**Original Research**

# Evaluating glycemic control for patient-aligned care team clinical pharmacy specialists at a large Veterans Affairs medical center

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## Abstract

**Background**: Management of diabetes mellitus (DM) remains a challenge in the US, as almost half of patients with diabetes are uncontrolled with a hemoglobin A1c (HbA1c) >7%. Over the last decade there has been increasing evidence supporting the integration of Clinical Pharmacy Specialists (CPSs) to multidisciplinary medical teams which have demonstrated improved glycemic control and better clinical outcomes in the primary care setting.

**Objectives**: The primary objective of this study was to evaluate the change in HbA1c levels in patients with diabetes followed by a CPS. The secondary objectives of this study were to evaluate the percent of patients who reached American Diabetes Association (ADA) goal HbA1c (<7%) by study conclusion and evaluate documentation of hypoglycemic events in progress notes.

**Methods**: A retrospective chart review evaluating glycemic control was conducted on patients with DM managed by a CPS at a large Veterans Affairs Medical Center. Patients with a diagnosis of Type 1 or Type 2 DM with a baseline HbA1c ≥9% and at least three CPS visits over twelve months were included in this study. Patients with cognitive impairment as documented by ICD-9 codes or with less than three CPS visits over twelve months were excluded.

**Results**: A sample of 79 patients was identified. The mean HbA1c declined by 1.5 percentage points (from 10.6%, SD=1.4 to 9.1%, SD=1.5) after one year. No patients reached ADA goal of HbA1c <7% at study conclusion, however 23% of patients reached a less stringent goal of <8%. All CPS progress notes assessed episodes of hypoglycemia and provided education, and no hospitalizations were related to hypoglycemic events.

**Conclusions**: Integration of a CPS into a veteran's diabetes care was associated with improved outcomes and enhanced hypoglycemic education. Our results advance the existing literature by demonstrating a positive association between CPS intervention and improved glycemic control in a complex veteran population.

## Keywords

Diabetes Mellitus; Pharmaceutical Services; Pharmacists; Patient Care Team; Ambulatory Care; Patient Outcome Assessment; Retrospective Studies; Texas

## INTRODUCTION

Diabetes mellitus (DM) is the seventh leading cause of death in the United States (US), affecting more than 30 million Americans and accounting for USD245 billion annually in direct and indirect costs.[1] The prevalence has more than doubled over the past two decades, and continues to grow.[2] Complications are preventable, but if DM is left uncontrolled it can lead to renal failure, lower-limb amputations, and blindness. Appropriate glycemic control has proven to delay onset and reduce risk of long-term complications, thereby decreasing hospitalizations.[3] Management of DM remains a significant challenge in the US, as estimates indicate that greater than 40% of diabetes patients are uncontrolled with a hemoglobin A1c (HbA1c) >7%.[4]

Over the last decade there has been increasing evidence supporting the integration of Clinical Pharmacy Specialists (CPSs) into multidisciplinary medical teams. CPSs can make

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a positive impact on patients with diabetes by promoting medication adherence, assessing appropriate use of medications, optimizing and individualizing drug therapy, as well as providing education, especially in a high-risk population, which has resulted in improved glycemic control and better outcomes in the primary care setting. In a Veteran Affairs (VA) study conducted by Cioffi *et al*. in 2004, HbA1c levels were reduced by about 3%, from 10.3% to 6.9%, over a 12 month period in a pharmacist-managed outpatient diabetes clinic.[5] In a more recent VA study in 2014, Collier et al found that the addition of a CPS to a multidisciplinary care team decreased baseline HbA1c by 1%, from 9.1% to 7.9%, over three months.[6] Clinical pharmacists in these studies provided continuity of care between physician visits by adjusting insulin and oral medications according to patient self-monitored blood glucose values. In addition to improving glycemic control, engaging pharmacists resulted in positive economic outcomes and reduced health care costs.[7] Iyer *et al*. showed a 30% reduction in hospital admissions and a 24% reduction in emergency room visits during a one-year period due to CPS interventions.[3]

