

Cost-Effectiveness Analysis of Pharmacist-Led Diabetes Management Across Primary Care Clinics

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Abstract

Purpose: Ambulatory care pharmacists (ACPs) on healthcare teams improve patient outcomes and can manage multiple chronic disease states. ACPs have demonstrated clinical benefit but need to prove financial sustainability. The primary objective of this study was to determine the cost-effectiveness of utilizing ACPs for diabetes mellitus (DM) management. **Methods:** This was a quasi-experimental, retrospective, single health system, multi-clinic cohort study of 406 patients living with DM, ≥ 18 years of age, with a HbA1c of $\geq 8\%$, receiving primary care services within an academic health system between May 2015 to March 2018. In the ACP group, the ACP was part of the care team for DM management while in the PCP group, patients were managed only by a PCP with or without an endocrinologist (usual care). The incremental cost-effectiveness ratio (ICER) was calculated to determine the clinic-associated cost of an ACP-led DM management clinic. **Results:** Based on the ICER calculation, clinic-associated cost for ACP-led DM management was \$126 per patient per year for each additional HbA1c percent lowered. Additional ICER calculations demonstrated the clinic-associated cost to move one patient with HbA1c $\geq 9\%$ to HbA1c $< 9\%$ was \$612. Change in HbA1c over 12 months was -2.5% in the ACP group and in the PCP group $+1.08\%$ ($p < 0.001$). Based on quality metrics at 12-months, the ACP group met the goal of 75% of patients having a HbA1c $< 9\%$ and being prescribed a statin vs. the PCP group only met the metric for statin use. Based on facility fee billing, the ACPs cover approximately 70% of their annual salary and benefits from face-to-face visits. **Conclusions:** ACPs led to significantly improved clinical outcomes with marginal up-front costs that could lead potential future cost savings through reductions in DM related complications or improving incentivized returns by achieving goal quality metric levels.

Key Words: ambulatory care, pharmacist, diabetes mellitus, pharmacist cost-effectiveness

BACKGROUND

According to the Centers of Disease Control (CDC), 34.2 million (10.5%) individuals in the United States have diabetes mellitus (DM) of which 1.6 million are living with Type 1 DM. Additionally, 88 million people (34.5% of the population) have pre-diabetes.¹ Due to the increased prevalence and micro- and macrovascular complications associated with DM, the combined direct and indirect costs of DM was estimated to be \$412.9 billion in 2022. The annual healthcare expenditure per patient living with DM is \$19,736 which is 2.6 times higher than for a patient without DM. The per capita spending related to DM particularly escalated for inpatient hospital stays and prescription medications.²

Along with the economic burden, DM and its comorbidities place a large burden on primary care providers (PCPs). Multiple studies have shown that first line providers, including internal medicine, family medicine, and emergency department providers, have the highest rate of burnout which can cost the health system millions of dollars.³ Factors such as large panel sizes, short visit times, multiple acute and chronic diseases and conditions, polypharmacy, sporadic patient contact between visits, shortage of PCPs, and patient psychosocial issues may impede the management of DM.⁴⁻⁶

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Ambulatory care pharmacists (ACPs) have demonstrated clinical benefits to the patient by improving DM management and outcomes; however, there is limited data related to the financial sustainability or cost-effectiveness of ACP involvement in DM management.⁷⁻⁹ One study evaluated the incremental cost-effectiveness ratio (ICER) of a combined endocrinology with pharmacist appointment over a six-month period versus only primary care DM management within a Veterans Affairs (VA) Health System. The pharmacist in the endocrinology clinic was associated with a clinic-associated cost of \$21 per one percentage decrease in hemoglobin A1c (HbA1c). The study also found that clinic-associate costs for the pharmacist was \$115-\$164 per patient reaching HbA1c goal level when compared with the primary care group.¹⁰ One limitation of the study was the assumptions that patients would remain well controlled being discharged from the pharmacist-endocrinologist clinic and would only require two PCP appointments per year; however, this was not evaluated or confirmed. Also, while the pharmacist saw patients by themselves, it was limited to three 60-minute visits. The ICER calculation did not include cost of endocrinology visits.

