

# Clinical Pharmacist Team-Based Care in a Safety Net Medical Home: Facilitators and Barriers to Chronic Care Management

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## Abstract

Collaborative care models incorporating pharmacists have been shown to improve quality of care for patients with hypertension and/or diabetes. Little is known about how to integrate such services outside of clinical trials. The authors implemented a 22-month observational study to evaluate pharmacy collaborative care for hypertension and diabetes in a safety net medical home that incorporated population risk stratification, clinical decision support, and medication dose adjustment protocols. Patients in the pharmacy group saw their primary care provider (PCP) more often and had higher baseline systolic blood pressure (SBP) and diastolic blood pressure (DBP) and A1c levels compared to patients who only received care from their PCPs. There were no significant differences in the proportion of patients achieving treatment goals (SBP <140, DBP <90; A1c < 8) or the magnitude of change in BP or A1c among patients who underwent collaborative care versus those who did not. Age, race, and number of PCP encounters were associated with BP and A1c trends. The median time to achieve disease control was longer in the pharmacy group. Although 70% of all patients with poorly controlled hypertension achieved treatment goals within 7 months, less than 50% of patients with poorly controlled diabetes achieved A1c < 8 within 15 months, suggesting that diabetes was harder to manage overall. Contextual factors that facilitated or hindered practice redesign included organizational culture, health information technology and related workflows, and pharmacy caseload optimization. Future studies should further examine implementation strategies that work best in specific settings to optimize the benefits of team-based care with clinical pharmacists.

## Introduction

**H**YPERTENSION AND DIABETES are major public health challenges in the United States because of their high prevalence and the concomitant increase in risk of cardiovascular disease.<sup>1-3</sup> The efficacy and effectiveness of behavioral and pharmaceutical interventions on disease prevention and control are well established.<sup>4-6</sup> However, there are multiple system-,<sup>7-11</sup> provider-,<sup>12-15</sup> and patient-level<sup>16-19</sup> barriers to care rendering overall population disease control suboptimal despite advances in medical care. Subsequently, there is now a heightened awareness of the need to improve care coordination for patients with chronic medical conditions.

Effective interventions to improve care coordination include team-based collaborative models of care. Team-based care with the addition of new staff (eg, health coaches) and the changing roles of nurses and pharmacists have been shown to improve quality of care and clinical outcomes for patients with hypertension and/or diabetes.<sup>20-26</sup> A recent meta-analysis of pharmacist interventions demonstrated favorable results compared to usual care for blood pressure (BP), A1c, low-density lipoprotein cholesterol, medication adherence, patient knowledge, and quality of life.<sup>27</sup> The US Community Preventive Services Task Force further suggests that team-based care may be cost-effective.<sup>28</sup> This approach to task shifting or task sharing is useful for improving

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elements of and access to primary care in resource-limited settings.<sup>29</sup>

Few studies provide guidance on how to implement pharmacy interventions outside of well-controlled clinical trials. This article describes the practice transformation and quality improvement (QI) context of a safety net patient-centered medical home (PCMH) that offers hypertension and diabetes care management through collaborative care with a colocated clinical pharmacist. This collaborative care model includes risk stratification based on BP and/or A1c level, electronic medical record (EMR)-based clinical decision support, prescription of generic medications, and protocol-based medication adjustments. This 22-month observational study examined population trends of BP and/or glucose control over time among patients with poorly controlled conditions who received collaborative care with a clinical pharmacist versus those who did not. Also described are facilitators and barriers to implementing the pharmacist collaborative care model in a resource-limited primary care setting.

## Methods

### *Study design, setting, and population*

This is a retrospective observational study of adult patients (ages  $\geq 18$  years) with diabetes and/or hypertension seen at an academically affiliated community health center between July 2012 and April 2014. The center, which has maintained level 3 PCMH recognition by the National Committee for Quality Assurance (NCQA) since 2008, serves a population of mostly African Americans, publicly insured patients, and low-income working adults. The center is a major teaching site for residency training in internal medicine, psychiatry, and clinical pharmacy. In 2013, management of clinical services transferred from under a university to a federally qualified health center. Tulane University's Institutional Review Board approved this study.

