

Impact of Pharmacist-Led Diabetes Management in Primary Care Clinics

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ABSTRACT

Purpose: Current literature supports pharmacists effectively lower hemoglobin A1c (HbA1c) in diabetic patients. Little data exists on pharmacists' effects on comorbidity management, patient satisfaction, or the financial viability of these positions. This study looked to assess the impact of pharmacists on diabetes management compared to usual care.

Methods: This multi-site, two-part study includes a retrospective chart review of patients referred to the pharmacist versus usual care within a large academic health system. The pharmacists collaborated under a consult agreement with primary care physicians. The second part of the study assessed patient satisfaction through an abbreviated CG-CAHPS survey.

Results: A total of 206 patients with diabetes for an average of 12 years were included. The average patient age was 62 years with 60% of patients identifying as female and 81% as African-American. Patients were enrolled in a 2:1 fashion with 138 patients in the pharmacist-management group. Average baseline HbA1c was 10.1% in the pharmacist-management group and 9.3% in the usual care group ($p = 0.0125$). At 6 months, the mean change in HbA1c was -2.17% and 0.48% for the intervention and control groups respectively ($p < 0.001$).

Conclusion: Pharmacists are effective at lowering HbA1c in primary care clinics, and patients were highly satisfied with these services. While direct revenue from this service did not meet cost, the pharmacist did positively affect outcomes that contribute to reimbursement.

Keywords: ambulatory, diabetes, HbA1c, pharmacist, revenue, satisfaction

BACKGROUND

Diabetes mellitus is a prevalent and costly disease in the United States, which often results in costly micro- or macrovascular complications.¹ In 2017, approximately 7.6% of the U.S. population (an estimated 24.7 million people) had diabetes. This cost an estimated \$327 billion per year and is predicted to increase to \$336 billion per year by 2034.^{2,3,4}

With this significant prevalence and cost, there is a necessity for collaboration between multiple healthcare professionals and specialties. Pharmacists are uniquely positioned as medication experts to work collaboratively with other healthcare professionals and assist in drug therapy management which is key when managing a disease with multiple comorbidities such as diabetes. Pharmacists' positive impact on diabetes management has been shown in a variety of settings. Some examples include pharmacist-led interventions demonstrating an additional HbA1c lowering of 0.8% in an endocrinology clinic and of 1.2% in an internal medicine clinic.^{5,6} This lower HbA1c correlates to lower rates of cardiovascular disease and greater cost savings for health

systems.^{7,8} As pharmacists have differing provider statuses throughout the world, their roles in these studies have varied greatly. Their duties could consist of providing medication counseling, lifestyle education, protocol-led medication recommendations, or immediate medication changes with independent prescribing rights.

As the United States healthcare system continues to increase utilization of valued-based reimbursement strategies, a greater emphasis is placed on providing high quality care leading to high patient satisfaction.⁹ The two main quality programs currently in place are the STAR rating scale through the Center for Medicare & Medicaid Services (CMS) and the Healthcare Effectiveness Data and Information Set (HEDIS) measures through the National Committee for Quality Assurance. For both programs, high performing health systems receive bonus payments while low performing systems can expect a reduction in payment.¹⁰ Specifically for patients with diabetes, the STAR ratings and HEDIS measures both evaluate HbA1c levels (i.e. >9%, <9% or <7%). The HEDIS measures also monitor the percentage of diabetic patients on statin therapy, while the STAR ratings also sets quality standards concerning the percentage of patients completing annual diabetic eye exams, provider monitoring of kidney function, maintaining controlled blood pressure, and adherence to diabetes medication regimens.^{11,12}

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To assess patient satisfaction, CMS also created surveys to assess patients' experiences. Patients receive satisfaction surveys after provider appointments [Clinicians and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS)] and hospital encounters [Hospital Consumer Assessment of Healthcare Providers and Systems (H-CAHPS) survey].¹³ Currently, only the H-CAHPS survey is linked to reimbursement; however, the CG-CAHPS survey may impact reimbursement in the future.¹⁴ Since pharmacists are not yet providers in every state, CG-CAHPS surveys are not automatically sent out after office visits with the clinical pharmacists.