To prove cost-effectiveness, it is important to understand the different outlets for reimbursement. Quality programs including Healthcare Effectiveness Data and Information Set (HEDIS) measures, Center for Medicare & Medicaid Services (CMS) Star ratings, and Comprehensive Primary Care (CPC) + focus on quality of services and incentivize high performing health systems through greater reimbursement and/or incentivized bonuses while low performing health systems could have reductions in payments.¹¹⁻¹⁴ The traditional quality

metrics utilized by these programs include: percent of DM patients with HbA1c within the last 12 months and < 9% and percent of patients living with DM on statin therapy (target <25% and >75% of patients respectively).¹²⁻¹⁴ As previous studies have shown, pharmacists improve clinical outcomes; therefore, the pharmacists contribute to a healthcare system achieving the respective quality metrics and increasing the payments received.

The most direct method to evaluate cost-effectiveness is through direct billing opportunities for professional services rendered. Since pharmacists are not recognized providers at a national level and by CMS, professional billing opportunities for pharmacists are often limited and vary state by state. Demonstrating cost-effectiveness can help further expand reimbursement opportunities through payers.

This study assessed long-term DM control based on HbA1c reduction and further analyzed whether these services were cost-effective and financially sustainable. This study's goal was to establish cost-effectiveness of the ACP in the management of DM and continue to support the important role ACP provide within primary care clinics from the health system perspective.

METHODS

Study Population and Setting

The study population included patients living with DM who received DM care and primary care services within a large academic safety-net health system located in northeast Ohio. The health system includes over 20 community medical facilities and provides over one million outpatient visits annually. The health system serves a primarily low-income, underserved population. Nearly 20% of patients seeking treatment within the health system are living at or below the federal poverty line.

In April of 2016, the health system newly established ambulatory care pharmacy services. Three ACPs (2.6 full time equivalents (FTE)) were integrated into seven different primary care locations. Within this health system, the pharmacist's salary paid through the pharmacy department. Under a collaborative practice agreement (CPA), the ACP prescribed medications and assisted with lifestyle changes for patients living with chronic disease states. The primary focus being for patients living with DM, hypertension, and/or dyslipidemia. The ACP worked under the indirect supervision of the referring or supervising provider. Once a patient met and maintained their individualized DM-related goals and were stable on their medications for at least 3 months, the patient were eligible to be discharged to their PCP for future management.

As CPA and billing laws differ state to state, specifically in Ohio, pharmacists could work under a CPA with physicians, and it was not until 2019, when nurse practitioners and physician assistants were included. In 2019 in Ohio, pharmacists are

recognized as medical providers; however, pharmacists working in hospital-based outpatient clinics or those primarily servicing a Medicare or commercially insured population are still unable to directly bill for their services.

Study Design

This study was quasi-experimental two-arm study. It was designed as a retrospective, single health system, multi-clinic cohort study of DM patients within a large academic safety-net health system. The institutional review board approved this study with exempt status. All data was manually collected as a report was not available via the electronic health record (EHR). Because of this, it was not feasible to collect on all possible patients. To minimize selection bias, patients from each cohort/group were randomly selected via random number generator.

ACP management of DM is considered usual care within the health system's medical offices where the ACPs are located; however, these services are not considered the usual care for the entire health system due to a shortage of ACPs. Patients in the ACP group were identified by referrals to the ACPs within the EHR. In the ACP group, the ACP was part of the care team for DM management. The ACP group indicated \pm PCP as many PCPs took a hands-off approach to DM management once that patient was receiving DM care by the ACP. This allowed the PCP to have additional time to focus on other comorbidities. All patients in the ACP group were seen by a PCP at least annually in accordance with Ohio law. The PCP group only included providers located within primary care offices where no ACP was present. The PCP managed the patient's DM with or without an endocrinologist. Patients in the PCP group were identified through a PCP panel report within the EHR. The original methodology was not designed with the intent to include endocrinology; however, endocrinology visits were included because it was found in the early stages of data collection that in the PCP group, many patients with a HbA1c >8%, were referred to endocrinology which limited who could be included in the PCP group.