### *Historic context for practice transformation*

Between 2007 and 2010, the health center participated in the Primary Care Access Stabilization Grant (PCASG) along with 24 provider organizations to increase access to high-quality primary care for a mostly uninsured adult population in New Orleans, Louisiana.<sup>30</sup> PCASG incentivized local safety net providers to achieve NCQA PCMH recognition. Given that Louisiana opted out of Medicaid expansion, the health center participated in the Greater New Orleans Community Health Connection Medicaid 1115 Waiver program (2010–2014), which provided insurance coverage for medical and mental health services for adults who did not qualify for Louisiana Medicaid. However, the Medicaid Waiver program did not cover the cost of prescriptions. The practice simultaneously participated in the Crescent City Beacon Community (CCBC) Initiative to implement health information technology-enabled, evidence-based interventions of risk stratification, clinical decision support, population-based disease registries, and care team strategies for managing patients with diabetes and cardiovascular diseases.<sup>31–33</sup>

### *Pharmacist collaborative care management*

The health center implemented continuous QI for hypertension and diabetes targeting NCQA benchmarks for quality

of care for these conditions. Notably, the health center's rates of disease control were below NCQA benchmarks despite high rates of guideline-concordant processes of care (eg, A1c testing) and relative high rates of BP and glucose control compared to other safety net CCBC program participants. The practice added a clinical pharmacist (doctor of pharmacy [PharmD] with residency training and board certified in ambulatory care pharmacotherapy) to the PCMH's care team in 2010 to increase patient access to interval disease-focused clinic visits and telephone consultations. Pharmacy services were fully integrated into the practice by 2012. The health center had piloted use of a disease registry to proactively contact patients for appointments with the clinical pharmacist; however, patients and primary care providers (PCPs) were more receptive to collaborative care when PCPs initiated the referral as opposed to "cold calls" for disease care management. PCPs referred to the clinical pharmacist those patients: (1) who were newly diagnosed with diabetes or hypertension; (2) who needed counseling on initiation of insulin therapy or lifestyle modifications; or (3) who had poor disease control and needed medication management. The health center's PCPs and pharmacist shared the same EMR as well as administrative and exam room work space, which facilitated "warm handoffs" and shared treatment planning.

Given the volume of patients with diabetes and/or hypertension in the practice, the pharmacist's care management caseload focused on patients identified as being at high risk for disease complications defined as A1c  $\geq 9$  among patients with diabetes and systolic blood pressure (SBP)  $\geq 160$  or diastolic blood pressure (DBP)  $\geq 100$  among patients with hypertension. All pharmacy encounters were documented via care management note templates in an EMR (SuccessEHS; Greenway Health LLC, Carrollton, GA) shared with the primary care team. At each visit, the pharmacist assessed patients' biometrics (BP, pulse, weight, blood glucose) and reviewed the medical record for the status of other measures of disease control and prevention. Key components of the visit included exploring barriers to medication adherence, adjusting medication doses, teaching home self-monitoring, setting mutually agreed upon patient self-management goals, distributing easy-to-read education materials with visual aids (eg, 1-page handouts from the American Diabetes Association, the Centers for Disease Control and Prevention, and the US Department of Agriculture with a reading level at 5<sup>th</sup> grade or less) and giving patients written care plans.

Table 1 summarizes the medication management protocol vetted and approved by PCPs for the care management program. The pharmacist was authorized to adjust medication doses and notified PCPs of care plans via an electronic flag in the EMR. If patients required new medications or lab orders, the flags prompted PCPs to submit new orders. Care management programming emphasized prescribing generic low-cost medications (eg, \$4 formularies at local pharmacies). Eligible patients also had access to pharmacy assistance programs. Follow-up encounters focused on medication adherence, intensifying medications, and adjusting care plans. The length and frequency of the pharmacy intervention was tailored to individual patient circumstances. Telephone consultations between the clinical pharmacist and patients were offered as needed (eg, transportation problems). Patients were discharged from pharmacy care when they achieved