Within the VA Healthcare System, DM is the third most prevalent diagnosis, with a higher occurrence among veterans than the general population.[8] In order to help improve chronic disease state management, VA implemented multidisciplinary Patient-Aligned Care Teams

| Table 1. Baseline Characteristics | |
|---|---|
| **Characteristic (N=79)** | **Overall** |
| Age (years) - Mean | 65.3, (SD=7.9) |
| Sex (male) - N (%) | 75 (94.9) |
| Body Mass Index (kg/m$^2$) - N (%) | 32.3 (SD=5.6) |
| Ethnicity - N (%) | |
| White | 20 (25.3) |
| African American | 41 (51.8) |
| Hispanic | 18 (22.7) |
| Comorbidities - N (%) | |
| DM Type 1 | 0 (0) |
| DM Type 2 | 79 (100) |
| Hyperlipidemia | 64 (81) |
| Hypertension | 63 (79.7) |
| Coronary Artery Disease | 17 (21.5) |
| Chronic Kidney Disease | 16 (20.2) |
| Congestive Heart Failure | 6 (7.5) |
| Follow-up visits within 1 year; median | |
| Clinical Pharmacy Specialist | 5, (SD=1.8) |
| Primary Care Physician | 2, (SD=1.2) |
| Endocrinologist | 0, (SD=0.8) |
| Diabetes medications at baseline. N(%) | |
| Insulin | 58 (73.4) |
| Metformin | 44 (55.7) |
| Sulfonylurea | 32 (40.5) |
| Alpha Glucosidase Inhibitors | 8 (10.1) |
| Thiazolidinedione | 4 (5.1) |
| Dipeptidyl Peptidase-4 Inhibitors | 2 (2.5) |
| Incretin Analogs | 0 (0) |
| Pramlintide | 0 (0) |
| Meglitinides | 0 (0) |
| Sodium Glucose Cotransporter-2 | 0 (0) |

(PACTs) to include a CPS. At the Michael E. DeBakey VA Medical Center (MEDVAMC) in Houston, Texas, scope of practice agreements between CPS and primary care physicians have been established for over two decades. The MEDVAMC is an academic teaching institution that serves as the primary healthcare provider of more than 130,000 veterans with one million outpatient visits annually. Pharmacist-managed outpatient clinics are a highly utilized and reliable resource for veterans, providing knowledge and expertise that allows them to manage their chronic disease states. This study will evaluate the impact that the PACT CPS has on DM performance measures, including HbA1c target values and hypoglycemic patient education, at the MEDVAMC.

## METHODS

### Study Design

A single-center, retrospective, electronic chart review evaluating glycemic control was conducted on patients with DM managed by a CPS at MEDVAMC. Patients with a diagnosis of Type 1 or Type 2 DM with a baseline HbA1c ≥9.0% and at least three CPS visits over twelve months were included in this study. Patients with cognitive impairment as documented by ICD-9 codes or with less than three CPS visits over twelve months were excluded. Data collected at baseline included age, gender, ethnicity, body mass index, HbA1c level, co-morbidities including hypertension, hyperlipidemia, coronary artery disease, heart failure, and chronic kidney disease, initial CPS visit including time and date, and diabetes oral and injectable medications. Data collected during treatment period included HbA1c levels, addition or discontinuation of

diabetes oral and injectable medications, number of pharmacy, primary care or endocrine visits, and documentation of any hypoglycemic events in progress notes or hospitalizations related to hypo/hyperglycemia. The study was approved by the Institutional Review Board at the Baylor College of Medicine and the Office of Research and Development at the MEDVAMC.

### Study Objectives

The purpose of this study was to evaluate the impact that the PACT CPSs have on DM performance measures at the MEDVAMC. The primary objective of this study was to evaluate the change in HbA1c levels in patients with diabetes followed by a CPS. The secondary objectives of this study were to evaluate the percent of patients who reached American Diabetes Association (ADA) goal HbA1c (<7%) by study conclusion and evaluate documentation of hypoglycemic events in progress notes.

### Statistical analysis

Descriptive statistics were used to analyze baseline characteristics and medication use. Paired t-test was used to measure change in glycemic control and chi-square test was used to compare the proportion of patients reaching ADA goal HbA1c of <7%. A p-value of < 0.05 was accepted as statistically significant.

## RESULTS

A total of 184 patients managed in the CPS clinics at the MEDVAMC from October 2014 to October 2015 were evaluated for this study and 79 patients were identified that met inclusion criteria. Baseline characteristics (Table 1) showed a majority of African American obese male patients with an average age of 65.3 years (SD=7.9). All patients were diagnosed with Type 2 DM and about 80% also had hyperlipidemia and hypertension. The median number of follow-up visits within one year with a CPS was 5 (SD=1.8), 2 (SD=1.2) with a primary care physician, and few 0 (SD=0.8) with an endocrinologist. In the 79 patients included, the majority were prescribed insulin (73.4%), metformin (55.7%), and a sulfonylurea (40.5%) before CPS initial visit. Few were prescribed an alpha glucosidase inhibitor (10.1%), thiazolidinedione (TZD) (5.1%), and a dipeptidyl peptidase-4 (DPP-4) inhibitor (2.5%). No patients were prescribed a sodium glucose cotransporter-2 (SGLT-2), meglitinide, pramlintide, or incretin analog throughout the entire study.
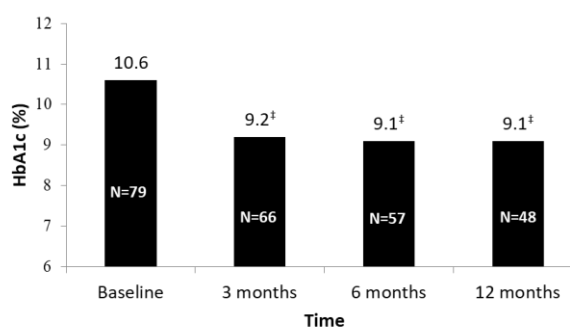