As part of the cost-effectiveness analysis for this study, an incremental cost-effectiveness ratio (ICER) was determined based the difference of the clinic-associated costs of the ACP group versus the PCP group divided by the change in HbA1c in ACP group versus PCP group ($[(ACP \text{ group costs}) - (PCP \text{ group costs})] / [(ACP \text{ group results}) - (PCP \text{ group results})]$). Clinic-associated costs were calculated based on standard salaries and benefits for ACPs, PCPs, and endocrinologists in the greater Cleveland, Ohio area. The salary and benefit cost per provider was divided by the total number of visits to determine the provider's cost per appointment. This estimated the clinic-associated cost for that provider to complete one patient appointment. It is important to note, the ICER calculation does not include revenue. ICER calculations were used to determine the clinic-associated cost required to decrease the HbA1c by 1%

per patient per year, the clinic-associated cost associated with improving one patient to HbA1c goal of < 7%, < 8%, and < 9%, and the health system related cost of decreasing the HbA1c by 1% per patient per year when including emergency room visit costs.

The study also analyzed the revenue generated by ACP services. This was done by interpreting revenue gained from standard facility fee billing at each ACP office visits and their associated billing codes (99211-99215, technical component only). To evaluate the quality metrics achieved specific to DM management through ACP services, the number of patients in specific HbA1c ranges were evaluated at baseline and at 12 months.

Inclusion criteria included patients 18 years of age or older, diagnosed with DM (type 1, type 2, or latent autoimmune diabetes in adults), and index HbA1c of $\geq 8\%$ between May 1, 2015 and February 28, 2017. An HbA1c of 8% was selected to identify those patients who were not at goal. Additional inclusion criteria specified that patients completed a HbA1c 12 months post-index visit (accepted HbA1c 10-14 months post-index), in the ACP group had to participate in two or more visits with the ACP within 12 months of the index visit, and in the PCP group, patients had to participate in two or more visits with their PCP or endocrinologist. Exclusion criteria for this study consisted of patients who were pregnant and/or utilizing an insulin pump.

Data Collection

Patient data was collected from a chart review. The data collection period for this study consists of patients with ACP or PCP index visits starting May 1, 2015 through February 28, 2017. Data were collected for 12 months following the index visit. The patient's first visit with the ACP was classified as the index visit in the ACP group. In the PCP group, the patient's first visit with their PCP or endocrinologist during this time frame was their index visit. Duration of diabetes was collected from progress note from DM provider (if available) otherwise, it was based on HbA1c data in EHR (both internal and external health systems). Data was extracted through the health system's EMR program and were collected and managed using REDCap electronic data capture tools hosted at MetroHealth System.

The DM-related comorbid disease states were identified utilizing the following ICD-10 codes: coronary artery disease (CAD): I25, depression: F32, heart failure (HF): I50, cerebrovascular accident (CVA): I60-I69 and end stage renal disease (ESRD) on hemodialysis (HD): N18.6.

Objectives

The primary objective was to determine the cost-effectiveness of pharmacist-led HbA1c reduction in patients living with DM within the primary care setting. Secondary objectives were to assess the change in HbA1c control in the setting of ACP

management versus PCP management, to determine the percentage of patients who met the quality metrics, to analyze any difference in the number of all-cause ED visits and DM-related hospitalizations, and to estimate the total revenue generated by services rendered by ACPs.

