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Original Research

A comparison of clinical pharmacist management of type 2 diabetes versus usual care in a federally qualified health center

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Abstract

Background: Clinical pharmacists have demonstrated their ability to improve patient outcomes over usual care for patients with type 2 diabetes and glycemic levels above goal, though reasons for this are not well defined. Numerous medications exist for the management of patients with type 2 diabetes and different patterns of medication use by clinical pharmacists may explain these benefits.

Objective: The objective of this study was to compare pharmacotherapy approaches to managing patients with uncontrolled type 2 diabetes receiving basal insulin by a clinical pharmacist versus usual care by a physician or advanced practice provider in a federally qualified health center.

Methods: A retrospective cohort study of patients 18 to 85 years old with type 2 diabetes, A1C ≥9%, receiving basal insulin was conducted. Patients were grouped into two cohorts: (1) those who received clinical pharmacist care and (2) those who received usual care from a physician or advanced practice provider. The primary outcome evaluated the proportion of patients treated with the addition of a non-basal insulin medication. Type of medication changes or additions as well as change in A1C and change in weight were also analyzed. Outcomes were evaluated at six months post-index A1C.

Results: A total of 202 patients were identified (n=129 in the usual care group and n=73 in the clinical pharmacist group). A non-basal insulin medication was added in 29% of patients receiving usual care versus 41% of patients receiving clinical pharmacist care (adjusted p=0.040). Usual care providers more frequently added metformin, sulfonylureas and thiazolidinediones, while clinical pharmacists more frequently added prandial insulin, DPP-4 inhibitors, GLP-1 agonists, and SGLT-2 inhibitors. A1C decreased 1.6% in the clinical pharmacist group versus 0.9% in the usual care group (adjusted p=0.055). No significant change in weight was observed between the clinical pharmacist and usual care group (0.2 kg versus -1.0 kg, respectively; adjusted p=0.175).

Conclusions: Pharmacotherapy approaches to managing patients with uncontrolled type 2 diabetes varied between clinical pharmacists and other clinician providers. For patients already on basal insulin, clinical pharmacists were more likely to intensify therapy with the addition of non-basal insulin, including more frequent initiation of prandial insulin and by adding newer antihyperglycemic agents.

Keywords

Diabetes Mellitus, Type 2; Insulin; Glycated Hemoglobin A; Disease Management; Pharmaceutical Services; Pharmacists; Community Health Centers; Patient Outcome Assessment; Comparative Effectiveness Research; Retrospective Studies; United States

INTRODUCTION

Type 2 diabetes is one of the most prevalent chronic diseases in the United States. According to the Centers for Disease Control, an estimated 30.3 million people in the United States were living with diabetes in 2015, a large majority of these with type 2 diabetes.[1] As the prevalence of type 2 diabetes has increased over the years, the availability of antihyperglycemic agents for management has also expanded.

Evidence-based guidelines provide detailed guidance on the management of diabetes.[2-7] While personalized treatment goals are recommended, the American Diabetes Association (ADA) recommends a target A1C of <7% for most patients with diabetes, and the American Association of Clinical Endocrinologists (AACE) recommends a more aggressive A1C target of ≤6.5%.[2,3] Pharmacotherapy is often needed in addition to lifestyle modifications to help patients reach and maintain their individualized glycemic goals. Metformin is the first-line treatment for patients without contraindications or tolerability concerns.[2-5] Thereafter, numerous guideline-recommended medications from different classes are available to aid with glycemic control including basal, prandial, and premixed insulins, glucagon-like peptide-1 (GLP-1) receptor agonists, dipeptidyl peptidase-4 (DPP-4) inhibitors, sodium-glucose co-transporter-2 (SGLT-2) inhibitors, sulfonylureas (SFUs), and thiazolidinediones (TZDs).[2-5] Selection of additional agents should be patient specific and consider a number of different factors. These include level of glycemic control, comorbidities (especially cardiovascular disease), hypoglycemia risk, effect on weight, potential adverse effects, medication costs, and patient preferences.[2-5,7] Therefore, pattern of medication use after metformin can vary greatly.

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Multiple studies have demonstrated the positive impact of clinical pharmacist intervention versus usual care on outcomes in patients with type 2 diabetes.[8-12] However, the explanation for clinical pharmacists' effectiveness remains unclear. This study compares pharmacotherapy approaches implemented by clinical pharmacists versus physicians or advanced practice providers (APP) for management of patients with uncontrolled type 2 diabetes on basal insulin in a Federally Qualified Health Center (FQHC) system.