The purpose of this study was to evaluate the impact of pharmacists' services on diabetes management compared to usual care. This will be assessed by evaluating the HbA1c, use of statin and aspirin therapy, and patient's satisfaction with pharmacist's services. In addition, this study will begin to investigate the cost of providing clinical pharmacy services.

METHODS

Study Design

The study consisted of two parts. The first part was a retrospective multi-clinic cohort of outpatients who had their diabetes managed by a primary care physician (PCP). These patients were seen every three to six months by their PCP. The PCPs managing this cohort of patients also had the option to refer patients to a clinical pharmacist for additional diabetes disease state management. The primary outcome of was change in HbA1c, compared between a group of patients receiving usual care alone and a group of patients receiving usual care with additional pharmacist-led disease state management. Pregnant women, insulin pump users, and patients being managed by a specialist (i.e. an endocrinologist) were not referred for pharmacist management. In order to match patients between the usual care and pharmacist-led disease state management groups, these patients were excluded from the usual care group. The second part of the study consisted of a cross-sectional survey evaluating patient satisfaction in patients receiving pharmacist-led disease state management.

The inclusion criteria for the cohort was comprised of being 18 years of age or older and having participated in two or more visits with the clinical pharmacist (pharmacist management group) or PCP (usual care group) during the study. The study had no exclusion criteria.

Cohort Design

The cohort was comprised of three internal medicine clinics in a single health system in northeast Ohio between July 17, 2015 and October 14, 2016. It was divided into patients who only received usual care by their PCP and patients who received

usual care but also received additional diabetes disease state management by a clinical pharmacist. The patients in the usual care group were managed by PCPs who either did not refer patients to or were under utilizers of clinical pharmacy services.

Patients in the pharmacist management group were managed under a collaborative practice agreement with the patient's PCP in the same clinic locations. Once the referral was placed by the PCP, the clinical pharmacist had the ability to order laboratory tests and initiate, discontinue, and adjust medications related to diabetes care. The clinical pharmacists' activities included additional scheduled in-office visits and telephone calls to assess self-monitored blood glucose, HbA1c, and medication side effects, which could lead to medication regimen changes. All patients in the pharmacist management group participated in a 60 minute initial visit with the clinical pharmacist and 30 minute follow-up visits scheduled as needed at the discretion of the clinical pharmacist.

At each pharmacist visit, the patients were vitalized, and the pharmacist would reconcile the patient's medications, review the patient's self-monitored blood glucose levels, and complete a symptoms assessment. The clinical pharmacist completed appropriate documentation in the electronic medical record and billed for the appointment utilizing facility fee codes 99212-99215 as incident to the PCP. PCPs were not involved with pharmacist visits. Based on this information, the pharmacist would develop an individualized plan, order necessary labs and medications, and provide education to the patient. Each pharmacist scheduled an average of 5-7 patients per half day of clinic (4 hours), and the pharmacists had 6-8 half days of clinic each week.

Data Collection

Patients had their index visit recorded, which was defined as their first visit documented within the study period. All patients were followed for six months after their index visit. The study period was initially May 1, 2016 through October 31, 2016. In the pharmacist management group, the index visit occurred between May 31, 2016 and October 14, 2016 and represented the first day the patient received pharmacist-led disease state management. In the usual care group the index visit occurred between July 17, 2015 and October 10, 2016. Due to the inclusion criteria of requiring at least two visits within the study period, the usual care group inclusion period was required to be extended to identify an appropriate number of patients for inclusion.

Data collected from the index visit included gender, ethnicity, duration of diabetes, HbA1c, serum creatinine, presence of statin therapy, and BMI. Data collected at subsequent visits included HbA1c and presence of statin therapy. From October

2016 to November 2016, patients who were being seen by the same clinical pharmacists evaluated in the cohort were offered the opportunity to complete the optional, anonymous, abbreviated CG-CAHPS survey after one of their encounters with the pharmacist. There were no incentives, and the refusal to answer the survey was not met with any repercussions for the patients.

