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Primary Care–based, Pharmacist–physician Collaborative Medication-therapy Management of Hypertension: A Randomized, Pragmatic Trial

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ABSTRACT

Purpose: A collaborative pharmacist–primary care provider (PharmD-PCP) team approach to medication-therapy management (MTM), with pharmacists initiating and changing medications at separate office visits, holds promise for the cost-effective management of hypertension, but has not been evaluated in many systematic trials. The primary objective of this study was to examine blood pressure (BP) control in hypertensive patients managed by a newly formed PharmD-PCP MTM team versus usual care in a university-based primary care clinic.

Methods: This randomized, pragmatic clinical trial was conducted in hypertensive patients randomly selected for PharmD-PCP MTM or usual care. In the PharmD-PCP MTM group, pharmacists managed drug-therapy initiation and monitoring, medication adjustments, biometric assessments, laboratory tests, and patient education. In the usual-care group, patients continued to see their PCPs. Participants were aged ≥18 years, were diagnosed with hypertension, had a most recent BP measurement of ≥140/≥90 mm Hg (≥130/≥80 mm Hg if codiagnosed with diabetes mellitus), were on at least 1 antihypertensive medication, and were English speaking. The primary outcome was the difference in the mean change from baseline in systolic BP at 6 months. Secondary outcomes included the percentage achieving therapeutic BP goal and the mean changes from baseline in diastolic BP and low- and high-density lipoprotein cholesterol.

Findings: A total of 166 patients were enrolled (69 men; mean age, 67.7 years; PharmD-PCP MTM group, n = 75; usual-care group, n = 91). Mean reduction in SBP was significantly greater in the PharmD-PCP MTM group at 6 months (–7.1 [19.4] vs +1.6 [21.0] mm Hg; $P = 0.008$), but the difference was no longer statistically significant at 9 months (–5.2 [16.9] vs –1.7 [17.7] mm Hg; $P = 0.22$), based on an intent-to-treat analysis. In the intervention group, greater percentages of patients who continued to see the MTM pharmacist versus those who returned to their PCP were at goal at 6 months (81% vs 44%) and at 9 months (70% vs 52%). No significant between-group differences in changes in cholesterol were detected at 6 and 9 months; however, the mean baseline values were near recommended levels. The PharmD-PCP MTM group had significantly fewer PCP visits compared with the usual-care group (1.8 [1.5] vs 4.2 [1.0]; $P < 0.001$).

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Implications: A PharmD-PCP collaborative MTM service was more effective in lowering BP than was usual care at 6 months in all patients and at 9 months in patients who continued to see the pharmacist. Incorporating pharmacists into the primary care team may be a successful strategy for managing medication therapy, improving patient outcomes and possibly extending the capacity of primary care. ClinicalTrials.gov identifier: NCT01973556. (*Clin Ther.* 2014;36:1244–1254) Published by Elsevier HS Journals, Inc.

Key words: collaborative care, hypertension, medication-therapy management, MTM, pharmaceutical care, pharmacist.

INTRODUCTION

Achieving blood pressure (BP) control is challenging for busy primary care providers (PCPs) and may become even more so because it is predicted there will be a shortage of 52,000 PCPs in the United States by 2015.[1] Pharmacists are an underutilized resource for extending the capacity of primary care with regard to medication-therapy management (MTM). In December 2011, the US Surgeon General released a letter supporting the greater involvement of pharmacists in patient care teams, stating, "policy makers should further explore ways to optimize the role of pharmacists to deliver a variety of patient-centered care and disease prevention, in collaboration with physicians or as part of the health care team."[2] In September 2013, the American College of Physicians issued a position paper that specifically included clinical pharmacists in the definition of *clinical care team*.[3] Evidence of favorable outcomes associated with the inclusion of pharmacists on the care team was reported in a systematic review of 298 studies and meta-analyses conducted using the outcomes of hemoglobin A1c and low-density lipoprotein cholesterol (LDL-C) concentrations, BP, and adverse events.[4] The review included data from studies of pharmacists who provided an array of MTM services, collaborative with physicians and stand-alone, in many settings (eg, inpatient hospitals, community pharmacies, outpatient clinics, emergency departments) and in many different types of patients (eg, those with diabetes, hypertension, asthma). A limitation of the report was that only a small percentage (7%) of the 298 studies were randomized controlled trials (RCTs).

