Hypoglycemic events occurring†	55 (51.4)	33 (30.6)	<b>0.002</b>
Medical history			
Hypertension	78 (75.7)	76 (78.4)	
Dyslipidemia	77 (74.8)	70 (72.2)	
Established ASCVD	38 (36.9)	18 (18.6)	
Heart failure	12 (11.7)	12 (12.4)	
Chronic kidney disease	21 (20.4)	37 (38.1)	
Transplant recipient	2 (1.9)	10 (10.3)	
Liver disease	14 (13.6)	5 (5.2)	
Cystic fibrosis	2 (1.9)	2 (1.9)	
Retinopathy	18 (17.5)	19 (19.6)	
Neuropathy	50 (48.5)	69 (71.1)	
Smoking history			0.093
Current	26 (23.9)	14 (12.8)	
Former	28 (25.7)	36 (33.0)	
Never	55 (50.5)	59 (54.1)	
Systolic blood pressure, mmHg	128.0 ± 19.9	133.0 ± 20.8	0.223
Diastolic blood pressure, mmHg	79.4 ± 11.0	79.7 ± 11.6	0.848
LDL cholesterol, mg/dL	85.0 ± 41.7	82.5 ± 39.1	0.571
eGFR, mL/min/1.73 m <sup>2</sup>			
≥60	82 (78.1)	66 (63.5)	
30–59	20 (19.0)	31 (29.8)	
15–29	3 (2.9)	5 (4.8)	
<15	0 (0)	2 (1.9)	
Urine albumin-to-creatinine ratio, mg/g			0.754
0	31 (44.9)	24 (42.9)	
1–29	18 (26.1)	15 (26.8)	
30–300	14 (20.3)	9 (16.1)	
>300	6 (8.7)	8 (14.3)	

Continued on p. 380

CONTINUED FROM P. 379

**TABLE 1** Baseline Characteristics (Continued)

	Medication Adjustment Clinic Cohort ( <i>n</i> = 109)	Usual Endocrinology Care Cohort ( <i>n</i> = 109)	<i>P</i>
Baseline diabetes therapy			
Oral agents	46 (42.2)	52 (47.7)	
Noninsulin injectables	6 (5.5)	6 (5.6)	
Insulin	109 (100)	97 (89.0)	
Baseline insulin regimen			
Basal-bolus	55 (50.5)	46 (42.2)	
Pre-mixed	29 (26.6)	37 (33.9)	
U-500	6 (5.5)	7 (6.4)	
Pump therapy	19 (17.4)	7 (6.4)	
Number of BBDC visits‡	3.2 ± 2.2	1.9 ± 1.4	<b>&lt;0.001</b>

Data are *n* (%) or mean ± SD. Bold type indicates statistical significance. \*Nearest A1C value on or before (within 6 months) the index visit date was considered the baseline A1C. †The percentage of patients reporting hypoglycemic events at the index visit (based on provider documentation). ‡The total number of BBDC visits within the 6 months post-index visit date (including pharmacist, provider, diabetes educator, and/or social worker visits). ASCVD, atherosclerotic cardiovascular disease; eGFR, estimated glomerular filtration rate.

with 89% of those in the usual endocrinology care cohort. A higher percentage of patients within the medication adjustment clinic cohort were managed on more complex insulin regimens such as basal-bolus or insulin pump therapy. The only statistically significant difference between groups was a higher percentage of patients experiencing hypoglycemia at baseline within the medication adjustment clinic cohort (51.4 vs. 30.6%, *P* = 0.002).

As shown in Table 2, change in A1C within 6 months post-index visit was greater within the medication adjustment clinic cohort than in the usual endocrinology care cohort, although this difference did not reach statistical significance (1.27 vs. 0.75%, *P* = 0.071). Prespecified subgroup analysis of the primary outcome showed statistically significantly greater decreases in A1C within two groups: females and patients with a baseline A1C of 9–12%.

The number of patients with decreased hypoglycemia frequency was statistically higher in the medication adjustment clinic cohort (28.3 vs. 13.5%, *P* = 0.002). Patients within the medication adjustment clinic cohort experienced statistically fewer diabetes-related hospital and/or ED visits (8.3 vs. 19.3%, *P* = 0.020). The most common reason for hospitalization within both groups was hyperglycemia-related complications (66.7 vs. 81.0%). Additional reasons for visits included microvascular complications (33.3 vs. 9.5%) and hypoglycemia-related complications (0 vs. 9.5%). Table 3 contains additional subgroup analysis.