Outcomes Analysis

The primary outcome measured was change in HbA1c from baseline to six months post-index visit. Baseline HbA1c was defined as an HbA1c obtained either at the index visit or within three months prior to the index visit. Secondary outcomes were percent of patients with HbA1c <9% and 7% and presence of statin therapy from index visit to six-month post-index visit. Change in HbA1c, percent of patients with HbA1c less than 9% and 7%, and presence of statin therapy were compared between the pharmacist-led disease state management group and the usual care group. Additional secondary outcomes included patient satisfaction from the CG-CAHPS survey and financial viability. Financial viability was evaluated only in the pharmacist management group and was measured by calculating the average reimbursement for appointments and multiplying this by the average number of patients seen per pharmacist for one year and subtracting the pharmacist's salary and indirect costs.

Statistical Analysis

Data for this quasi-experimental two-arm study were imported into SPSSv24.0 software. Demographic and other baseline summaries were stratified by study group. Numeric data were tested for mean equality between study groups via independent samples Student's t tests. Categorical data were compared for distributional equality via Pearson chi-square or Fisher's exact tests depending on cell sample size distribution. The primary outcome variable, hemoglobin A1c (%), was summarized at each post baseline study time point. The primary analysis was a repeated measures ANOVA model with between-subjects effect for study group and within-subjects effect for post-baseline study time point. The interaction effect for study group and time was not significant indicating no enhancement to the study group difference at either of the post-baseline time points. Also, the effect of time was not significant indicating that the study group differences that were observed at 3 months were consistently maintained at 6 months. Therefore, overall means from the repeated measures ANOVA were produced and compared between study groups.

As a supplemental sensitivity analysis, since repeated measures ANOVA requires data availability at both post-baseline time points, the means between study groups were compared for equality at each post-baseline time point

separately via independent samples Student's t test. There were no adjustments for multiple comparisons as this was an exploratory, sensitivity analysis. Changes from baseline were also determined and tested for mean equality to zero within each group via paired samples Student's t test. The distribution of values below 7% and 9% cut-offs was also compared between groups via chi-square and Fisher's exact tests. A line graph stratified by study group was also produced with 95% confidence interval error bars to depict mean A1c across time. To examine the potential confounding influence of baseline differences between groups, a multivariate linear regression model for A1c at 6 months post-baseline was determined with predictive factors for significant baseline differences and study group. Finally, the secondary outcome of statin use at 6 months was compared for distributional equality between study groups via Pearson chi-square test. All statistical testing was two-sided with $p < 0.05$ considered statistically significant.

RESULTS

A total of 181 patients were included in this study, which included 112 patients in the pharmacist-led disease state management group and 69 in the usual care group. Of these patients, 99 and 98 in the pharmacist-lead disease state management group and 24 and 64 in the usual care group had three month and six month visits respectively. For this study, the average age of patients was 64 years in the pharmacist-led disease state management group and 62 years in the usual care group with an average duration of diabetes of over 12 years in the pharmacist-led disease state management group and 10 years in the usual care group. In both groups, the majority of patients were African American and female. There were no significant differences between the groups except baseline HbA1c which was 10.1% in the pharmacist-led disease state management group and 9.3% in the usual care group ($p = 0.018$) and number of patients on statin therapy ($p < 0.05$). A full account of this cohort's baseline characteristics can be found in Table 1.

Unadjusted change in HbA1c from baseline to six months post index visit showed greater decrease in the pharmacist-led disease state management group compared to the usual care group (-2.2 vs 0.5; $p < 0.001$) (Figure 1). At six months post index visit, unadjusted results showed 32.1% of patients had HbA1c <7% in the pharmacist-led disease state management group versus 4.3% in the usual care group ($P < 0.0001$). Similarly, at six months post index visit, unadjusted results showed 69.6% of patients in the pharmacist-led disease state management group had a HbA1c <9% versus 43.5% in the usual care group ($p < 0.0001$) (Figure 2).