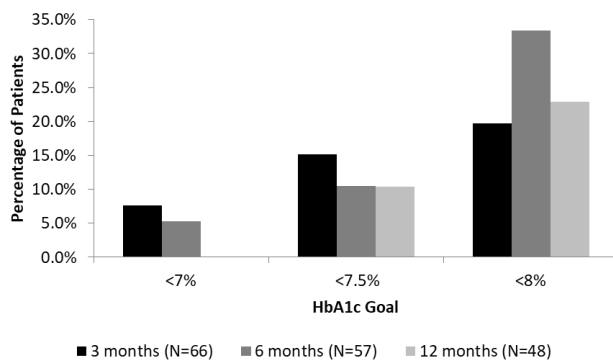Figure 1. HbA1c at baseline and 3, 6, and 12 months after CPS visit.
‡p <0.05

Figure 2. Percentage of patients at HbA1c goal



Figure 3. HbA1c excluding patients with documented non-adherence. ‡p <0.05

Significant reductions in HbA1c were seen at 3, 6, and 12 months. The mean HbA1c of all included patients was 10.6% (SD=1.4) at baseline and declined by 1.4 percentage points after 3 months to 9.2% (SD=1.6). After 6 months and one year, the mean HbA1c was 9.1% (SD=1.5), with an HbA1c lowering of 1.5 percentages points (Figure 1).

Figure 2 depicts the secondary objective to evaluate the percent of patients who reached ADA goal HbA1c of <7%. After 3 months, 5 out of 66 patients (7.6%) reached this goal, 3 out of 57 patients (5.3%) after 6 months and no patients at study conclusion. In addition, less stringent HbA1c goals were evaluated in our study and the largest group of patients met a goal HbA1c of <8%, with 13 out of 66 patients (19.7%) at 3 months, 19 out of 57 patients (33.3%) at 6 months and 11 out of 48 patients (22.9%) meeting this goal at study conclusion.

For the safety secondary objective, 21 patients (26%) had documented hypoglycemic events within computerized patient record system progress notes. CPS documentation of appropriate hypoglycemia education was included in all progress notes and no hospitalizations were related to episodes of hypoglycemia. Two hospitalizations occurred throughout the study time frame, one for diabetic ketoacidosis and the other for a diabetic foot ulcer.

A subgroup analysis was performed on patients with documented non-adherence (Figure 3). Thirteen patients had documentation in pharmacy progress notes of either not following instructions or not administering insulin regularly and were removed from the analysis. The mean HbA1c was 10.5% at baseline, 9.1% at 3 months, 8.8% at 6 months, and declined by nearly 2 percentage points after one year to 8.6%.

Another subgroup analysis was performed on patients who were only on oral diabetes medications throughout the study time frame (Figure 4). The mean HbA1c was 10.6% at baseline, 8.9% at 3 months, 8.4% at 6 months, and declined by 3 percentage points after one year to 7.6%. All patients in this subgroup were on metformin and a sulfonylurea.

## DISCUSSION

The results of our study show that care with a CPS had a significant improvement on glycemic outcomes in a veteran population. During each clinic visit, CPSs individualized and optimiz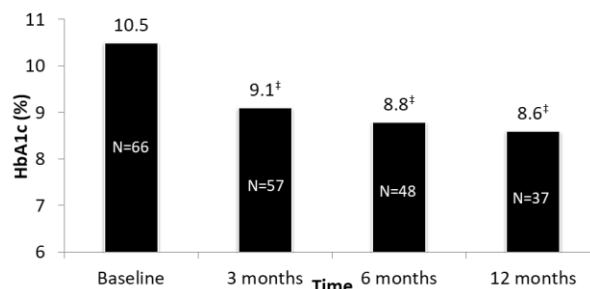ed diabetes medication therapy, provided and reinforced disease state and lifestyle modification education, and helped patients overcome any adherence barriers. By providing these services, CPSs at the MEDVAMC have enhanced overall diabetes care. Our study saw a greater decline in HbA1c at 3 months (1.5%) compared to another VA study by Collier and colleagues, which showed a 1.2% decline. However, veterans in our study were less controlled with a baseline HbA1c of 10.6% compared to 9.1%.[6] Helping veterans achieve ADA goal HbA1c presented a challenge for CPSs at our facility due to the complex patient population. Another major difference in the two studies was that our CPSs operated under a scope of practice and did not use a standardized protocol for diabetes management and insulin intensification.

