

Impact of an Advanced Practice Pharmacist Type 2 Diabetes Management Program: A Pilot Study

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Abstract

Background: The purpose of this study was to describe the impact of an Advanced Practice Pharmacist (APh) on lowering hemoglobin A1c (HbA1c) in patients with type 2 diabetes within a patient centered medical home (PCMH) and to classify the types of therapeutic decisions made by the APh.

Methods: This was a retrospective study using data from electronic health records. The study evaluated a partnership between Chapman University School of Pharmacy and Providence St. Joseph Heritage Healthcare that provided diabetes management by an Advanced Practice Pharmacist in a PCMH under a collaborative practice agreement. Change in the HbA1c was the primary endpoint assessed in this study. The type of therapeutic decisions made by the APh were also evaluated. Descriptive analysis and Wilcoxon signed rank test were used to analyze data.

Results: The study included 35 patients with diagnosis of type 2 diabetes mellitus managed by an APh from May 2017 to December 2017. Most of the patients were 60-79 years old (68.5%), 45.7% were female, and 45.7% were of Hispanic/Latino ethnicity. The average HbA1c was 8.8%±1.4% (range=6.0%-12.4%) and 7.5%±1.4% (range=5.5%-12.4%) at the initial and final APh visit, respectively ($p<0.0001$). Therapeutic decisions made by the APh included drug dose increase (35.5% of visits), drug added (16.4%), drug dose decrease (6.4%), drug switch (5.5%), and drug discontinuation (1.8%).

Conclusion: The Advanced Practice Pharmacist's interventions had a significant positive impact on lowering HbA1c in patients with type 2 diabetes mellitus in a PCMH. The most common therapeutic decisions made by the APh included drug dose increase and adding a new drug.

Keywords: accountable care organization, collaborative practice agreement, diabetes, patient centered medical home, therapeutic decisions, advanced practice pharmacist

Background

According to the Centers for Disease Control (CDC), as of 2015, 30.3 million people representing 9.4% of the US population have diabetes.¹ Uncontrolled diabetes can lead to serious complications including an increased risk of cardiovascular disease such as heart attack and stroke. The optimization of patient care is imperative to prevent disease progression and the development of complications. Through collaborative practice agreements (CPAs), the clinical pharmacist can optimize care by providing chronic disease management and independently perform therapeutic interventions to improve quality of care and patient outcomes.

Clinical pharmacists also play an important role in the patient centered medical home (PCMH). PCMH is a primary care delivery system with emphasis on multi-disciplinary team-based care and inter-professional collaboration among healthcare providers.²⁻³ The PCMH care model aims to improve

the patient care experience and control cost through the provision of safe, high quality, evidence-based medicine.³ Physicians have an average panel of about 2500 patients.⁴ As a result, physicians may not have enough time during a patient visit to manage chronic illnesses, diagnose acute illnesses, and maintain a positive relationship with their patients.⁴ Co-management of patient panels by physicians, nurses, pharmacists and other PCMH team members allows for the expansion of primary care services and improvement in quality performance metrics.³

Previous studies have looked at providers' perception of pharmacy services in PCMH and how a pharmacist-physician collaboration for diabetes care can impact patient disease management.⁵⁻⁹ Providers consider pharmacists to be valuable and integral members of the health care team because the pharmacist can assist in patient management and improve quality as well as performance metrics.^{3,10-11} Other studies have evaluated the impact of pharmacist's involvement on adherence in a team based model and how pharmacist's involvement can lead to reducing drug and overall health care costs.¹² Many studies concluded that a pharmacist's involvement positively affects diabetes management and could reduce cost.¹²⁻²⁴

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In the state of California, pharmacists can hold the special designation of Advanced Practice Pharmacist (APh) if they satisfy certain criteria. The APh is authorized to perform patient assessments, refer patients to other health care providers and initiate, adjust, and discontinue drug therapy. The APh works upon referral from a patient's treating provider and under a protocol. In addition, in collaboration with patient's primary care physician (PCP), the APh can order and interpret drug therapy-related tests and participate in evaluation and management of patient's health conditions. There are limited number of studies that describe the impact of Advanced Practice Pharmacists who practice as mid-level providers in a PCMH and who make decisions and medication adjustments independently under a CPA.

The objectives of this study were to assess the impact of an APh working in a PCMH on reduction in the HbA1c values for patients with type 2 diabetes and to classify the types of therapeutic decisions made by the APh.