Our literature review yielded 10 RCTs using a collaborative pharmacist–physician team approach in MTM in patients with hypertension.[5–14] The inclusion criteria varied, targeting different patient groups: patients using specific high-cost antihypertensive medications,[6] high-risk patients (ie, a large number of medications, doses per day, or medication changes, and/or poor adherence),[7] and patients with uncontrolled hypertension (with varying criteria on systolic and diastolic BP [SBP and DBP, respectively]).[5,8–14] The durations of intervention also varied, from 6 months (n = 5),[5,6,10–12] to 9 months (n = 1),[9] to 12 months (n = 4).[7,8,13,14] Despite these variances, all of the studies reported reductions in SBP and DBP that were greater with the team approach compared with usual care (range of mean differences: SBP, 5.5–12 mm Hg; DBP, 1.8–6.7 mm Hg). The between-group differences in the percentages of patients at BP goal ranged from 18% to 64%. Although pharmacists were integrated into the patient care team in each study, the role of the pharmacists differed. In 3 studies,[12–14] pharmacists independently initiated and changed medication therapy (with various levels of oversight and participation by the physician). Seven of the studies[5–11] included pharmacists only in an advisory role, that is, making recommendations on medication-therapy changes to physicians. Only 1 study involved the new implementation of a pharmacist into the patient-care team[7]; all others were conducted in environments with preexisting pharmacists' services.

A collaborative pharmacist–physician team model in which pharmacists independently initiate and change medication therapy and see patients at office visits separate from those with the PCP might result in time savings for PCPs as well as improved patient outcomes. However, little is known about this model that would be a likely scenario for many organizations wishing to newly integrate pharmacists into the care team for the treatment of hypertension.

We conducted a randomized, pragmatic trial examining the outcomes and processes of initiating and integrating a pharmacist–physician team model, with the pharmacist having ability to initiate and change medication therapy for the management of uncontrolled hypertension within a university-based internal medicine medical group. Our primary objective was to examine BP control in hypertensive patients who were collaboratively managed by a newly formed pharmacist–physician team versus those who were managed by solely their PCPs, over a 9-month period.

PATIENTS AND METHODS

We randomly assigned patients with uncontrolled high BP to either a pharmacist–physician collaborative MTM (PharmD-PCP MTM) or to usual care in a university general internal medicine clinic where each patient had a PCP. The institutional review boards of the University of California–San Diego (UCSD) and the University of California–Los Angeles (UCLA) approved the study protocol.

Patients

Patients with uncontrolled hypertension were identified through a database of electronic medical records (EMRs). Inclusion criteria were: age $\geq$18 years, diagnosis of hypertension with most recent BP measurement $\geq$140/$\geq$90 mm Hg ($\geq$130/$\geq$80 mm Hg if a patient also had diabetes mellitus), current treatment with at least 1 antihypertensive medication, *continuous active* status with the clinic (defined as having a record of at least 1 visit in the 6 months before screening [January 1, 2010, to June 30, 2010]), English speaking, and able to complete a questionnaire in English.

Patients were excluded if they did not meet provisions of the clinical collaborative-practice protocol in the opinion of the patient's PCP or the clinical pharmacist.

Eligible patients were randomly assigned, via a computer-generated random sequence, to either the PharmD-PCP MTM group or the usual-care group. The study coordinator contacted the patients in the PharmD-PCP MTM group to determine their interest in participation and to schedule the first clinical pharmacist visit, during which written informed consent was obtained. Usual-care patients were not contacted but continued to see their PCPs. A random subset of usual-care patients was selected for retrospective chart review covering the same time interval as the active intervention. An additional inclusion criterion of having had a clinic visit in the 6-month period before screening was applied to ensure that data from only patients who continued to receive PCP care for at least 9 months after the index visit were included.

Intervention

Two clinical pharmacists (M.L. and R.S.) and an internal medicine physician who served as the medical director of the clinic (Y.W.) collaborated closely to develop a clinical collaborative-practice protocol using national hypertension-treatment guidelines and updated hypertension-management literature for the PharmD-PCP MTM group. The collaborative-practice protocol was approved by the UCSD Medical Center and by the institutional review boards as a part of the study-approval process.

The protocol specified the types of patients to whom clinical pharmacists would provide services (ie, patients with BP above target goals) and the MTM activities, which included initiating, adjusting, or discontinuing treatment with antihypertensive medications and approving appropriate antihypertensive-drug refill requests. Therapeutic decisions and timing of patients' laboratory testing and follow-up visits (except for the visit at month-9 study close) were left to the pharmacists' clinical opinion, in consultation with a physician if needed.