TABLE 1. HYPERTENSION (HTN) AND DIABETES (DM) CARE MANAGEMENT MEDICATION PROTOCOL

<i>HTN—First visit protocol</i>	
<i>Clinical Assessment</i>	<i>Plan</i>
140–159/90–99 not on drug treatment	Start diuretic; reinforce lifestyle modification.
140–159/90–99 on 1–2 medications	Increase dose or add another medication. Reinforce lifestyle modifications
≥160/≥100 not on drug treatment	Start combination of diuretic and second drug. Reinforce lifestyle medications.
≥160/≥100 on 1 medication	Add combination of two drugs; reinforce lifestyle modification.
≥180/≥110 on 3 medications	Consult PCP regarding reasons for resistant HTN. If already ruled out, make sure patient is adherent to regimen, add 4th drug.
Nonadherence to regimen	Address reasons for nonadherence, remove barriers, adjust regimen if necessary, monitor adherence.
At goal, no adherence barriers	Continue present treatment; reinforce lifestyle modifications.
<i>HTN—Follow-up visit protocol</i>	
At goal	Continue present treatment, reinforce lifestyle modifications.
BP <10 mmHg above goal	Increase dose or add another drug.
BP >10 mmHg above goal	Add another drug and increase doses or other agents. If other agent(s) at or above mid-dose, add a combination of 2 additional drugs.
Nonadherence to regimen	Address reasons for nonadherence, enlist family members and other social support, use pill counts, pill boxes to provide feedback and reinforcement.
>180/>110 mmHg on 3 BP medications	Address adherence, if secondary causes of hypertension ruled out add 4th medication and monitor every 2 weeks until at goal.
<i>DM visit protocol</i>	
Determine if patient experienced signs or symptoms of hyperglycemia or hypoglycemia in the last 2 weeks.	
Adjust current medications if A1c not at goal.	
<ul style="list-style-type: none"> <li>• Increase oral antihyperglycemics to maximum effective dose provided no contraindications or adverse effects have been noted previously.</li> <li>• Recommend basal insulin for patients with symptoms of hyperglycemia and an A1C ≥10%.</li> <li>• Increase basal insulin incrementally until fasting plasma glucose (FPG) is 70–130 2 units every 3–5 days until FPG 70–130. If FPG is &gt;180 may increase by 4 units per day.</li> <li>• Increase preprandial insulin incrementally until postprandial glucose is &lt;180. Increase by 2 units according to which mealtime reading is elevated</li> </ul>	

BP, blood pressure.

their BP or A1c goals, declined further care, or were lost to follow-up. All encounters with the clinical pharmacist incorporated pharmacy students or residents as part of a teaching clinic and were free of charge. Counseling that included students was conducted under the direct observation of the clinical pharmacist to ensure accuracy of all patient education provided.

*Data collection*

Data were abstracted from the EMR for patients ages ≥18 years who had a diagnosis of hypertension (*International Classification of Diseases, Ninth Revision* [ICD-9] code range 401.xx–405.xx) or diabetes (ICD-9 codes: 250.xx, 648.0x, 775.1x) and had at least 2 PCP encounters between July 2012 and April 2014. The main outcome variables were A1c level for diabetics and BP for patients with hypertension. Included in the analysis were patients with diabetes who had at least 2 A1c readings recorded (N=296) and patients with hypertension who had at least 2 BP readings (N=1111). Patients with diabetes were identified as eligible for pharmacist collaborative care management on the first date for which an A1c ≥8 was recorded. Time to glucose control was coded as number of months to reach A1c ≥8. The study team recognized that clinical guidelines recommend targeting A1c <7 for diabetes control; however, as a

population health management strategy, the team targeted A1c <8 given the complexity of care for their underserved population. Patients with a diagnosis of hypertension were eligible for collaborative care management on the first date for which SBP ≥140 or DBP ≥90 was recorded. Time to BP treatment response was coded as the number of months to reach BP targets. Other variables abstracted from the EMR included age, sex, insurance type, diagnosis codes, encounter visit counts, and length of time under continuous care with PCPs or the clinical pharmacist, defined as the number of days or months between the first and last encounter with each type of provider during the study period.