Setting

Providence St. Joseph Heritage Healthcare was founded in 1994. It consists of 8 medical groups and supports six affiliated physician networks in California. There are approximately 175 clinics, 915 medical group providers and 1,327 affiliate providers within Heritage. In May 2017, the administration at Providence St. Joseph Heritage Healthcare was interested in piloting a pharmacist-run, protocol-driven, disease state management (DSM) program at one of its clinics in Southern California, St. Jude Heritage Medical Group (SJHMG). At the time, this PCMH clinic consisted of 6 primary care providers (PCPs), one nurse practitioner (NP), one registered nurse (RN), and a case manager. The aim of the DSM program was to improve chronic care quality metrics, provide better access to care for patients and evaluate the impact of clinical pharmacy services on measures such as HbA1c.

Although our study was a pilot study with only one APh pharmacist, currently, there are seven pharmacists practicing in PCMH clinics consisting of a team of 5-7 PCPs or family medicine physicians, and other health care providers. The team provides collaborative interdisciplinary care for patients. Most recently, a behavioral health provider was also added to the team in some clinics. The clinical pharmacists spend between 1 and 4 days per week at the clinical practice site and attend daily multidisciplinary huddles.

The clinical pharmacists are credentialed by the PCMH at Heritage. Due to the fast expansion of the pharmacy program in the last year, not all the pharmacists have a California Advanced Practice Pharmacist license; however, they plan to apply for this license in the immediate future. The clinical pharmacists work with physicians who are part of the PCMH under a CPA that includes management of type 2 diabetes, hypertension and dyslipidemia. The CPA excludes patients with type 1 and gestational diabetes.

Physicians refer patients to the pharmacists who do not meet the American Diabetes Association (ADA) glycemic goal, as well as patients needing education about medications or lifestyle modification counselling. After obtaining the referral, the clinical pharmacist can independently initiate, modify and discontinue drug therapy; evaluate drug adherence; order and review lab values and vital signs; and recommend lifestyle modifications as needed. The office staff schedules the patients' visits with the pharmacist and each pharmacist has her own schedule. Initial in-office pharmacist visits are scheduled for 1 hour and follow up in-office visits are scheduled for 30 minutes. The clinical pharmacists also manage patients via electronic patient portal or telephonically.

Methods

This was a retrospective study using electronic health records data. The study was conducted under a partnership between Chapman University School of Pharmacy and Providence St. Joseph Heritage Healthcare System. During the study period, one APh from Chapman University School of Pharmacy spent 1-2 days per week in a PCMH clinic at Jude Heritage Medical Group and provided diabetes management under a CPA. The change in HbA1c pre and post APh management was the primary endpoint assessed in this study. APh was requested to show the value of the interventions within 6 months of starting the program. Thus, the change in HbA1c was considered an appropriate measure for detecting the effect of the interventions in the relatively short period of analysis. The study included patients diagnosed with diabetes mellitus type 2 and referred to the clinical pharmacist regardless of HbA1c levels. Patients with type 1 and gestational diabetes were excluded from the study. A chart review was performed of each patient's medical record. The data collected included patient demographics, number of APh visits, type of visit, and the HbA1c value at the first and successive APh visits. Information was also collected about APh's interventions including adding a new drug, increasing or decreasing the dose of existing drugs, switching to a different drug, and discontinuing a drug. With the help of the Accountable Care Organization (ACO) partner, Blue Shield, and the administration at Heritage Healthcare, the APh pharmacist selected these types of interventions in order to best show the impact of APh presence within the PCMH model.

Data collected were stored in password protected Microsoft Excel file, de-identified and saved in a secure computer. Microsoft Excel and IBM SPSS Statistics 25 software programs were used to analyze the data. Descriptive analysis and Wilcoxon signed rank test were used for the analysis. The effect size and post-hoc power analyses were performed using G*Power. Both Providence St. Joseph Heritage Healthcare and Chapman University IRB approvals were obtained prior to study initiation.

Results

The study included 35 patients who received comprehensive drug therapy management services for type 2 diabetes mellitus

by an APh in a St. Jude Heritage PCMH from May 2017 to December 2017. Patients' ages ranged from 30-95 years, with 68.5 % of patients between 60-79 years old. Female patients represented 45.7% of the patients and 45.7% of the patients were of Hispanic/Latino ethnicity (Table 1).