METHODS

Study setting

FQHCs are community-based health care centers that receive funds from the United States Health Resources and Services Administration Health Center Program to provide primary care services in underserved areas.[13] Clinica Family Health (CFH) is a system of five FQHCs providing care to over 50,000 predominantly underserved patients in Colorado.[14] In 2016, 96% of patients served were at or below 200% of the federal poverty level, 30% were uninsured, 78% were of Hispanic/Latino ethnicity, and more than 13% had a diagnosis of diabetes.[15] Three clinical pharmacists were embedded into Clinica's patient care teams during the summer of 2015 to focus on chronic disease management for patients, including uncontrolled diabetes. The clinical pharmacists utilize collaborative drug therapy management protocols to optimize medication regimens of patients referred by CFH primary care providers. Patients referred to a clinical pharmacist for diabetes management most often have poor glycemic control, defined as an A1C 9% or higher. An initial clinical pharmacist visit usually consists of a face-to-face appointment with a thorough review of medical, social, and family histories, allergies, current medications, previous antihyperglycemic medication trials, and medication adherence, as well as education related to diabetes, goals of therapy, and lifestyle modifications. Subsequent follow-up is performed via face-to-face encounters or telephone outreach and focuses on efficacy, tolerability, and safety of therapies, need for adjustment, and adherence.

Study design

A retrospective cohort study of patients with uncontrolled type 2 diabetes on basal insulin therapy was conducted across all CFH sites. Patients 18 to 85 years of age with type 2 diabetes, an A1C ≥ 9% between January 1, 2016 and December 31, 2016, and an active prescription for basal insulin at the time of index A1C measurement were identified from electronic health records. Patients were grouped into two cohorts: (1) those who received clinical pharmacist care and (2) those who received usual care from a physician or APP. Patients with a clinical pharmacist encounter within 45 days of index A1C were assigned to the clinical pharmacist care group while patients with a physician or APP encounter but no clinical pharmacist contact within 45 days of the index A1C were assigned to the usual care group. Patients who were pregnant, deceased during the study period, or had clinical pharmacist contact between 45 and 180 days post index A1C were excluded. All data were validated by manual chart review. The study protocol was approved by the Colorado Multiple Institutional Review Board.

Study outcomes

The primary outcome was the proportion of patients treated with the addition of a non-basal insulin medication compared to other pharmacotherapy approaches. Secondary outcomes included description of the distribution of pharmacotherapy approaches implemented in each group, and change in A1C and weight. All outcomes were assessed from baseline to 6 months post-index A1C. Pharmacotherapy approaches were categorized into five groups, including: (1) addition of a non-basal insulin medication, (2) basal insulin titration only, (3) non-basal insulin medication titration only, (4) basal insulin and non-basal insulin medication titration, or (5) no change.

Statistical analysis

A sample size of 129 patients per cohort was needed to detect an absolute difference in the primary outcome of 5% between the two groups with 80% power and an alpha of 0.05. Patient characteristics were compared using Pearson chi square or Fisher's exact as appropriate. The primary outcome comparing the proportion of patients for whom a non-basal insulin medication was added was compared between groups using both univariate analysis and multivariate logistic regression to control for potential confounding factors, including age, gender, ethnicity, race,