*Data analysis*

The study team compared baseline characteristics of patients who only had encounters with their PCP to patients who had additional encounters with the clinical pharmacist (PCP + PharmD) using the Student *t* test for continuous variables and chi-square analysis for categorical variables. The team examined the proportion of patients in each study group who achieved SBP <140, DBP <90, and A1c <8 by the end of the study using chi-square analysis. Median time to reaching BP and A1c treatment goals and interquartile range (IQR) were reported if available. The log-rank test was used to test for significant differences between

TABLE 2. CHARACTERISTICS OF ADULT PATIENTS AGE 18+ YEARS SEEN BETWEEN JULY 2012 AND APRIL 2014

	<i>All patients seen</i>	<i>PCP encounters only</i>	<i>PCP + PharmD encounters</i>
	N = 5044	N = 4654	N = 390
Age (mean, SD)*	47 (14.4)	46.9 (14.5)	53.5 (11.6)
Black, non-Hispanic (n, %)*	3564 (71.2)	3245 (70.3)	319 (82.0)
Female (n, %)*	3100 (61.5)	2897 (62.3)	203 (52.1)
Insurance (n, %)*			
Medicaid or 1115 Waiver	2231 (44.2)	2047 (44.0)	184 (47.2)
Medicare	554 (11.0)	496 (10.7)	58 (14.9)
Commercial	683 (13.5)	641 (13.8)	42 (10.8)
Uninsured	1576 (31.3)	1470 (31.6)	106 (27.2)
Clinic encounter types (mean, SD)			
Number of PCP visits*	3.1 (2.7)	3.0 (2.5)	5.2 (3.0)
Number of PharmD visits	2.2 (2.0)	...	2.2 (2.0)
Chronic conditions			
Hypertension*	2241 (44.4)	1916 (41.2)	325 (83.3)
Diabetes*	900 (17.8)	665 (14.3)	235 (60.3)
Depression	780 (15.5)	727 (15.6)	53 (13.6)
Anxiety	426 (8.5)	400 (8.6)	26 (6.7)
Charlson comorbidity score*	0.9 (1.7)	0.8 (1.6)	1.9 (1.8)

\* $P < 0.05$  comparing PCP + PharmD vs PCP only.

PCP, primary care physician; PharmD, doctor of pharmacy.

cumulative probability curves for achieving BP or glucose control. To examine longitudinal data collected in the normal course of clinical care, generalized estimating equations (GEEs) were used to examine associations between the main outcome variables (SBP, DBP, and A1c), study group assignment, time, interaction between time and group assignment, and covariates of interest. Covariates considered included age, sex, race, insurance type, number of PCP visits, number of BP or A1c readings, Charlson comorbidity score, history of anxiety or depression, and time. Number of BP or A1c readings was not associated with changes in SBP, DBP, or A1c in the bivariate analysis of covariates, was confirmed as not statistically significant in GEE analysis, and was subsequently excluded from the final model. The GEE analysis was stratified to address concerns that changes in BP and A1c in the clinical pharmacist group may represent the tendency for outliers to regress toward the mean rather than the effects of care management.

QI team meeting notes were examined to identify and classify facilitators/barriers to program implementation and performance monitoring using the Model for Understanding Success in Quality.<sup>34</sup> This framework identifies contextual factors at multiple levels of health care systems likely to influence the perception of success of QI efforts including external environment, organization, microsystems (clinic/department), QI teams, data infrastructure, and resource availability.

## Results

### *Patient characteristics*

Among 5044 unique patients served by the health center during the study period, most were middle-aged, black females who were either uninsured or on Louisiana Medicaid or the 1115 Waiver (Table 2). Approximately 44% of patients had hypertension and 18% had diabetes. Most patients who saw the clinical pharmacist had a higher prevalence of

comorbidities compared to patients who only received care from their PCP (PharmD + PCP vs PCP, mean [standard deviation (SD)]: 1.9 [1.8] vs 0.8 [1.6],  $P < 0.05$ ). Patients who saw the pharmacist also had a higher rate of encounters with their PCP compared to patients who only received care from their PCP (5.2 [3.0] vs 3.0 [2.5],  $P < 0.05$ ).

### *Length of pharmacy intervention*

Among the 2241 patients with a diagnosis of hypertension, 1111 patients with poorly controlled BP were included in the analysis. The BP ranges were similar in both study groups. Up to one third of these patients met the study definition of high risk (SBP  $\geq 160$  or DBP  $\geq 100$ ). Less than 25% of these patients were referred to the clinical pharmacist. The median number of days under the pharmacist's care for hypertension was 22 days (IQR 1 to 94).