The APh provided 110 visits; with an average \pm standard deviation of 3.1 ± 1.3 visits per patient (range 2-6 visits). Visits were conducted in-person (84.5%), over the phone (11.8%) or via a patient portal of the electronic medical record (3.6%). The average interval between each visit for patients was 100.4 ± 53.6 days (median 84.0 days).

The APh performed 72 therapeutic interventions with an average of 2.1 ± 1.4 interventions per patient (range 0-5) and 0.7 ± 0.4 interventions per visit. The therapeutic interventions performed by the APh included dose increase (35.5% of visits), drug added to the patient's regimen (16.4%), drug switch (5.5%), dose decrease (6.4%), and drug discontinuation (1.8%) (Table 2). The most common drugs involved in the APh therapeutic interventions were glimepiride (11.8%), glipizide (5.5%), insulin glargine (10.9%), and metformin (19.1%).

The percentage of patients with a HbA1c value of $>10.0\%$ was 14.3% and 2.8% pre and post intervention by the APh, respectively. The percentage of patients with elevated HbA1c values decreased, while the percentage of patients with lower HbA1c values increased pre and post intervention by the APh. (Table 3) The average \pm standard deviation HbA1c changed from $8.8\% \pm 1.4\%$ at baseline to $7.5\% \pm 1.4\%$ at the last visit ($Z = -4.408$, $p < 0.001$). The effect size was large ($d = 0.93$), indicating that the pre-post HbA1c difference was important. In addition, the result of post-hoc power analysis was large ($1 - \beta = 0.9994$). Thus, we might assume that the intervention by APh caused a significant reduction in HbA1c. Changes in HbA1c values varied by patient (Table 4). There were 24 (68.6%) patients that experienced an HbA1c reduction, 18 (51.4%) patients that had an absolute HbA1c reduction of at least 1.0% and 15 (42.9%) patients that achieved an HbA1c level $\leq 7.0\%$ at the end of the study.

Discussion

This study demonstrated the impact of an APh providing care to patients with type 2 diabetes under a CPA in a PCMH. The study found a significant reduction in HbA1c post APh intervention and it discerned the type of therapeutic decisions that the APh adopted during patient visits.

Previous studies also found positive effects of pharmacists' interventions in diabetes care outcomes. A meta-analysis of 14 clinical trials found that pharmacist interventions resulted in a HbA1c reduction of $1.36\% \pm 1.53\%$ (95% CI: 0.83%-1.89%) in type 1 and type 2 diabetes patients.²⁵ Another meta-analysis including 22 studies found that pharmacists interventions in outpatient clinics resulted in a reduction of 0.85% in HbA1c (95% CI: 0.65%-1.06%, $p < 0.0001$) in type 2 diabetes patients.²⁶

Furthermore, another study found a large HbA1c reduction in patients who enrolled in the pharmacist-management group compared to usual care.²⁷

In our study, the APh made independent therapeutic decisions during patient visits. The primary care physicians at the clinic did not change any of the therapeutic decisions made by the APh. Several other studies have also shown that pharmacists working under a collaborative practice agreement are well accepted by physicians in group practice settings.^{28,29}

While cost was not assessed in this study, previous studies demonstrated that pharmacists are cost-effective in managing diabetes in collaborative care programs.³⁰ A previous study compared patients who achieved and did not achieve a decrease in HbA1c and found that patients with a decrease in HbA1c had 24% and 17% lower average annual healthcare costs during the first and second year of follow up, respectively.³¹

In addition to other outcome measures, Blue Shield, our ACO partner, has contracted measures on HbA1c reduction for patients. Thus, this pilot study was important to show that APh engagement can help improve performance metrics.

Our study found that the two most common therapeutic decisions made by the APh were drug dose increase and adding a new drug to the patient's regimen. Other therapeutic decisions included drug dose decrease, drug switch, and drug discontinuation. Those decisions may explain the reduction in HbA1c observed in this study.

The results of our study confirm the positive impact of the APh on diabetes care outcomes. The utilization of pharmacists to manage patients with complex chronic diseases not only improves patient outcomes, but it may also help to address the current shortage of primary care physicians.³²

There were 10 patients who did not have a reduction in HbA1c values. These patients had varying levels of HbA1c and we did not observe a pattern related to the number of visits, number of interventions, and type of interventions these patients had in relation to patients who exhibited a change in HbA1c. Although the pharmacist intervention did not result in the HgA1c reduction for 10 patients, it is important to note that these patients also did not see an increase in HbA1c. Future analysis should evaluate factors that explain why some patients do not experience a reduction in HbA1c levels.