## Discussion

This study showed a larger decrease in A1C trending toward significance in endocrinology practice patients referred to and seen within a pharmacist-led medication adjustment clinic.

Previous studies have shown improvements in A1C with pharmacist involvement within endocrinology practices in smaller cohorts of patients. Alfayez et al. (12) found significant A1C lowering (8.77 vs. 7.59%, *P* = 0.040) in a retrospective study of 28 patients with the addition of a pharmacist to an endocrinology interdisciplinary care team. Another study found a significant increase in participants achieving an A1C reduction ≥1% (58 vs. 40.7%, *P* = 0.041) and those reaching an A1C <8% (32.1 vs. 18.5%, *P* = 0.047) (13). Although the decrease in A1C in this study was less than in the previous studies, it is important to note that these studies were pre-/post-intervention analyses that lacked a control group, and all had smaller cohorts than the current study.

In comparison with similar studies, improvements in A1C were coupled with statistically lower rates of hypoglycemia and diabetes-related hospital/ED visits in this cohort of medically complex patients in an endocrinology clinic. Because of the increased complexity of diabetes management in endocrinology patients, less stringent A1C goals may be required to minimize the risk of adverse events from medications, including hypoglycemia, and thereby to balance efficacy and safety (14). Because pharmacists are trained to focus on safe medication use, they may be essential members of the diabetes care team for complex patients who are at higher risk for adverse events and complications. Whether in an endocrinology office, a primary care setting, or a community pharmacy, pharmacists can contribute by helping to ensure that patients are working toward attainment of their glycemic goals safely.

Patient populations more likely to benefit from the addition of a pharmacist to the diabetes care team were identified in this study. These key populations include females,

**TABLE 2** Primary and Secondary Outcome Findings

Outcome	Medication Adjustment Clinic Cohort		Usual Endocrinology Care Cohort		P
	n	Value	n	Value	
<i>Primary outcome</i>					
Decrease in A1C at 6 months, %	109	1.27 ± 2.14	109	0.75 ± 2.12	0.071
<i>Secondary outcomes</i>					
Decrease in A1C at 3 months (1–4 months), %	98	1.22 ± 2.02	94	0.90 ± 2.06	0.274
Decrease in A1C at 6 months (5–8 months), %	77	1.06 ± 2.39	77	1.18 ± 2.28	0.746
A1C <7% reached*	109	14 (13)	109	13 (12)	0.838
A1C of <8% reached*	91	22 (24)	90	18 (20)	0.501
A1C of <9% reached*	75	37 (49)	71	27 (38)	0.171
Post-index visit A1C reduction ≥1%	109	49 (45.0)	109	44 (40.4)	0.494
Decreased hypoglycemia frequency†	109	30 (28.3)	109	13 (13.5)	<b>0.002</b>
Diabetes-related hospital/ED visits‡	109	9 (8.3)	109	21 (19.3)	<b>0.020</b>

Outcome data are n (%) or mean ± SD. Bold type indicates statistical significance. \*Patients only included within each goal A1C analysis if baseline A1C was at or above the A1C threshold at baseline. A1C used in this analysis was based on A1C at 6 months. †The percentage of patients with decreased frequency of hypoglycemia events per week (based on provider documentation) from index visit to 6 months post-index visit. ‡The percentage of patients with diabetes-related hospital and/or ED visits at UKHC within 6 months post-index visit.

individuals with type 2 diabetes, and those with a shorter duration of diabetes; a baseline A1C of 9–12%; hypoglycemia; frequent hospital/ED visits related to diabetes; or less frequent visits to the endocrinology clinic. Interestingly, the medication adjustment clinic cohort saw significantly greater reduction in A1C in the subgroup of patients who were seen less than two times within 6 months, illustrating the impact of a single visit with a pharmacist.

One of the more unexpected subgroup findings included the greater lowering of A1C among females. The literature is mixed with regard to sex differences in diabetes management; some studies have shown females with higher A1C values than their male counterparts (15). This finding could be related to differences in glucose homeostasis, treatment response, or psychological factors (16). Involvement in pharmacist-led medication adjustment services may alleviate psychosocial barriers in females by decreasing stress, increasing social support, and providing closer follow-up. Further exploration of this finding would be beneficial.