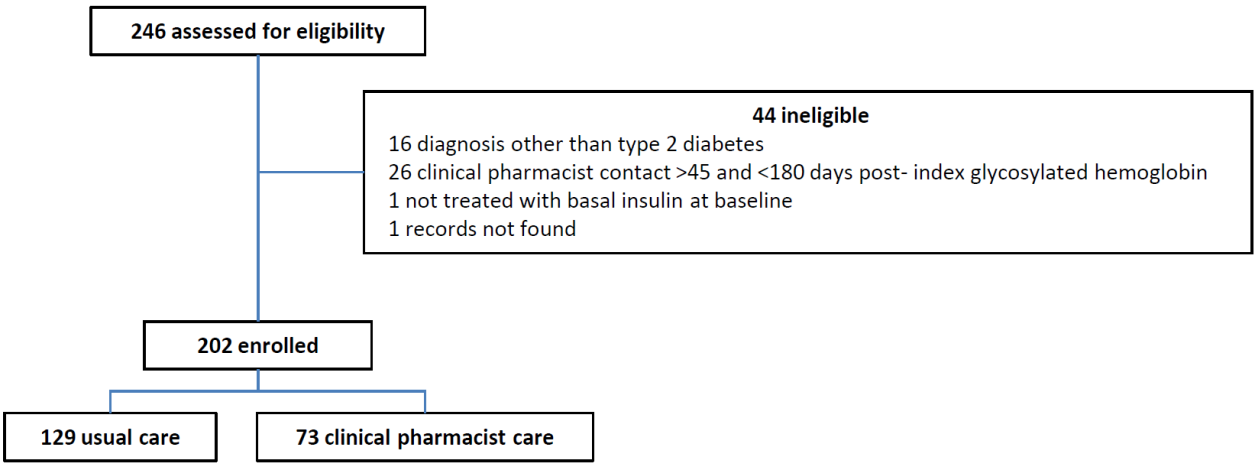

Figure 1: Eligibility and Group Assignment

Table 1. Patient Demographics and Clinical Variables

Variable	Usual Care (n = 129)	Clinical Pharmacist Care (n = 73)	p-value
Mean (SD) age, years	56.3 (11.4)	54.9 (11.0)	0.739
Female, no. (%)	79 (61.2)	48 (65.8)	0.524
Mean (SD) weight, kg	87.6 (21.2)	87.6 (23.2)	0.425
Mean (SD) BMI, kg/m^2	32.9 (7.6)	33.3 (6.4)	0.182
Hispanic ethnicity, no. (%)	115 (89.1)	54 (74.0)	0.005
Race, no. (%)			0.186
White	119 (92.2)	64 (87.7)	
Other	7 (5.4)	2 (2.7)	
Asian	2 (1.6)	4 (5.5)	
Native American	1 (0.8)	2 (2.7)	
African American	0 (0.0)	1 (1.4)	
Mean (SD) index A1C, %	10.6 (1.4)	10.9 (1.7)	0.072
Basal insulin product, no. (%)			0.014
Insulin detemir	83 (64.3)	61 (83.6)	
Insulin glargine	23 (17.8)	7 (9.6)	
Insulin NPH	23 (17.8)	5 (6.8)	

A1C = glycosylated hemoglobin, BMI = body mass index, NPH = isophane insulin, SD = standard deviation

baseline body mass index (BMI), index A1C, and type of baseline basal insulin. Descriptive statistics were used to describe the distribution of pharmacotherapy approaches utilized. Student's T-test was used to compare the change in A1C and weight between the groups, and an adjusted p value was calculated using a general linear model to control for the potential confounding factors listed above as well as pharmacotherapy management strategy.

RESULTS

A total of 246 patients were identified, and 202 met inclusion criteria (Figure 1). Of those, 129 patients received usual care and 73 patients received clinical pharmacist care.

Patients were an average of 55 years old, mostly female (62.9%), white (90.6%), and obese (mean BMI = 33 kg/m^2). There were more Hispanic patients in the usual care group than the clinical pharmacist care group (89.1% vs. 74%, p=0.005). Index A1C was similar between groups (10.6% vs. 10.9%, p=0.072). Insulin detemir was the most common basal insulin therapy at baseline in both groups but was higher in the clinical pharmacist care group (p=0.014) (Table 1).

Significantly more patients in the clinical pharmacist care group were managed with the addition of a non-basal insulin medication (30/73, 41%) compared to usual care (37/129, 29%, unadjusted p=0.072, adjusted P=0.040, OR=1.9 [1.0-3.8]) (Figure 2).

The most common pharmacotherapy approach implemented by usual care providers was basal insulin titration only (58/129, 45%, unadjusted p=0.137, adjusted p=0.129), while clinical pharmacists most commonly added a non-basal insulin medication (30/73, 41%, unadjusted p=0.072, adjusted P=0.040) followed by basal insulin titration only (25/73, 34%) (Figure 2). Usual care providers were less likely to titrate the combination of non-basal insulin medications and basal insulin compared to clinical pharmacists (8% vs. 19%, respectively, unadjusted p=0.016, adjusted p=0.047). No therapy changes were made during the six month study period for 17% of usual care patients versus only 3% of clinical pharmacist patients (unadjusted p=0.003, adjusted P=0.008).