There were 3 patients who received counseling and had their medications reviewed by the APh and who did not have any change in therapy. These patients also experienced a reduction in HbA1c. Future studies should assess the separate effects of APh's medication review and patient counseling on diabetes health outcomes.

This study has some limitations. The study included a limited number of patients; however, differences in the primary outcome of the analysis were statistically significant with enough power to detect differences in the study outcome. An ongoing study with participation of additional clinical pharmacists is currently being conducted. While patients were asked and educated about adverse events such as hypoglycemia at each visit with the APH, we did not track these outcomes. Our study also did not track APH lifestyle modifications counseling interventions. Some patients may be able to lower their HbA1c values with diet and exercise alone and without medications or medication changes. The period of analysis was relatively short, but enough to demonstrate significant results and justify the expansion of the clinical pharmacist program.

Conclusions

An Advanced Practice Pharmacist led comprehensive type-2 diabetes management program under a collaborative practice agreement in a patient-centered medical home resulted in improvement in HbA1c values. Changes in drug therapy, including drug dose increase and adding a new medication were the most common interventions made. APH pharmacists are a valuable part of the interprofessional health care team.

Key Points

- Advanced Practice Pharmacist is an integral part of an inter-professional team within a patient centered medical home.
- Independent therapeutic decision making by an Advanced Practice Pharmacist can improve HbA1c values.
- Pharmacist led chronic disease management is an important part of health care delivery within a health system.

List of Abbreviations

ACO – Accountable Care Organization
 ADA – American Diabetes Association
 APH – Advanced Practice Pharmacist
 CDC – Centers for Disease Control
 CI – Confidence Interval
 CPA – collaborative practice agreement
 DSM – disease state management
 HbA1c – Hemoglobin A1c
 NP – Nurse Practitioner
 PA – Physician Assistant
 PCMH – patient centered medical home
 PCP – Primary Care Physician
 RN – Registered Nurse
 SJMG – St. Jude Heritage Medical Group

Declarations

The authors do not have any conflicts of interest to disclose

Ethics approval and consent to participate

- Providence St. Joseph Heritage Healthcare and Chapman University IRB were obtained prior to study initiation.

Consent for publication

- Not applicable

Availability of data and material

- All data generated and analyzed during this study are included in this published article

Competing interests

- The authors declare that they have no competing interests

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Authors' contributions

- All authors read and approved the final manuscript
- JL, TN, HA, MA, and ES collaborated on the conceptualization, study design, methodology design, data collection, data analysis, results interpretation, writing the manuscript, revising and providing comments to the manuscript
- BB, DK, and SC helped with conceptualization and study design as well as with revising and providing comments to the manuscript

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Table 1. Patient Demographics

Parameters	Patients, n (%)
Age groups (years)	
30-39	1 (2.9%)
40-49	3 (8.6%)
50-59	6 (17.1%)
60-69	13 (37.1%)
70-79	11 (31.4%)
80+	1 (2.9%)
Total	35 (100.0)
Sex	
Female	16 (45.7 %)
Male	19 (54.3%)
Race	
Asian	2 (5.7%)
Black or African	1 (2.9%)
Native Hawaiian	1 (2.9%)
Patient Declined	1 (2.9%)
Two or more Races	4 (11.4%)
White	26 (74.3%)
Ethnicity	
Hispanic or Latino	16 (45.7%)
Non-Hispanic or Latino	16 (45.7%)
Patient Declines	3 (8.6%)
BMI	
25.0-29.9	10 (28.6 %)
30-35.9	8 (22.9 %)
36 +	9 (25.7%)
Unknown	8 (22.9%)
Pharmacist interventions (n)/ Patient over multiple visits	
2	16 (45.7%)
3	10 (28.6%)
4	5 (14.3%)
5	1 (2.9%)
6	3 (8.6%)

Table 2. Clinical Pharmacist Therapeutic Interventions and Antidiabetic Drugs Involved