These subgroup analysis findings can facilitate a more systematic approach for a health system to determining which patient populations benefit most from receiving care in a pharmacist-led medication adjustment clinic. Population health management is an effective strategy used to proactively manage patient populations with higher-quality care, aiding in the achievement of quality metrics necessary within the pay-for-performance health care model in the United States (17). By focusing pharmacist resources on individuals most likely to achieve improved outcomes, health systems may enhance care

for people with diabetes, thereby improving payer reimbursement and ultimately decreasing health care costs.

This study had some limitations. First, a portion of the data collection period occurred within the coronavirus disease 2019 pandemic, which led to reduced rates of clinic follow-up, fewer documented A1C values, increased patient stress, and impaired lifestyle management (18). All of these factors could have dampened the effect of pharmacist-led intervention, with impaired glucose management overall during the pandemic. Many patients were excluded from the study because of a lack of documented A1C post-index date, likely because of the decreased clinic follow-up. Another limitation was related to electronic health record restrictions. Hospital and ED visits outside of UKHC could not be obtained consistently; therefore, encounters at outside facilities could not be captured. Additionally, rates of hospital/ED visits were not captured before patients' index date, which may have limited interpretation of those findings. An additional drawback to this study was the possible presence of an inherent selection bias within the clinic referral system. Patients included in the pharmacist-led medication adjustment cohort were referred by their provider because of their likelihood of achieving additional benefit from comprehensive diabetes medication management. Although this process could have resulted in biased cohorts, this referral system is commonly used in pharmacist-led services, providing a practical representation of clinical practice.

In conclusion, this study found that pharmacist involvement in diabetes care through a medication adjustment clinic

**TABLE 3** Decrease in A1C (%) at 6 Months: Subgroup Analysis

Subgroup	Medication Adjustment Clinic Cohort		Usual Endocrinology Care Cohort		P
	n	Value	n	Value	
All patients	109	1.27 ± 2.14	109	0.75 ± 2.12	0.071
Diabetes type					
Type 1	31	0.56 ± 1.54	30	0.31 ± 1.30	0.494
Type 2	76	1.58 ± 2.31	75	0.97 ± 2.39	0.110
Diabetes duration, years					
≤10	26	2.25 ± 2.95	30	1.01 ± 2.58	0.098
11–20	30	1.31 ± 1.61	27	1.09 ± 2.64	0.697
>20	36	0.77 ± 1.80	33	0.29 ± 1.30	0.217
Sex					
Male	46	1.32 ± 2.45	56	1.12 ± 2.43	0.687
Female	63	1.23 ± 1.90	53	0.35 ± 1.67	0.010
Insurance type					
Medicare	42	0.87 ± 2.06	32	0.22 ± 1.85	0.166
Medicaid	31	1.40 ± 1.78	30	0.99 ± 2.58	0.468
Private	31	1.69 ± 2.32	33	1.00 ± 1.93	0.201
Baseline A1C, %					
<9	34	0.01 ± 0.99	38	0.05 ± 1.30	0.890
9–12	56	1.25 ± 1.71	50	0.48 ± 1.88	0.029
>12	19	3.61 ± 2.80	21	2.81 ± 2.58	0.358
Total number of visits*					
<2	19	1.90 ± 3.00	54	0.28 ± 1.82	0.038
2–3	53	1.09 ± 1.30	44	1.30 ± 2.48	0.634
>3	37	1.20 ± 2.09	11	0.79 ± 1.44	0.546

A1C outcome data are mean + SD. \*Total number of visits within the BBDC (including pharmacist, provider, diabetes educator, or social worker visits) within the 6 months post-index visit.

within an endocrinology practice resulted in a greater decrease in A1C trending toward significance and in decreased rates of adverse events. These findings support the theory that pharmacists can play a vital role on the interdisciplinary diabetes care team in helping patients successfully reach clinical treatment goals and reduce their likelihood of developing diabetes complications.

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#### DUALITY OF INTEREST

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

#### AUTHOR CONTRIBUTIONS

M.C.S. researched data, wrote the manuscript, and reviewed/edited the manuscript. K.W.N. researched data and reviewed/edited the manuscript. A.D.S. completed the statistical analysis and contributed to the methods and results sections of the manuscript. K.W.N. is the guarantor of this work and, as such, had full access to all the

data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

#### PRIOR PRESENTATION

This research was presented as a poster at the Vizient Pharmacy Network Meeting Virtual Conference in December 2020.

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