Usual care providers most commonly added metformin, followed by prandial insulin and DPP-4 inhibitor therapies (41%, 24%, and 22% respectively), while clinical pharmacists most commonly added prandial insulin, followed by DPP-4 inhibitors and GLP-1 agonist therapies

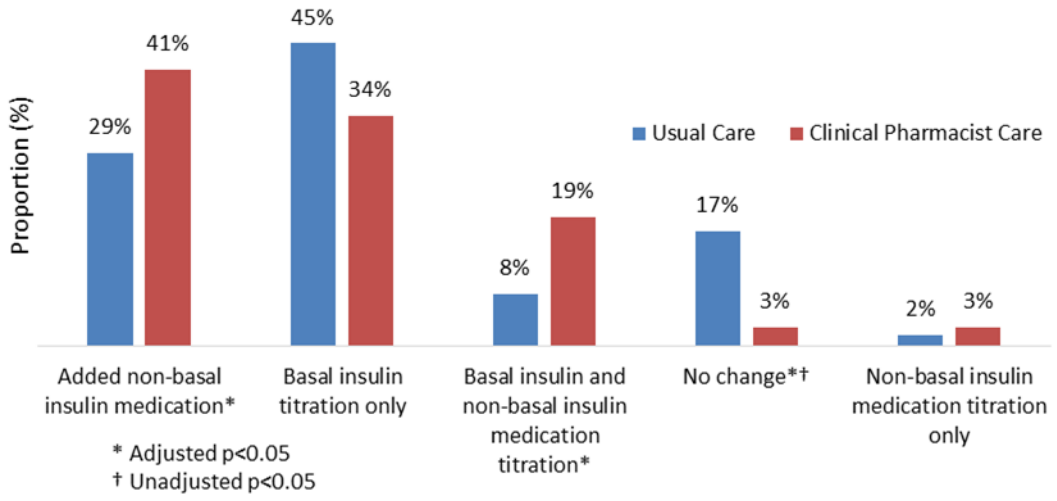

Figure 2. Distribution of therapeutic approaches

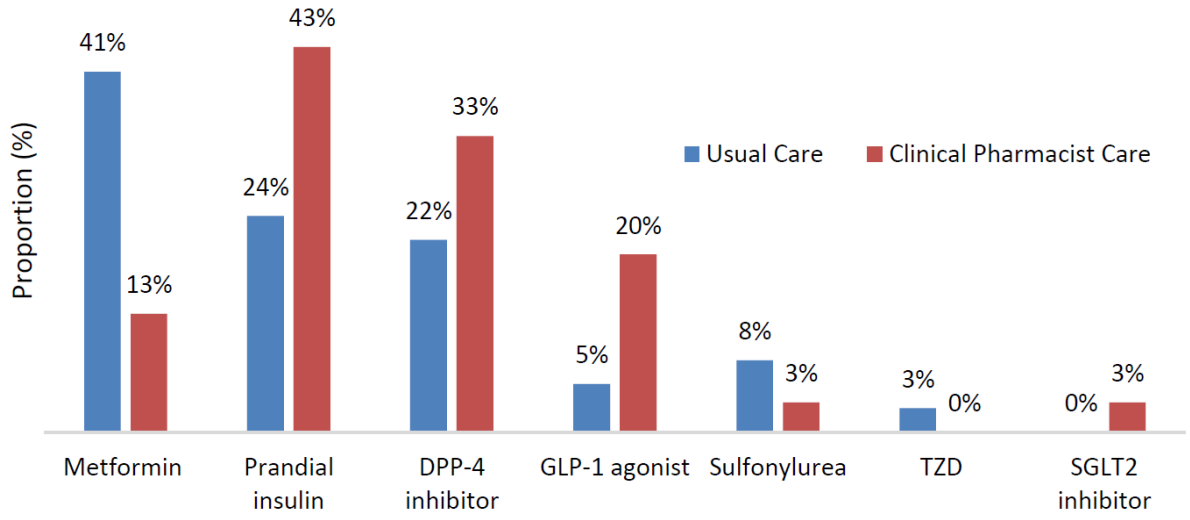

Figure 3. Non-basal Insulin Medications Added
DPP-4 = dipeptidyl peptidase-4, GLP-1 = glucagon-like peptide-1, SGLT2 = sodium-glucose co-transporter-2, TZD = thiazolidinedione

(43%, 33%, and 20%, respectively). Metformin, SFUs, and TZDs were all more commonly added by usual care providers compared to clinical pharmacists. Conversely, prandial insulin, GLP-1 agonists, DPP-4 inhibitors, and SGLT2 inhibitors were all more commonly added by clinical pharmacists compared to usual care providers (Figure 3).