Statistical Analysis

Data for this quasi-experimental two-arm study were imported into SPSSv24.0 software. Baseline categorical characteristics were compared for distributional equality via Pearson chi-square or Fisher's exact test with Bonferroni adjusted z-tests performed in the presence of overall statistical significance ($p < 0.05$ via two-sided tests). Numeric data was compared for mean equality via independent samples Student's t-tests. Repeated measures were performed to compare equality of mean HbA1c between study groups across post-baseline time points at 6 and 12 months. Significant interaction between time and study group was encountered; therefore, between-group comparisons were performed separately for each post-baseline time point. The distribution of patients with scaled HbA1c using 7%, 8%, and 9% cutoffs was compared for equality between groups at baseline and 12-month study time points via linear association chi-square tests. Finally, a multivariable regression model was employed to model 12-month HbA1c in terms of univariate differences between the two groups along with a treatment effect. Model effects with tests of significance from zero were determined. All statistical testing was two-sided with $p < 0.05$ considered statistically significant.

RESULTS

Baseline Characteristics

A total of 406 patients were included with 265 patients in the ACP group and 141 in the PCP group. A full account of this cohort's baseline characteristics can be found in Table 1. Average age was 61 years and the majority of patients had type 2 DM (N=398, 98.3%), were Black/African American (N=263, 64.9%), and female (N=250, 61.7%). Statistically significant baseline demographic differences between the two groups included: the ACP group baseline HbA1c was higher than the PCP group (10.5% (SD 1.5) vs. 9.8% (SD 1.9); $p < 0.001$), fewer proportion of patients with HbA1c < 9% in the ACP group than in the PCP group (23% vs. 36.9%; $p = 0.003$), the ACP group had a longer duration of DM at baseline compared to the PCP group (12.2 years vs. 6.6 years; $p < 0.001$), greater proportion of patients in the ACP group on insulin as opposed to the PCP group (62.6% vs. 36.2%; $p < 0.001$), greater proportion of patients were on statins in the ACP group versus the PCP group (87.9% vs. 68.8%; $p < 0.001$), and less patients had commercial insurance were in the ACP group vs. the PCP group (30.9% vs. 43.3%; $p = 0.041$).

Outcome Measures

The primary endpoint of cost-effectiveness of pharmacist-led HbA1c reduction in patients living with DM within the primary care setting demonstrated a clinic-associated cost of \$126 per

one percent HbA1c reduction per patient per year based on the ICER calculation. When cost of ED visits were included into the ICER calculation, it resulted in a health system-associated cost of \$59 per one percent HbA1c reduction per patient per year. There were fewer ED visits in the ACP group vs. the PCP group; however, this was not statistically significant (0.53 vs. 0.60; $p=0.615$). Additional costs of utilizing an ACP in the outpatient setting to achieve various goal HbA1c were summarized in Table 2. In terms of number of provider visits, there was on average 7.24 ACP visits per patient per year in the ACP group. Patients in the ACP group had on average fewer PCP visits annually (3 vs. 4.3; $p<0.001$). There were also fewer endocrinology visits in the ACP group vs. the PCP group (0.15 vs. 0.51; $p=0.003$).

We further investigated the clinic-associated and health system-associated costs to improvement of their DM-related quality metric scores. At baseline, 77% of patients in the ACP group had an HbA1c > 9% vs. 63.1% in the PCP group ($p<0.001$); at 12 months only 22.3% of patients had an HbA1c > 9% in the ACP group vs. 36.9% in the PCP group ($p<0.001$). Additionally, a greater proportion of patients achieved an HbA1c < 7% at 12 months in the ACP group vs. the PCP group (29.8% vs. 18.4%; $p<0.001$) (Figure 1). The unadjusted change in HbA1c from baseline to 12 months post index visit showed greater decrease in the ACP group compared to the PCP group (-2.44% vs. 1.08%; $p<0.001$) (Figure 2). A regression ANOVA analysis was conducted and was significant ($P<0.001$). Variables that were statistically significant included HbA1c at baseline, duration of DM, and baseline statin use. Insurance type and insulin use at baseline were not significant in the presence of the other variables and therefore were removed from the final model. After controlling for those significant factors, the ACP effect on HbA1c still resulted in a -1.1% change in HbA1c ($p<0.001$). The last DM-related quality metric evaluated in this study demonstrated a greater proportion of patients on statins in the ACP group vs. the PCP group (91.7% vs. 80.9%; $p=0.001$).