The HbA1c reductions seen in our study were significant compared to values prior to being followed by a CPS, however a limited number of veterans met ADA goal of <7% throughout the study. The ADA guidelines state that less stringent HbA1c goals (such as <8%) may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, or long-standing diabetes in whom the general goal may be more difficult to attain.[9] Additionally, the VA guidelines for management of diabetes recommend a range of 7-8.5% as appropriate for individuals with established microvascular or macrovascular disease, comorbid conditions, or 5-10 years life expectancy.[10] The patient population in our study was on average older with multiple comorbid conditions, and therefore we also assessed those patients who met goal HbA1c of <7.5% and <8%. Approximately 80% of the population had concomitant hypertension and hyperlipidemia, and about 20% had coronary artery disease and chronic kidney disease. These percentages may also be
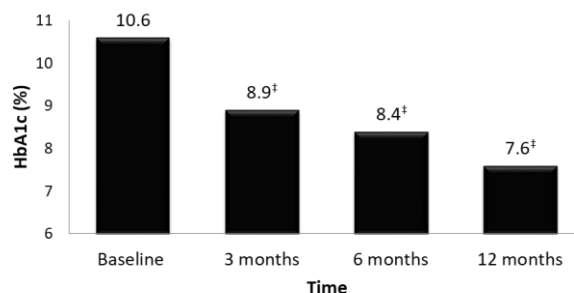


Figure 4. HbA1c of patients on oral medications. ‡p <0.05

underestimated as the "active problem list" used on the VA computerized patient record system is not always updated. The average age of the population was 65 years old, further suggesting that less stringent HbA1c goals, such as <8%, may be an appropriate target for our study.

The majority of patients were prescribed insulin, metformin, and a sulfonylurea before their first visit with a CPS. No patients were prescribed a sodium glucose cotransporter-2 (SGLT-2), meglitinide, pramlintide, or incretin analog throughout the entire study as these were all non-formulary medications at the VA during the study period. Four patients had metformin discontinued from their diabetes regimen due to worsening renal function, and four patients were initiated on metformin by a CPS to optimize glycemic control. Eleven patients were discontinued from their sulfonylurea, likely due to older age and increased risk of hypoglycemia with concomitant insulin therapy. A large portion of patients were already prescribed insulin before their first visit with a CPS (73.4%), and 15 additional patients were started on insulin therapy throughout the study. This was expected as all patients included had an HbA1c ≥9% at baseline. The subgroup analysis performed on patients who were only on oral diabetes medications showed a decline by three percentage points after one year (Figure 4). This significant reduction may have been due to CPS optimizing oral medication dosing, lifestyle modification education, and assessing adherence at every visit.

Clinical pharmacists faced barriers when assisting patients to achieve optimal glycemic control. Documented medication and dietary non-adherence accounted for 16% of the population. This number is likely underreported as approximately one third of all diabetes patients prescribed insulin do not properly adhere to their regimen.[8] When patients with documented non-adherence were excluded, a more significant glycemic improvement was seen. Another barrier was the lack of self-monitored blood glucose readings available to the CPS. Patients with diabetes often forget to monitor their blood glucose readings or bring their glucometer to visits. This limits the appropriate insulin intensification strategies that a pharmacist is able to safely recommend. Finally, no-show clinic rates are another barrier to optimal chronic disease state management. Pharmacists make attempts to call and remind patients before their scheduled appointments, however no-show rates remain high.[11]

There were further limitations to this study. The study design was a retrospective, observational chart review and can only be used to show associations. The sample size was small with the majority of the population being elderly men, which may affect external validity. Ideally, a comparator group of diabetes patients managed by primary care physicians only would have allowed us to better assess CPS interventions and effect on diabetes management compared to other primary care providers. Another limitation was that the follow-up time frame was only one year, and drastic changes in glycemic control may have occurred after study conclusion. Finally, this study did not assess a decrease in diabetes related hospitalizations, mortality or cost savings.

## CONCLUSIONS

In summary, the study shows that integration of a CPS into a veteran's diabetes care was associated with improved HbA1c values and enhanced hypoglycemic education in a primary care setting at an academic teaching institution. Clinical Pharmacy Specialists at a Veterans Affairs hospital are a valued resource for both patients and other health care professionals. Our results advance the existing literature by demonstrating a positive association between CPS intervention and improved glycemic control in a complex veteran population.

## CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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