Unadjusted statistics also showed an increase in statin therapy was seen at six months post index visit where 96% of patients

in the pharmacist-led disease state management group were on statin therapy compared to 80.6% of patients in the usual care group ($p=0.001$).

Based on the abbreviated CG-CAHPS survey, patients were highly satisfied with pharmacist services. Pharmacist services were rated as “always” >90% of the time and were rated a 9/10 or a 10/10 in 97.4% of cases (Table 2). After running the linear regression model adjusting for baseline HbA1c and statin use, pharmacist management showed a 6-month HbA1c lowering of 2.1 ($p<0.001$) independent of these baseline differences.

The majority of patient visits were billed at 99213 (level 3) or 99214 (level 4). The clinics no show rates average 21-31% depending on location, and a financial model was run to estimate financial viability using hard dollar reimbursement. In order to assess financial viability, a model was created for two FTEs of a PharmD. It was assumed that, divided amongst them, they completed 14 half days of clinic per week. Once no show and cancelled appointments are subtracted from the total, approximately 2500 patient visits per year are conducted. Of these appointments, approximately 90% were billed at a level three or four. Based on the revenue received by the health system, approximately 75% of each PharmD’s salary and benefits are covered by this revenue. This estimate does not include additional income sources for the PharmD such as quality-based outcome reimbursement from CMS, reimbursement for residency training, compensation for precepting pharmacy students, or reimbursement for being shared faculty within a college of pharmacy.

Discussion

The HbA1c lowering results of our study reflect results that have been reported in the past literature. Pharmacist management of diabetes was effective at lowering HbA1c. In this study, a larger number of patients were also able to reach HbA1c goals set by the CMS star rating scale and the HEDIS measures (<7% and <9%) in the pharmacist management group. This not only is associated with better cardiovascular outcomes for patients but also leads to increased cost savings for health systems and increased reimbursement from CMS and managed care organizations. While the reimbursement directly tied to the pharmacist services are below costs, the health system will decrease cost through less diabetic complications and increase revenue through these quality-based reimbursement pathways. When all of this is considered, this study showed a pharmacist’s ability to significantly contribute to quality based reimbursement and cost savings for health systems when they manage patients with diabetes.

While patient satisfaction is not currently utilized to affect reimbursement in the outpatient setting, CMS may move in that direction in the future. As such, a pharmacist’s results on

a patient satisfaction survey, such as the CG-CAHPS, may have future monetary repercussions. The results of this study show that pharmacists score higher than the average scores reported by the CAHPS database.⁸

Limitations

In this study, the higher HbA1c at baseline in the pharmacist-led disease state management group compared to the usual care group was a limitation, but the effects of this difference was minimized through the use of logistic regression. It may be possible to show a more significant lowering in HbA1c due to this difference, but the study also showed that more patients were able to obtain goal HbA1c’s (<7% and <9%) in the pharmacist management group. Being able to bring more patients to their goal HbA1c shows the efficacy of pharmacist management despite the difference in baseline HbA1c. There was also a fluctuation in the number of in the usual care group at 3 months. This was likely due to the providers in the evaluated clinics often requesting 6-month follow-up with their patients without consideration for current HbA1c. Lastly, the CG-CAHPS survey has not been validated to assess pharmacist services, but in this study, pharmacists are filling a similar role to primary care providers, who the survey was validated for. Also, the survey that was offered to patients was an abbreviated CG-CAHPS survey. The investigators chose to include only those questions that were more likely to be influenced by the person providing the clinical services. If the CG-CAHPS survey is used in the future for reimbursement, the scores on the other questions that were omitted would also be included.

Another limitation includes the need to extend the inclusion period for the usual care patients in the cohort. This led to patients in the usual care group being included for an additional 9 months. This is a concern for adding additional variable as new diabetes medications could have been released, services available in individual clinics could have changed, and changes in support staff could have occurred. While this is true, care for any individual patient is unlikely to be dramatically affected. To further elucidate the point, during the time period in question, no new novel classes of diabetes medications received FDA approval, which means the average patient would have the same medication options despite this difference.