When isolating ACP-generated revenue, ACPs (2.6 FTEs) completed approximately 3150 patient visits per year. The majority of these visits (66%) were billed at a Current Procedural Terminology (CPT) code 99214: established patient office or other outpatient visit. Due to laws in Ohio, this CPT code was billed with the technical component modifier as pharmacists in hospital based outpatient clinics are not permitted to bill for the professional component. Based on revenue received from the CPT code facility fees component only, approximately 70% of the total cost of each ACP (salary plus benefits) is covered.

DISCUSSION

Overall, ACP-led DM management has marginal upfront clinic-associated costs, and the ACPs improved quality metrics to a greater extent than usual care which can increase reimbursement or result in incentivized bonuses. The ACP

group achieved the HbA1c quality metric goal of <25% of patients living with DM having an A1c >9% where the PCP group did not. When comparing our study to the Hirsch, *et al.* our study had slightly higher upfront cost.¹⁰ Our study's setting (public hospital system vs. VA) and practice model differed from Hirsch, *et al.*, because the ACP is embedded in primary care and can manage patients' primary DM needs over an extended period versus a limited three visits.¹⁰ Our model can also improve patients' access to care as the ACP services are located directly within the primary care office. Additionally, the ACPs in this study managed patients on their own under the indirect supervision of the referring or supervising provider. Thus, our study more accurately evaluated pharmacist-led DM management versus Hirsch, *et al.*, which looked at interdisciplinary or team based management.¹⁰

Despite increased negligible upfront costs, there are several points that help rationalize these additional costs. Based on the results from this study, ACP-led DM management can result in increased cost savings to the patient, the insurance company, and the health care system. This study demonstrated that seeing the ACP several times in a 12-month period decreases visits to the PCP and/or endocrinology. Payers and health care systems stand to gain the largest absolute reduction in cost, as an increase in the number of patients with well managed DM is directly correlated with a significant reduction in hospitalizations related to diabetic complications.⁷ These savings to payers are passed on to the health system via shared savings plans and risk-based contracts. In addition to the cost benefits, the use of ACP can help address the growing issue of PCP burnout and shortage that is occurring across the US by providing additional workforce.⁵⁻⁶

The revenue results demonstrate that ACPs cover most of their salary just through facility fee billing for their visits. While Ohio pharmacists have recently been recognized as providers, pharmacists are not able to consistently bill for services rendered. The current billing opportunities with provider status are primarily limited to Medicaid payers and for Ohio pharmacists in certain clinic settings (i.e. physician-based outpatient clinics, Federally Qualified Health Centers).¹⁵ Once all ACPs can bill and be consistently reimbursed for a professional fee, reimbursement for these visits will significantly increase. These results show that ACP services can help mitigate that issue by decreasing excess visits with the PCP and reserving the truly complex cases for endocrinology care. Additionally, while there were a higher number of ACP visits initially, these visits are usually within the first 12 months. After the patient is controlled and discharged to PCP only care, they do not see the ACP afterwards as long as they remain at their DM goal.