Among the 900 patients with a diagnosis of diabetes, 296 had A1c levels  $\geq 8$  and were included in the analysis. The range of A1c levels was similar in both study groups. Approximately 60% of these patients met the study definition of high risk (A1c  $> 9$ ). Only 46% were referred to the clinical pharmacist. The median number of days under the pharmacist's care for diabetes was 44 days (IQR 1 to 183).

### *Comparison of group trends in BP control*

In the unadjusted analysis, although there were statistically significant group differences in baseline SBP and last follow-up readings (Table 3), there were no group differences in the average change in SBP over time or the proportion of patients who achieved SBP control (PCP + PharmD vs PCP: 67% vs 69%,  $P = 0.5$ ) by the end of the study. The median time to achieve control was longer in the group who underwent care management with the clinical pharmacist (7 months, IQR 3 to 15) compared to those who only saw their PCP (6 months, IQR 3 to 12,  $P < 0.01$ ). More

TABLE 3. UNADJUSTED COMPARISON OF BASELINE AND FOLLOW-UP BLOOD PRESSURE READINGS AND A1C LEVELS (MEAN, SD)

	Baseline		Follow-up		Difference	
	PCP only	PCP + PharmD	PCP only	PCP + PharmD	PCP only	PCP + PharmD
Systolic blood pressure*	(N=835) 156.6 (15.3)	(N=236) 161.3 (18.7) <sup>†</sup>	(N=835) 140.3 (19.5)	(N=236) 145.2 (21.6) <sup>†</sup>	-16.2 (21.8)	-16.1 (24.2)
Diastolic blood pressure*	(N=642) 96.5 (7.0)	(N=186) 98.1 (8.6) <sup>†</sup>	(N=642) 87.0 (10.7)	(N=186) 87.0 (11.1)	-9.5 (11.2)	-11.1 (12.8)
Hemoglobin A1c*	(N=160) 9.3 (1.7)	(N=136) 10.2 (2.2) <sup>†</sup>	(N=160) 8.4 (1.6)	(N=136) 9.3 (2.3) <sup>†</sup>	-0.9 (1.9)	-0.9 (2.4)

\*Systolic blood pressure ranges: PCP 140 to 241 vs. PCP + PharmD 140 to 231; diastolic blood pressure ranges PCP 90 to 142 vs PCP + PharmD 90 to 149; A1c 8 to 15 both study groups.

<sup>†</sup>*P* < 0.05 comparing group differences at baseline and follow-up; however, the difference-in-difference analysis shows no significant group difference in change in blood pressure or A1c over time.

PCP, primary care physician; PharmD, doctor of pharmacy.

than 70% of the patients who achieved SBP control maintained it by the end of the study. There were no significant differences in the baseline or follow-up DBP, the proportion of people who achieved DBP control, or the median time to achieving control. More than 78% of the patients achieving DBP control maintained it.

In the GEE modeling of BP, there were statistically significant group differences in baseline SBP (Table 4). Time trends revealed a significant decrease in BP for the PCP group after adjusting for baseline BP, age, race, insurance status, PCP encounter rates, comorbidity index scores, or presence of mental health conditions. However, there were

no significant between-group differences in BP changes over time. This trend was observed regardless of baseline SBP or DBP. Age was associated with increases in SBP and decreases in DBP. Female sex was associated with decreases in DBP. Blacks had higher SBP trends compared to whites. The number of PCP encounters was associated with decreases in SBP and DBP.

*Comparison of group trends in glucose control*

In the unadjusted analyses, there were statistically significant group differences in baseline and last follow-up

TABLE 4. STRATIFIED GEE MODEL OF TRENDS IN BLOOD PRESSURE AMONG PATIENTS WITH UNCONTROLLED HYPERTENSION (ESTIMATE, SE)