CONCLUSION

Pharmacist management of diabetes, compared to usual care, in primary care clinics led to a significant reduction in HbA1c, which is associated with decreased rates of cardiovascular events and increased reimbursement from CMS. Patients were also highly satisfied with the service provided. While revenue from pharmacy services was slightly below costs, the HbA1c lowering seen is associated with increased quality-based

reimbursement and cost savings for the health system. If these cost savings and increased quality-based reimbursements are taken into consideration, providing pharmacist services is a cost-effective way to assist physicians in improving control of patients' diabetes.

Treatment of Human Subjects: IRB review/approval required and obtained

Conflict of Interest: none

Funding: none

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Table 1: Baseline Characteristics

	Intervention (n = 112)	Control (n = 69)
Gender: Male n (%)	42 (37.5%)	26 (37.7%)
Ethnicity: African American n (%)	92 (82.1%)	55 (79.7%)
Age, years Mean (Std)	64.1 (9.59)	61.8 (13.2)
BMI, kg/m² Mean (Std)	34.4 (7.7)	34.9 (9.1)
Duration of diabetes, years Mean (Std)	12.4 (10.4)	10.4 (7.5)
Number of patients on statin therapy^A n (%)	98 (87.5%)	50 (72.5%)
Serum creatinine, mg/dL Mean (Std)	1.07 (0.43)	1.09 (0.40)
HbA1c^A Mean (Std)	10.1 (2.0)	9.3 (2.2)
Number of patients with HbA1c <7% n (%)	3 (2.7)	3 (4.3)
Number of patients with HbA1c <9%^A n (%)	34 (30.4)	36 (52.2)

A: P-value less than 0.05.

Table 2: CG-CAHPS Survey Results. Responding “always” or 9/10 or 10/10.

Question	Responses for Pharmacist Services (n=80)	CG-CAHPS 2015 Average Scores ¹⁴
When calling this provider’s office, how often were questions answered the same day?	92.4%	57%
How often did the provider explain things in a way that was easy to understand?	98.7%	91%
How often did the provider listen carefully to you?	100%	93%
How often did the provider seem to know important information about your medical history?	98.8%	85%
How often did this provider show respect for what you had to say?	100%	95%
How often did this provider spend enough time with you?	98.8%	92%
How often did this provider’s office follow up to give you the results of a test?	92.1%	85%
How would you rate this provider from 0 to 10 with 10 being the best provider possible?	97.4%	83%

Footnote: Currently, for the H-CAHPS survey, only a response of “always” or a 9/10 or 10/10 contributes positively financially for health systems, which led to the results being reported as such.

Figure 1: Change in Mean HbA1c (95% CI)