Limitations

Study design was a retrospective cohort study and included differences in baseline HbA1c, baseline HbA1c <9%, duration of

DM, baseline insulin use, use of statin therapy, and having commercial insurance. The baseline differences may have been due to chance from the random number generator or due to the referral process to ACP. As the ACP primarily receives referrals from the PCP for patients that are not at goal this would have resulted in a greater number of patients meeting the inclusion criteria in the ACP group. Since PCP continue to manage all patients, their patient lists would include patients across the spectrum of DM management. These differences were taken into account through a linear regression model. After controlling for the differences, the ACP group still demonstrated greater reduction in HbA1c over the 12 month period than the PCP group. Additionally, HbA1c only indicates glucose control within the last three months and does not account for extreme lability that might average to an appropriate level. Other indicators of DM management including hyperglycemia episodes, hypoglycemia episodes, time in range utilizing a continue glucose monitor, diabetic ketoacidosis episodes, and patient-reported outcomes which were not evaluated in our study.¹⁶

CONCLUSIONS

Overall, ACPs had negligible clinic-associated costs which led to improved clinical outcomes. Although clinical providers often see and fully understand the benefits of having an ACP, administrators are often still concerned about the financial implications of adding an ACP to a team. This study clearly indicates that ACPs contribute to HbA1c lowering and increase reimbursement for achieving quality metric goals. Furthermore, this study demonstrates the cost-effectiveness of ACP services and shows the importance of expanding ACP services.

Disclosures

At time research and writing was completed, Cynthia King was employed at MetroHealth System. As of Aug 19, 2024, she is employed at Abbott Diabetes Care.

Disclaimer: The statements, opinions, and data contained in all publications are those of the authors.

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Table 1: Baseline Demographics

	ACP group (n=265)	PCP group (n=141)	P-value
Type of DM			
Type 2 DM, n (%)	261 (98.5)	137(97.2)	0.457
Gender (assigned at birth)			
Male, n (%)	104 (39.2)	51 (36.2)	0.544
Race			
Black/African American, n (%)	177 (66.8)	86 (61.0)	0.349
Age (in years), mean (SD)	61.8 (11.6)	61.23 (13.0)	0.610
BMI (kg/m ²), mean (SD)	35 (8.2)	33.4 (8.0)	0.060
Duration of DM (years), mean (SD)	12.2 (9.8)	6.6 (6.1)	<0.001
Statin therapy, n (%)	234 (87.9)	97 (68.8)	<0.001
CrCl (mL/min), mean (SD)	65.3 (28.9)	68.3 (29.3)	0.318
Baseline HbA1c, mean (SD)	10.5 (1.9)	9.8 (1.5)	<0.001
Baseline HbA1c < 9%, n (%)	61 (23.0)	52 (36.9)	0.003
Insurance			
Commercial, n %	82 (30.9%)	61 (43.3)	0.041
Baseline Therapies			
Biguanide, n (%)	180 (67.9)	94 (66.7)	0.797
Glucagon-like peptide-1 receptor agonist, n (%)	8 (3.0)	3 (2.1)	0.754
Insulin, n (%)	166 (62.6)	51 (36.2)	<0.001
Sulfonylureas, n (%)	177 (44.2)	75 (53.2)	0.082
Lifestyle only, n (%)	22 (8.3)	9 (6.4)	0.488
Comorbid Disease State			
CAD, n (%)	29 (10.9)	25 (17.7)	0.055
Depression, n (%)	35 (13.2)	27 (19.1)	0.113
HF, n (%)	25 (9.4)	11 (7.8)	0.582
CVA, n (%)	13 (4.9)	9 (6.4)	0.531
ESRD on HD, n (%)	11 (4.2)	1 (0.7)	0.065