A1C decreased by 0.9% in the provider group versus 1.6% in the clinical pharmacist care group (unadjusted p=0.024, adjusted p=0.055) six months post-index A1C (Table 2). Weight decreased by 1.6 kg in the provider group and increased by 0.2 kg in the clinical pharmacist care group (unadjusted p=0.191, adjusted p=0.175).

DISCUSSION

For patients with uncontrolled type 2 diabetes, guidelines recommend implementation of additional therapeutic approaches when initiation and titration of basal insulin fails to provide optimal glycemic control.[2-4] This study compared prescribing practices for patients already receiving basal insulin who had uncontrolled type 2 diabetes and were managed by clinical pharmacists or usual care, and the results confirm several differences in prescribing practices between these two groups. Clinical pharmacists were more likely to add a non-basal insulin medication in patients with uncontrolled type 2 diabetes compared to usual care prescribing. Importantly, clinical pharmacists were also more likely to initiate newer antihyperglycemic agents and less likely to make no medication changes at all compared to usual care prescribers.

One possible reason for differences in frequency of initiating other pharmacotherapy options may be attributed to the nature of the visit as well as the provider conducting the visit. For example, the focus of several provider visits was for a chief complaint other than type 2 diabetes. Additionally, patients in the usual care group may have received care from physicians or APPs other than their assigned primary care provider. At times, adjustment of antihyperglycemic regimens was deferred to the primary care provider despite awareness of less than optimal glycemic control during the visit. Initiating a new medication is time intensive and requires shared decision-making, including comprehensive patient education. In the presence of time constraints and other medical issues requiring attention, initiating a new antihyperglycemic agent may not be a priority. In contrast, clinical pharmacist visits for patients with uncontrolled diabetes are largely focused on glycemic control. This allows for dedicated time to adequately discuss initiation of other antihyperglycemic therapies and provide comprehensive patient education to ensure optimal benefits from therapy. While this may account for some of the prescribing variances noted, it does not justify the large percent of patients in the usual care group in which no regimen change was pursued within the six-month post-index A1C period.

Clinical inertia, defined as the lack of treatment intensification despite not meeting glycemic goals, is pervasive in the management of diabetes and other chronic diseases.[16-18] Studies have demonstrated that clinical inertia is more pronounced in patients with diabetes

Table 2. Secondary Outcomes

Outcome	Usual Care	Clinical Pharmacist Care	Unadjusted p-value	Adjusted p-value
Mean (SD) change in A1C (%)	-0.9 (2.0)	-1.6 (2.1)	0.024	0.055[a]
Mean (SD) change in weight (kg)	-1.0 (6.2)	0.2 (6.0)	0.191	0.175[b]

A1C = glycosylated hemoglobin, SD = standard deviation
[a]Adjusted for age, gender, index A1C, baseline basal insulin product, race, ethnicity, and treatment strategy
[b]Adjusted for age, gender, baseline BMI, baseline basal insulin product, race, ethnicity, and treatment strategy

managed by primary care providers versus specialists. A prospective observational study comparing clinical inertia between a primary care clinic and an endocrinology clinic observed treatment intensification in 28% versus 75% of patients taking insulin (p<0.02).[19] Similarly, an analysis by Shah, et. al. comparing clinical inertia between primary and specialty care noted lower rates of treatment intensifications in the primary care group (37.4% vs. 45.1%, respectively, p=0.009).[20] Failure to intensify therapy was lower in our study than these examples, however, clinical pharmacists were still more likely to intensify treatment than usual care providers (17% and 3%, respectively). Clinical inertia is recognized as a multifactorial issue, with provider, patient, and system-level barriers all contributing to this problem.[17-18] Provider-related issues may include lack of knowledge regarding different pharmacotherapy treatments, resistance to prescribing new medications, skepticism regarding industry data, concerns about medication costs, and challenges with provider access.[17-18] Clinical pharmacists are uniquely trained in all aspects of medication management, including clinical use, medication access and cost.[21-22] Treatment intensification can shorten uncontrolled hyperglycemia intervals and reduce the risk of diabetes-associated complications.[23] This finding speaks to the value of incorporating pharmacists onto health care teams and the positive impact they can have on improving patient outcomes.