Parameters	Value, n (%)
Type of Interventions	
Dose increase	39 (35.5 %)
Drug added	18 (16.4 %)
Dose decrease	7 (6.4 %)
Drug switch	6 (5.5 %)
Drug discontinuation	2 (1.8 %)
Drugs	
metformin	21 (19.1%)
glimepiride	13 (11.8%)
insulin glargine	12 (10.9%)
glipizide	6 (5.5%)
insulin degludec	1 (0.9%)
exenatide	1 (0.9%)
glyburide	1 (0.9%)
sitagliptin	1 (0.9%)

Table 3. Hemoglobin A1c levels Pre and Post intervention

Parameters	Pre intervention n (%)	Post intervention n (%)
HbA1c range		
<6%	0	2 (5.7%)
6-6.9%	3 (8.6%)	15(42.9%)
7-7.9%	6 (17.1%)	9 (25.7%)
8-8.9%	10 (28.6%)	3 (8.6%)
9-9.9%	11 (31.4%)	5 (14.3%)
>10%,	5 (14.3%)	1(2.8%)
Total	35 (100.0)%	35 (100.0)%
Average* ±SD	8.8%±1.4%	7.5% ±1.4%
Range	6.0%-12.4%	5.5%-12.4%
95%CI	8.3%-9.3%	7.0%-8.0%

HbA_{1c} = glycosylated hemoglobin

*p<0.0001

Table 4. Pre and Post Intervention Hemoglobin A1c Levels, Visits and Therapeutic Interventions

Patient	Pre HbA1c	Post HbA1c	Pre-Post HbA1c Difference	Number of Visits	Number of Interventions	Type of Intervention (Number)
1	6.00%	6.20%	-0.20%	3	1	drug added (1)
2	6.60%	6.60%	0.00%	4	1	dose decrease (1)
3	6.80%	6.80%	0.00%	4	1	dose increased (1)
4	7.30%	6.50%	0.80%	2	2	dose increased (1), drug discontinue (1)
5	7.50%	6.90%	0.60%	2	0	none
6	7.70%	7.60%	0.10%	2	1	dose increased (1)
7	7.70%	7.70%	0.00%	3	2	dose increased (2)
8	7.80%	7.80%	0.00%	5	4	dose increased (2), dose decrease (2)
9	7.90%	6.50%	1.40%	3	1	drug added (1)
10	8.00%	6.40%	1.60%	4	1	drug added (1)
11	8.00%	7.00%	1.00%	2	1	drug added (1)
12	8.10%	7.50%	0.60%	6	5	dose increased (3), drug added (2)
13	8.10%	8.10%	0.00%	2	1	drug added (1)
14	8.20%	8.20%	0.00%	2	0	none
15	8.50%	6.80%	1.70%	2	1	drug added (1)
16	8.50%	7.10%	1.40%	2	3	dose increased (2), drug added (1)
17	8.60%	5.90%	2.70%	6	3	dose increased (2), drug switch (1)
18	8.80%	6.70%	2.10%	5	4	dose increased (1), dose decrease (1), drug switch (2)
19	8.80%	5.50%	3.30%	2	1	drug discontinue (1)
20	9.00%	6.70%	2.30%	3	2	dose increased (1), drug added (1)
21	9.20%	6.80%	2.40%	2	1	dose increased (1)
22	9.20%	9.20%	0.00%	2	1	drug added (1)
23	9.20%	6.70%	2.50%	3	2	dose increased (2)
24	9.40%	7.90%	1.50%	3	4	dose increased (2), drug added (1), dose decrease (1)
25	9.40%	9.40%	0.00%	2	1	dose increased (1)
26	9.40%	7.90%	1.50%	3	2	dose increased (2)
27	9.50%	7.10%	2.40%	4	0	none
28	9.60%	6.00%	3.60%	2	2	dose increased (1), dose decrease (1)
29	9.60%	9.20%	0.40%	3	3	dose increased (2), drug switch (1)
30	9.90%	9.90%	0.00%	2	3	dose increased (2), drug switch (1)
31	10.10%	9.50%	0.60%	3	4	dose increased (2), drug added (2)
32	10.20%	8.30%	1.90%	4	3	dose increased (1), drug added (2)
33	12.10%	6.70%	5.40%	6	5	dose increased (1), drug added (2), drug switch (1), dose decrease (1)
34	12.10%	6.10%	6.00%	3	2	dose increased (2)
35	12.40%	12.40%	0.00%	4	4	dose increased (4)