	All patients	Patients stratified by SBP			All patients	Patients stratified by DBP	
	SBP ≥140 (N=1071)	SBP 140–159 (N=697)	SBP ≥160 (N=374)		DBP ≥90 (N=828)	DBP 90–99 (N=611)	DBP ≥100 (N=217)
<b>Group comparison of trends in blood pressure (BP)</b>							
Baseline BP difference: PharmD + PCP vs PCP	4.7 (1.2)*	1.5 (1.1)	1.9 (2.0)		1.3 (0.7)	-0.2 (0.6)	1.5 (1.2)
6-month trend of BP for PCP only	-4.6 (0.4)*	-2.5 (0.4)*	-9.0 (0.9)*		-2.7 (0.3)*	-2.2 (0.3)*	-4.1 (0.6)*
6-month trend of BP difference PharmD + PCP vs PCP	0.4 (0.7)	0.7 (0.8)	2.5 (1.3)		0.1 (0.5)	-0.8 (0.6)	-0.2 (0.9)
<b>Covariate associations with blood pressure trends</b>							
Age	0.2 (0.04)*	0.2 (0.04)*	0.1 (0.1)		-0.2 (0.02)*	-0.1 (0.02)*	-0.3 (0.1)*
Sex: Female vs male	-0.4 (0.9)	-0.2 (0.8)	-1.6 (1.8)		-1.3 (0.5)*	-1.1 (0.5)*	-1.3 (1.1)
Race:							
Black	3.9 (1.1)*	1.9 (1.1)	3.3 (2.1)		0.7 (0.7)	-0.5 (0.7)	2.9 (1.9)
Other minorities	-5.2 (5.0)	-6.8 (4.4)	0.9 (3.3)		-1.9 (2.6)	-4.5 (2.6)	1.2 (3.9)
White (reference group)	-	-	-		-	-	-
Insurance:							
Commercial	0.3 (1.4)	1.8 (1.4)	-1.4 (2.7)		0.1 (0.8)	1.3 (0.8)	-3.6 (2.1)
Medicare	0.5 (1.5)	-0.5 (1.5)	2.0 (2.6)		0.3 (0.9)	0.7 (0.8)	-2.2 (2.3)
Medicaid	-0.7 (1.2)	-0.4 (1.1)	-1.0 (2.2)		0.4 (0.7)	0.4 (0.7)	-1.2 (1.9)
Uninsured (reference group)	-	-	-		-	-	-
Number of PCP visits	-0.4 (0.2)*	-0.2 (0.2)	-0.4 (0.4)		-0.2 (0.1)*	-0.1 (0.1)	-0.4 (0.3)
Charlson comorbidity score	0.1 (0.2)	0.3 (0.2)	-0.2 (0.5)		-0.04 (0.1)	-0.2 (0.1)	-0.1 (0.4)
History of anxiety disorder	-1.1 (1.4)	0.8 (1.4)	-4.1 (2.9)		-0.4 (0.8)	0.1 (0.9)	-0.2 (1.9)
History of depression	-0.5 (1.1)	-0.4 (1.1)	0.4 (2.2)		0.3 (0.6)	-0.3 (0.6)	0.6 (1.3)

\**P* < 0.05.

DBP, diastolic blood pressure; GEE, generalized estimating equation; PCP, primary care physician; PharmD, doctor of pharmacy; SBP, systolic blood pressure.

TABLE 5. STRATIFIED GEE MODELING TRENDS IN A1C AMONG PATIENTS WITH UNCONTROLLED DIABETES (ESTIMATE, SE)

	<i>Patients stratified by A1c</i>		
	<i>All patients</i> A1c $\geq 8$ (N = 296)	A1c 8–8.9 (N = 117)	A1c $\geq 9$ (N = 179)
<b>Group comparison of trends in A1c</b>			
Baseline A1c difference: PharmD + PCP vs PCP	0.7 (0.2)*	0.3 (0.1)*	0.5 (0.3)
3-month time trend for PCP only	–0.2 (0.04)*	0.0 (0.04)	–0.3 (0.06)*
3-month time trend difference PharmD + PCP vs PCP	0.01 (0.06)	0.03 (0.08)	0.08 (0.08)
<b>Covariate associations with A1c trends</b>			
Age	–0.04 (0.01)*	–0.002 (0.01)	–0.02 (0.01)*
Sex: Female vs male	–0.2 (0.2)	0.05 (0.2)	–0.1 (0.3)
Race:			
Black	0.7 (0.2)*	0.1 (0.2)	0.8 (0.3)*
Other minorities	–0.5 (0.3)	–0.01 (0.2)	–1.8 (0.4)*
White (reference group)	–	–	–
Insurance:			
Commercial	–0.4 (0.3)	0.1 (0.2)	–0.5 (0.4)
Medicare	–0.04 (0.3)	–0.1 (0.2)	–0.2 (0.4)
Medicaid	–0.001 (0.2)	–0.03 (0.2)	0.03 (0.3)
Uninsured (reference group)	–	–	–
Number of PCP visits	–0.04 (0.02)	–0.04 (0.03)	–0.03 (0.04)
Charlson comorbidity score	–0.02 (0.1)	–0.04 (0.04)	–0.04 (0.1)
History of anxiety disorder	0.7 (0.4)	0.9 (0.4)*	0.8 (0.5)
History of depression	–0.3 (0.2)	–0.1 (0.2)	–0.5 (0.3)

\* $P < 0.05$ 

GEE, generalized estimating equation; PCP, primary care physician; PharmD, doctor of pharmacy.