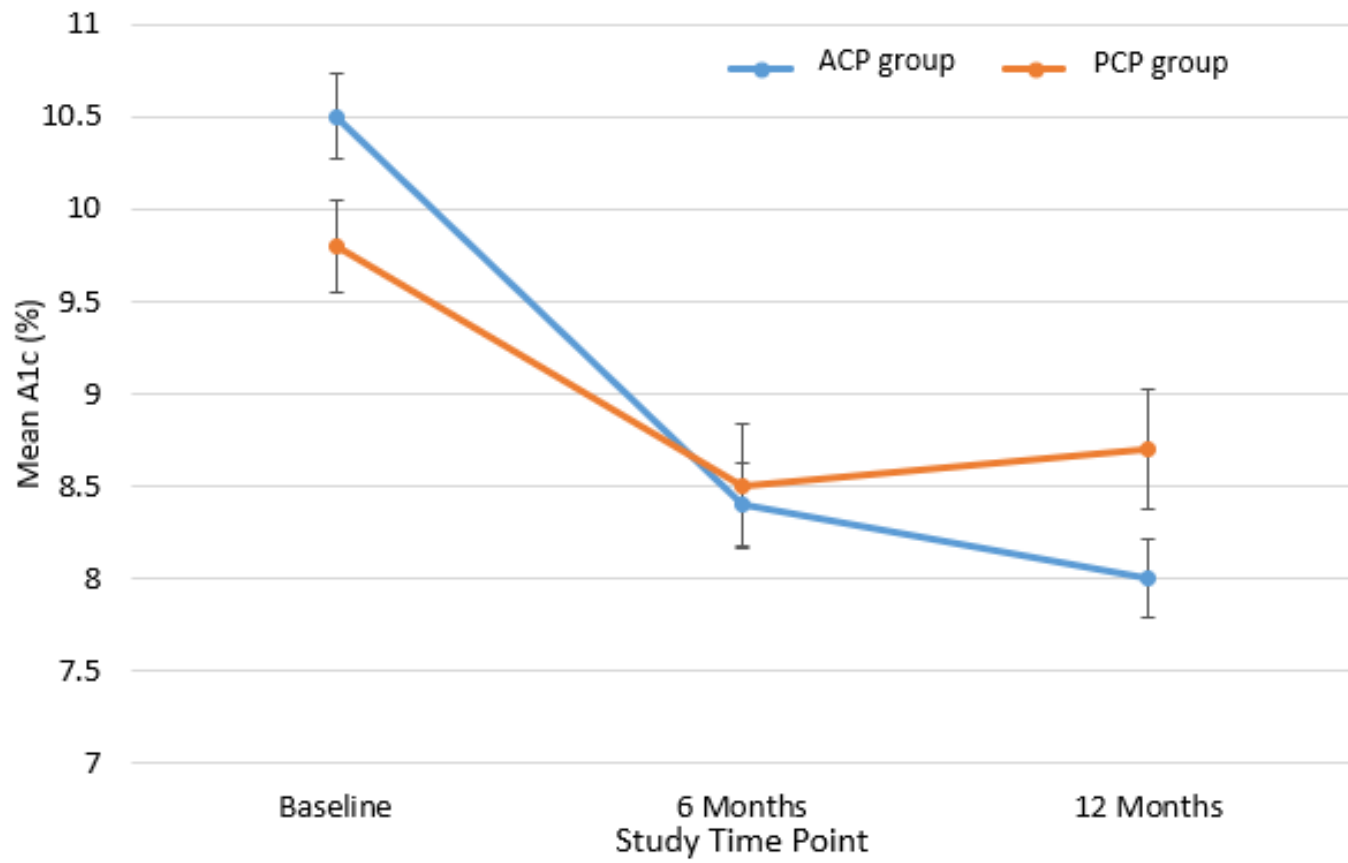
ACP = Ambulatory Care Pharmacists

PCP = Primary Care Providers

Table 2: Average Cost Based on ICER to Achieve Different A1c Goals

Baseline HbA1c	Goal HbA1c	Cost based on ICER
> 9%	< 9%	\$612
> 9%	< 8%	\$775
> 9%	< 7%	\$1492