The 2 clinical pharmacists providing MTM services had a Doctor of Pharmacy degree, $\geq$1 year of pharmacy practice residency training, and $>$7 years of experience in ambulatory care. Before study initiation, they reviewed the BP-assessment method used at the clinic with the medical director to ensure consistency of the measurements between the PharmD-PCP MTM and usual-care groups.

BP was assessed using a manual wall-mounted sphygmomanometer, with the patient seated in a chair for at least 5 minutes before measurement, and with the measured arm elevated to heart level. In the PharmD-PCP MTM group, the pharmacist measured the BP at the beginning of each study visit, as was standard practice for all internal medicine clinic patients, whereas the nursing staff measured BP in the usual-care patients.

Patients were scheduled for four 30-minute pharmacist visits (baseline, 3, 6, and 9 months), independent of PCP visits, and as needed for follow-up with the pharmacist (additional clinic visit or via phone). The intervention was to be a limited time period (9 months) of intensive MTM, after which a patient would return to the PCP for the treatment of hypertension. At the initial pharmacist visit, the pharmacist assessed the patient's knowledge of hypertension and his or her current treatment and reviewed current treatment goals, self-monitoring behavior, medical and medication history, and current medications. The pharmacist also helped the patient to set individual BP goals, reviewed and/or ordered laboratory tests, made adjustments to the antihypertensive-medication regimen (ie, dosage adjustments and initiation or discontinuation of medication).

Each visit was documented in the EMR system and routed to the patient's PCP. During subsequent visits, the pharmacist reviewed progress toward goals, laboratory values, medication adherence, and self-monitoring behavior and continued to make changes to the antihypertensive-medication regimen as needed. A physician was always present in the medical practice during the pharmacist clinic visits and was available for consultation as needed. Patients received US $22 for each pharmacist visit ($25 for the month-9 visit).

Outcome Measures

The primary outcome measure was the change in systolic BP (SBP) at 6 months after the initial visit. Secondary outcomes included the percentage of patients at BP goal (≤140/≤90 mm Hg [≤130/≤80 mm Hg if a patient also had diabetes mellitus]), change in diastolic BP (DBP), and low- and high-density lipoprotein cholesterol (LDL-C and HDL-C) concentrations. In addition, in the PharmD-PCP MTM group, outcomes included the number and types of medication changes, the number and types of anti-hypertensive drug-therapy problems (eg, drug dose too low) identified, and patients' satisfaction with the clinical pharmacist, as assessed using the 22-item Pharmacist Service Questionnaire.[15] Questions were related to the patient's perception of the quality of the pharmacist-provided care and the pharmacist–patient relationship, and overall satisfaction. Higher scores (0–100 scale) indicated greater satisfaction. All data, except for patient-reported satisfaction, were collected from the EMR. Existing data in the usual-care group were collected via retrospective chart review after the completion of the PharmD-PCP MTM intervention period. Because the usual-care group did not have scheduled visits, data collected on the dates closest to those at 6 and 9 months after the index date were used, with a ±6-week window, for the best estimate of BP. Chart reviews were conducted by 2 clinical coordinators (one of whom was the study coordinator for this study) from the Clinical and Translational Research Institute, UCSD.

Statistical Analysis

A target sample size of 85 patients per group was estimated as sufficient to detect a mean (SD) between-group difference in change in SBP of 5 (10) mm Hg with 90% power, assuming a 2-sided test for significance and an α level of 0.05. The between-group difference in mean SBP change at 6 months was evaluated using a *t* test. Descriptive statistics were calculated on all variables. Percentages were used to describe categorical variables, and significance of between-group differences was identified with χ^2 tests. A sensitivity analysis was conducted, because of imbalance in age, sex, Charlson comorbidity index, and total number of medications, to determine whether the findings were sensitive to these differences. SAS version 9.2 (SAS Institute Inc, Cary, North Carolina) was used to conduct all analyses.

RESULTS

Figure 1 presents the flow of patients from randomization to study completion in each group. The first patient was enrolled in July 2010, and the last patient completed the intervention in June 2012. A total of 64 (85.3%) of the enrolled and active study patients (n = 75) had continued in the pharmacist program at 6 months and 52 (69.3%), at 9 months. EMR data were included in the study analyses using the intent-to-treat approach in 19 patients who had returned to their PCPs. A total of 91 patients in the usual-care comparison group were included in the baseline, month-6, and month-9 observations.