A1c (Table 3). However, there were no group differences in the average change in A1c over time. There were group differences in the proportion of patients who achieved an A1c  $\leq 8$  (PCP + PharmD vs PCP: 29% vs 40%); however, this difference was not statistically significant. The median time to achieve control was longer in the group who had additional visits with the clinical pharmacist (20 months, IQ<sub>25</sub> 10 to IQ<sub>75</sub> – unable to estimate) compared to patients who only saw their PCP (15 months, IQ<sub>25</sub> 6 to IQ<sub>75</sub> – unable to estimate,  $P = 0.01$ ). The study team was unable to estimate the IQ<sub>75</sub> because there were not enough events (A1c reaching  $< 8$ ) measured among patients still being observed by the end of the study period. More than 75% of patients who achieved glucose control maintained control by the end of the study.

In GEE modeling of glucose control, patients who saw the clinical pharmacist had higher baseline A1c (Table 5). Time trends revealed a significant decrease in A1c for the PCP group among patients with baseline A1c  $\geq 9$  after adjusting for covariates of interest. There were no significant between-group differences in A1c changes over time. Age and race were associated with changes in A1c level for patients with baseline A1c  $\geq 9$ .

#### *Facilitators and barriers to collaborative care management*

Major facilitators and barriers to program implementation and performance monitoring were related to organizational culture, availability of internal and external resources, and health information technology data infrastructure. Clinic-level promotion of general wellness health programming, coloca-

tion of social and mental health services, use of a shared EMR, and financial incentives for medical home transformation made program implementation a natural fit. A noteworthy barrier included physician hesitation to relinquish disease management to a pharmacist, resulting in lack of uniform agreement to grant the pharmacist prescriptive authority (Collaborative Drug Therapy Management agreement). There also were delayed referrals to care management, especially among patients assigned to the primary care residents' panels, who failed to achieve treatment goals under their PCPs' care plan. Identifying physician champions, educating PCPs on strategies for successful population health management, and organizational pressure to reduce wait times for PCP appointments subsequently increased referrals to the pharmacist. However, lack of a full-time clinical pharmacist led to service capacity limitations given the volume of patients who were eligible for care management. Telephone consultations were limited by the frequent transient nature of patients' phone numbers. Limitations in EMR functions hampered workflows and real-time monitoring of protocol adherence or deviations. Patient registry design made it difficult for the pharmacist to track active caseloads. The study team could not reliably abstract data on PCP response times to flags sent by the pharmacist. The team also could not abstract data on serial changes in medication doses within the EMR because the reporting tool only exported data from patients' "active" medication lists. Therefore, tracking adherence to the medication dose adjustment protocol was difficult. The study team also did not have access to local pharmacy records or claims data to assess medication adherence or prescription refill patterns among the largely uninsured and underinsured population (eg, lacked prescription coverage).

## Discussion

In contrast to previously published studies,<sup>25–27</sup> this 22-month observational study of a pharmacist collaborative care model implemented in a safety net medical home did not demonstrate differences in trends in BP or glucose control between primary care patients whose hypertension and diabetes were comanaged compared to patients who did not receive such care. PCPs referred to the pharmacist those patients who had poorer disease control at baseline in accordance with protocol recommendations for stratifying patients at high risk for complications. These patients showed similar magnitudes of improvement in BP and glucose control over time compared to patients who only saw their PCP for disease management regardless of baseline BP and/or A1c levels. Age, race, and number of PCP encounters were associated with BP and A1c trends. Notably, patients who saw the clinical pharmacist saw their PCPs more often than patients who did not receive care under the collaborative care model. Therefore, the absence of differences in rates of disease control between study groups does not necessarily indicate that there were no clinical benefits from the pharmacy intervention.