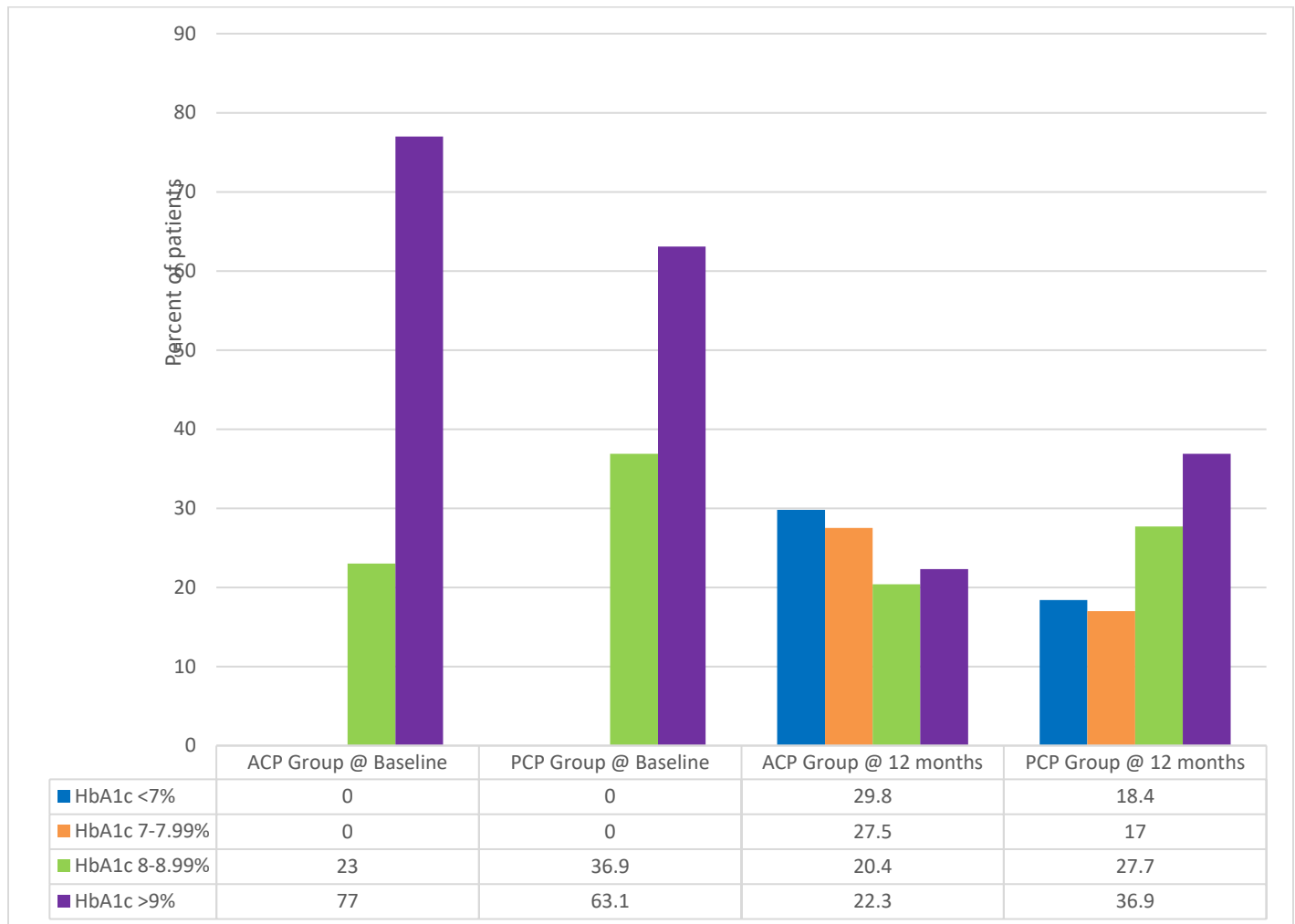
Figure 1- Mean change in HbA1c by study time point



ACP = Ambulatory Care Pharmacists

PCP = Primary Care Providers

Figure 2: Percent of Patients at HbA1c Levels



ACP = Ambulatory Care Pharmacists

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