At the initial visit, all 8 measured clinical variables were statistically similar between the PharmD-PCP MTM group (n = 75) and the usual-care group (n = 91); however, the PharmD-PCP MTM group was slightly younger (mean age, 65.4 [13.0] vs 69.6 [11.4] years; $P = 0.03$), had a lower Charlson comorbidity index (5.3 [2.6] vs 6.6 [3.2]; $P = 0.004$), and was more likely to have been male (53.3% vs 31.9%; $P = 0.005$) (Table I). The difference in the mean number of antihypertensive medications between the PharmD-PCP MTM and usual-care groups was not significant (1.7 [0.8] vs 1.8 [1.0]; $P = 0.44$). However, the PharmD-PCP MTM group had a lower total number of medications than did the usual-care group (8.8 [4.2] vs 11.3 [5.2]; $P = 0.001$).

At 6 months, the mean (SD) change in SBP was significantly greater in the PharmD-PCP MTM group than in the usual-care group (–7.1 [19.4] vs +1.6 [21.0] mm Hg; $P = 0.008$), but the difference was not statistically significant at 9 months (–5.2 [16.9] vs –1.7 [17.7] mm Hg; $P = 0.22$) on intent-to-treat analysis (Table II). No significant between-group differences in changes in LDL-C or HDL-C were detected at 6 and 9 months; however, at baseline in