These findings suggest that the benefits of pharmacy interventions may vary in different clinical settings among diverse populations. Given that this clinic served a mostly low-income, uninsured, or underinsured population, the overall care strategy focused heavily on delivering high-quality affordable services. The relative impact of the pharmacist collaborative care model may have been tempered by the health center's overall approach to care, in which<sup>35</sup>: (1) a PCP-led multidisciplinary care team (psychiatrists, social workers, clinical pharmacist, and community health workers) was colocated in the same facility to provide a comprehensive, holistic approach to patient care; (2) care team members shared an EMR for clinical care and had access to the same clinical decision-support tools; (3) access to low-cost medications and laboratory services was central to clinical decision making; and (4) physician leadership in QI was the cornerstone of practice decisions.

Although 70% of patients with poorly controlled hypertension achieved their treatment goal by the end of the study, less than 50% of patients with poorly controlled diabetes achieved A1c < 8. The median time to achieve disease control was longer in the pharmacy intervention group. Notably, both study groups took more than 12 months to achieve A1c targets, suggesting that diabetes management was more challenging in the population served. Given the volume of patients with suboptimal disease control, it may have been effective and efficient for the health center to focus the clinical pharmacist's care management caseload on diabetes alone. Prescriptive authority for the pharmacist would have circumvented potential delays in PCPs responding to recommended evidence-based changes in treatment plans. Incorporating validated, short, easy to score, and preferably publicly-available patient-reported outcome measures of medication adherence and activation/engagement in self-management into the EMR could help identify patients at risk for nonadherence. Although variations in the length and frequency of the pharmacy intervention and/or PCP visits also may have contributed to differences in time to achieving treatment target, follow-up visits for this low-income working population were ultimately scheduled in accordance with patients' availability—unlike clinical trials in

which patients are incentivized to follow up at predetermined intervals. Although newer approaches to care management such as text messaging and other electronic reminders may be a promising alternative to in-person visits,<sup>36–39</sup> the transient nature of phone numbers observed in the study population must be surmounted to achieve results.

This study has several limitations. The study reflects the experience of only 1 organization and has limited external generalizability. Patients were not randomized into study groups. Instead, patients were referred to the clinical pharmacist at their PCP's discretion. Selection bias remains a major factor as suggested by group differences in patient characteristics evident in Table 2. Accordingly, these characteristics were included in the adjusted analysis to account for the association of these differences with clinical outcomes. As a retrospective study, data interpretation is limited by missing or incomplete data. The study team could not definitively determine all indications for referring (or not referring) patients with elevated BP or A1c to the clinical pharmacist. For example, some patients may have declined referral or may have been receiving care from outside specialists (eg, cardiologist, endocrinologist). It is possible that the pharmacy intervention (eg, standardized medication adjustment) diffused to other patients on a provider's panel through changes in provider prescribing habits. Use of standardized protocols has a number of benefits including reduction of clinical variability; consistency in the initiation, titration, and adjustment of medications; and more cost-effective selection of medications and treatment approaches.<sup>40</sup> Adoption of such algorithms into routine clinical practice may actually help busy clinicians provide guideline concordant care. Although the health center's pharmacist was a board-certified ambulatory care pharmacy specialist, this pharmacist was not a certified diabetes educator (CDE). It is unclear to what extent not having a CDE contributed to study results. The study pharmacist followed the *Standards of Practice for Pharmacist in Diabetes Education* developed by the Pharmacy Specialty Practice Group within the American Association of Diabetes Educators.<sup>41</sup> Finally, there was no routine access to information on urgent care use, emergency department visits or inpatient hospitalizations. Therefore, the study team cannot determine whether this programming generated cost savings for the high-risk population served.

Notwithstanding these limitations, this study's purpose was to share lessons learned from the efforts to integrate pharmacist collaborative care management in a safety net medical home. Optimization of team-based care is the cornerstone of the collaborative care model. However, few studies provide guidance on which factors to consider when implementing this model in resource-limited settings serving medically complex, vulnerable populations. Careful attention to organizational culture, health information technology, and pharmacy caseloads are critical to program design. Future studies should further examine implementation strategies that work best in specific settings to optimize the benefits of team-based care with clinical pharmacists.

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