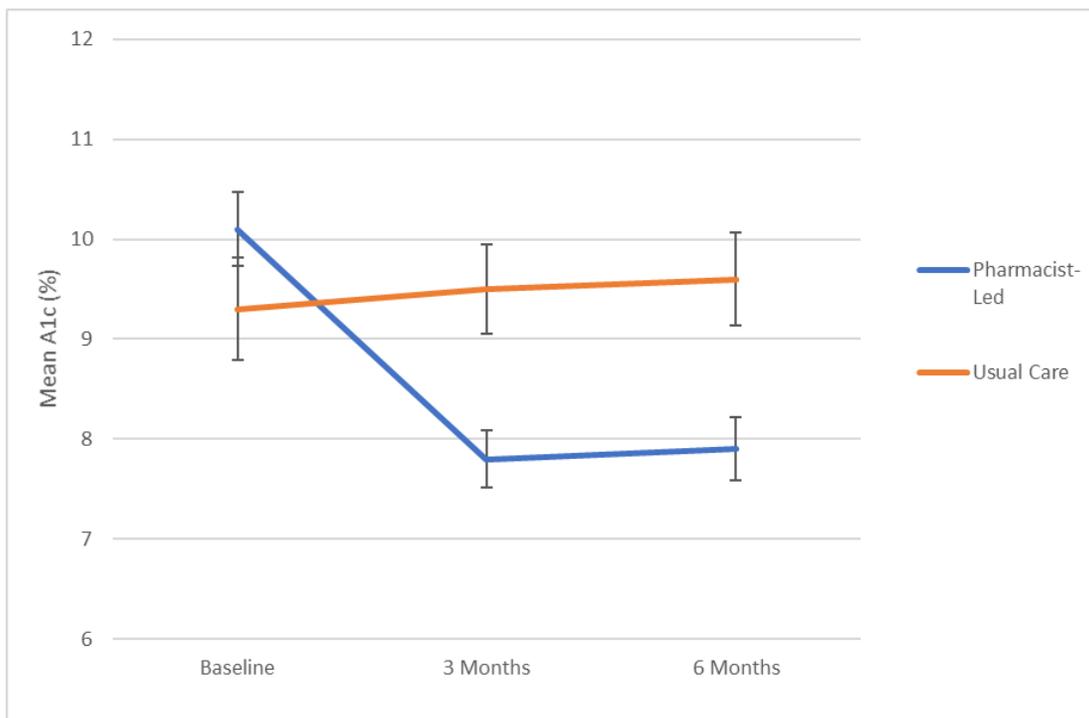
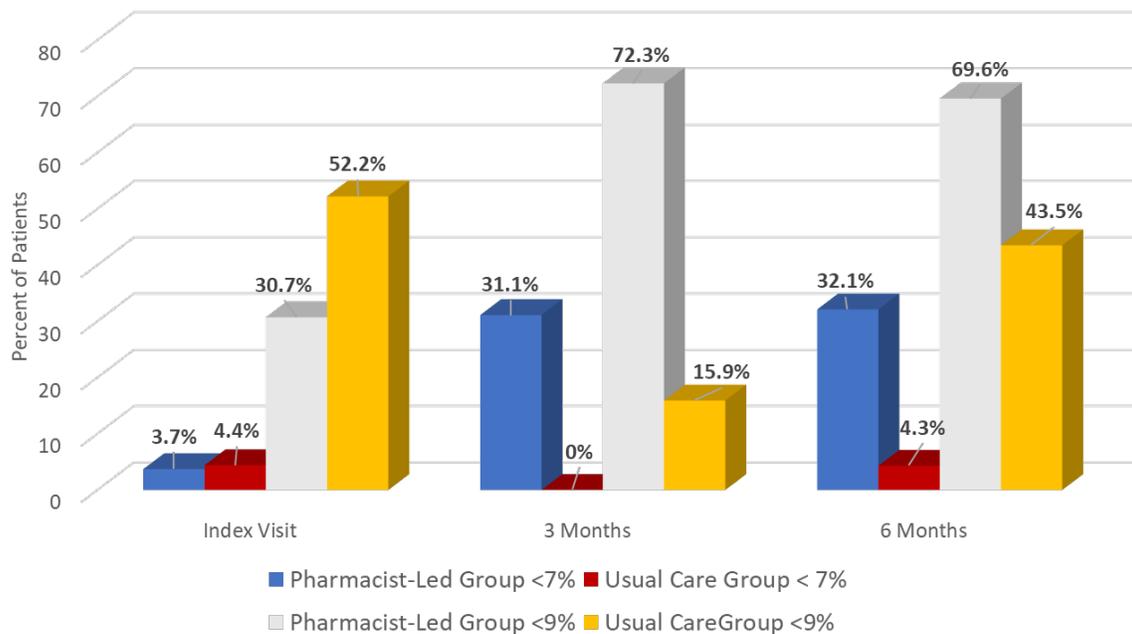


Figure 2: Percent of Patients with HbA1c <7% and <9%.



Footnote: There was a statistically significant difference between both groups at each time point except HbA1c <7% at index visit.