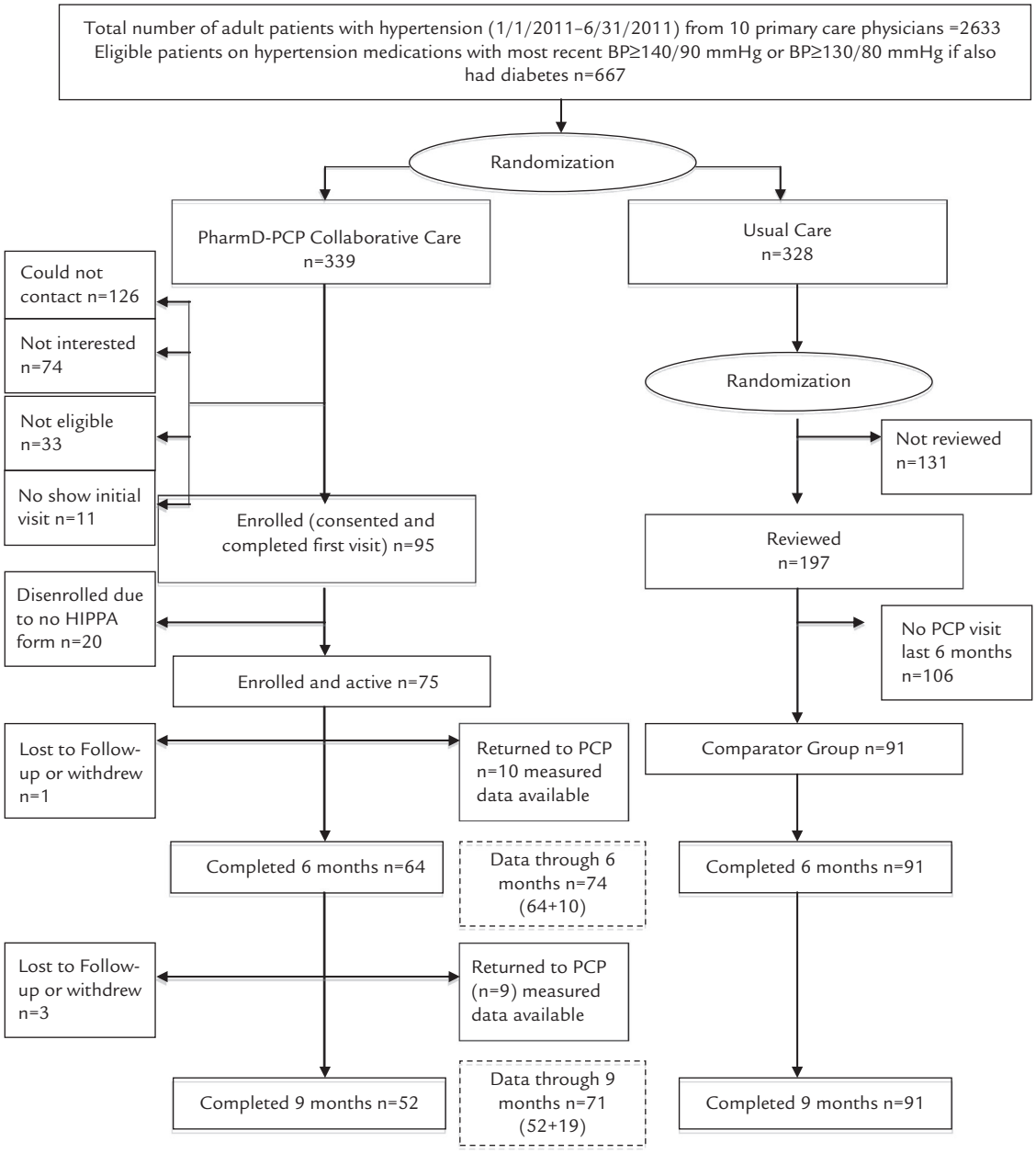

Figure 1. Selection, randomization, and flow of the study patients. *Defined as those with uncontrolled hypertension (most recent blood pressure measurement $\geq$140/$\geq$90 mm Hg [$\geq$130/$\geq$80 mm Hg with comorbid diabetes] despite antihypertensive treatment) selected from a pool of 2633 adult active patients (active = having a record of an office visit dated between January 1, 2010, and June 30, 2010, in the electronic medical records from 10 primary care physicians). PharmD-PCP MTM = pharmacist–physician team approach to medication-therapy management; HIPPA = Health Insurance Portability and Accountability Act; PCP = primary care provider.

Table I. Baseline demographic and clinical characteristics of the study patients. Data are given as mean (SD) unless otherwise noted.

Characteristic	PharmD-PCP MTM (n = 75)	Usual Care (n = 91)	*P*
Age, y	65.4 (13.0)	69.6 (11.4)	0.03
Male, no. (%)	40 (53.3)	29 (31.9)	0.005
SBP, mm Hg	134.8 (17.4)	134.4 (16.5) (n = 89)	0.89
DBP, mm Hg	75.1 (12.5)	75.7 (13.4) (n = 89)	0.75
At recommended BP goal, no. (%)*	40 (53.3)	41 (46.1) (n = 89)	0.35
HDL-C, mg/dL	59.7 (23.6)	58.1 (22.3) (n = 90)	0.65
LDL-C, mg/dL	99.5 (31.9) (n = 74)	98.6 (31.0) (n = 90)	0.85
HbA_{1c}, %	6.6 (1.2) (n = 50)	6.5 (1.5) (n = 68)	0.85
BMI, kg/m^2	30.2 (6.3) (n = 70)	29.8 (5.7) (n = 82)	0.71
BUN, mg/dL	19.7 (12.5)	18.5 (7.2) (n = 90)	0.45
Creatinine, mg/dL	0.9 (0.2)	0.9 (0.2) (n = 90)	0.18
Charlson comorbidity index (age adjusted)	5.3 (2.6)	6.6 (3.2)	0.004
No. of total medications	8.8 (4.2)	11.3 (5.2)	0.001
No. of hypertensive medications	1.7 (0.8)	1.8 (1.0)	0.44

BMI = body mass index; BUN = blood urea nitrogen; DBP = diastolic blood pressure; Hb = hemoglobin; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; PharmD-PCP MTM = pharmacist–physician team approach to medication-therapy management; SBP = systolic blood pressure.
*Defined as 140/90 mm Hg (130/80 mm Hg if patient also had diabetes).

both groups, the mean values were near recommended goal levels (Table I). The patterns of statistical significance in Table II did not change after adjustments for age, sex, Charlson comorbidity index, total number of medications, and number of PCP visits. The percentages of patients at SBP and DBP goals at 6 and 9 months were greater in the PharmD-PCP MTM group than in the usual-care group (6 months, 81% vs 44% [$P < 0.001$]; 9 months, 70% vs 52% [$P = 0.02$]) (Figure 2).

The PharmD-PCP MTM group had significantly fewer PCP visits during the intervention period

Table II. Mean (SD) changes from baseline in clinical characteristics (ITT population).