Another noteworthy finding in this study was the differences in types of medication classes added. Clinical pharmacists initiated prandial insulin in 43% of the patients in which a non-basal insulin medication was added, while usual care providers implemented this treatment approach in approximately a quarter of these patients. Newer classes of medications (i.e.,GLP-1 agonists, DPP-4 inhibitors, and SGLT-2 inhibitors) were more commonly started by clinical pharmacists than usual care providers. In contrast, usual care providers more frequently initiated SFUs and TZDs. Current guidelines such as those offered by the ADA and AACE encourage individualized regimens but give preference to some of these newer agents (i.e. GLP-1 agonists and SGLT-2 inhibitors), in patients with a history of, or additional risk factors for, atherosclerotic cardiovascular disease (ASCVD) as well as heart failure, chronic kidney disease, or when weight loss is a priority.[2-4] Use of these newer agents is also now recommended by other organizations such as the American College of Cardiology and the American Heart Association due to the growing body of evidence for benefit in patients with or at risk of ASCVD.[7,24] Conversely, SFUs and TZDs are less preferred by current guidelines due to their potential adverse effects and concern for cardiac-related issues.[2-5] SFUs also carry the largest risk of hypoglycemia out of any oral antihyperglycemic and should be used with extreme caution with insulin.[2-4] In comparing the approaches by clinical pharmacists and usual care providers, clinical pharmacists more commonly followed evidence-based practices.

An additional prescribing practice we found interesting was that of the rate of metformin prescribing. Metformin was added to a patient's regimen in 41% of patients in the usual care group and 13% of patients in the clinical pharmacist care group. Because metformin is considered the first-line agent in the management of type 2 diabetes, it is typically already a part of a patient's regimen by the time basal insulin is initiated. Thus, the prescribing rates of metformin for patients already on basal insulin were higher than the authors expected.[2-5] We speculate that some of this prescribing may have been related to medication re-trials due to previous adverse effects or intolerances but think it an unlikely explanation for the total number observed.

In addition to pharmacotherapy approaches, the clinical outcomes of A1C and changes in weight were also measured at baseline and six months post-index A1C. Considering weight changes when selecting antihyperglycemic agents is essential, as some agents are weight neutral while others are associated with weight gain or weight loss. The most recent ADA guidelines now also offer recommendations for agent selection for patients when the need to minimize weight gain or promote weight loss is a priority.[2] A greater reduction in A1C was seen in the clinical pharmacist care group (1.6% vs. 0.9%) without a change in weight between the groups. Both of these findings were encouraging, however, our study was underpowered to show significant differences.

The main reason for patient exclusion was clinical pharmacist contact outside of the pre-specified range of greater than 45 days and less than 180 days post-index A1C. While this is a limitation, it may be explained by loss to follow-up due to many migrant patients traveling outside of the United States as well as large no show rates. Additionally, because this was an observational study and the period between potential pharmacotherapy changes and measurements varied with usual course of care, evaluation for changes in A1C and weight within 6 months post-index A1C may not have been long enough to detect a meaningful change in these outcomes. Third, documentation of plans related to drug therapy, including medication lists, may not have always been accurate, consistent, or complete in the electronic health record. Lastly, providers frequently consult with clinical pharmacists regarding pharmacotherapy changes in diabetes treatment and these consultations are not always documented. It is possible that clinical pharmacist recommendations influenced prescribing practices for individual patients designated in the usual care group.

Characterizing therapeutic approaches beyond basal insulin in our patients with uncontrolled type 2 diabetes identified gaps and needed interventions to increase adherence to current standard of care practices. The findings from this study will help guide future quality improvement efforts toward optimizing pharmacotherapy treatment intensification practices within our organization. Patients with improved blood glucose control have better outcomes, a lower risk of complications, and lower risk of mortality due to poorly controlled diabetes. Continued studies evaluating treatment intensification as well as education surrounding appropriate and timely management of this disease are imperative in providing our patients with the best opportunity to successfully manage their diabetes.

CONCLUSIONS

Pharmacotherapy approaches to management of uncontrolled type 2 diabetes vary between clinical pharmacists and other clinician providers. Clinical pharmacists are more likely to pursue treatment intensification in patients treated with basal insulin with the addition of non-basal insulin medications. This includes more frequent initiation of prandial insulin as well as newer antihyperglycemic agents such as DPP-4 inhibitors, GLP-1 agonists, and SGLT-2 inhibitors. Clinical pharmacists are also more likely to intensify treatment through titration of existing therapies, which reduces clinical inertia and its potential deleterious effects on patients and the healthcare system.

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CONFLICT OF INTEREST

Authors declare that they have no conflict of interest..

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