	6 Mo			9 Mo		
Characteristic	PharmD-PCP MTM	Usual Care (n = 89)	*P*	PharmD-PCP MTM (n = 71)	Usual Care (n = 89)	*P*
SBP, mm Hg	−7.1 (19.4) (n = 73)	+1.6 (21.0)	0.008	−5.2 (16.9)	−1.7 (17.7)	0.22
DBP, mm Hg	−3.8 (10.5) (n = 73)	+1.7 (13.9)	0.006	−2.5 (10.2)	−0.3 (13.8)	0.27
LDL-C, mg/dL	+0.1 (19.9) (n = 74)	+4.6 (24.1)	0.21	−3.5 (26.3)	−3.1 (41.9)	0.95
HDL-C, mg/dL	+2.4 (28.3) (n = 74)	+0.3 (11.5)	0.54	−1.0 (20.4)	+0.4 (20.9)	0.67

DBP = diastolic blood pressure; HDL-C = high-density lipoprotein cholesterol; ITT = intent to treat; LDL-C = low-density lipoprotein cholesterol; PharmD-PCP MTM = pharmacist–physician team approach to medication-therapy management; SBP = systolic blood pressure.

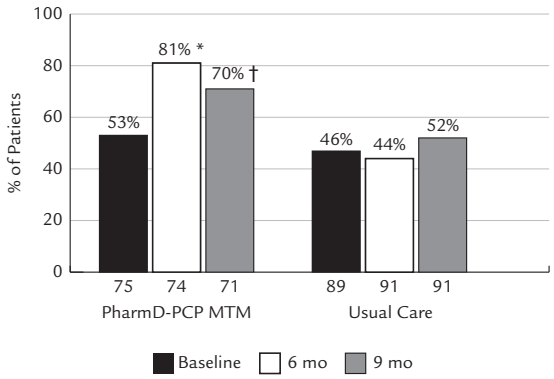

Figure 2. Percentages of patients achieving blood pressure goal (<140/<90 mm Hg [<130/<80 with comorbid diabetes]). *$P < 0.001$ versus usual care; †$P = 0.02$ versus usual care.

than did the usual-care group (1.8 [1.5] vs 4.2 [1.0]; $P < 0.001$). The mean number of total visits during the intervention period (PCP and pharmacist visits combined) was not significantly greater in the PharmD-PCP MTM group than in the usual-care group (4.4 [1.9] vs 4.2 [1.0]; $P = 0.38$) (data not shown).

In the PharmD-PCP MTM group, the mean change in SBP from baseline to 9 months in the subgroup that had returned to the PCP (n = 19) was +1.9 (13.8) mm Hg compared with –7.8 (17.3) mm Hg in those who continued to see the MTM pharmacist (n = 52) through the month-9 visit ($P = 0.03$). Similarly, the mean changes in DBP were +2.8 (9.9) mm Hg in the subgroup that had returned to the PCP and –4.5 (9.7) in the group that continued to see the MTM pharmacist through 9 months ($P = 0.007$). The percentages of patients who were at blood pressure goal (SBP and DBP) in the subgroup that returned to the PCP after 6 months were 63.6% at 6 months and 47.4% at 9 months, compared with 88.5% and 78.9%, respectively, in the group that continued to see the MTM pharmacist (data not shown).

The differences in baseline characteristics between the subgroup that returned to the PCP after 6 months versus those who continued to see the MTM pharmacist through 9 months were nonsignificant. The mean scores for patient satisfaction with the pharmacist were 92.4 (10.9) at 6 months (n = 49) and 92.7 (11.0) at 9 months (n = 44). In the subgroup that was at BP target or better at the initial visit (index visit in the usual-care group), greater percentages remained in control in the PharmD-PCP MTM group versus the usual-care group at both 6 and 9 months (85% vs 53.7% [$P = 0.002$] and 81.6% vs 63.4% [$P = 0.07$], respectively) (data not shown).

In the PharmD-PCP MTM group, at the initial visit, the clinical pharmacist identified at least 1 hypertension-related drug-therapy problem in almost half (45.2%) of the patients (Table III). The 2 most prevalent problems were the need for additional therapy (42.4%) and the need for a dosage increase (33.3%). Approximately one third (34.2%) of patients had a medication change at the initial visit; the most common changes (increased dosage and added medication) aligned with the types of medication problems most frequently detected. The percentage of patients with drug-therapy problems and subsequent medication changes was much lower at 6 months (20.0% and 11.7%, respectively). At 9 months, only 2 patients (3.9%) required a medication adjustment (increased dosage).

DISCUSSION

Compared with usual care, the PharmD-PCP team approach was associated with significantly greater mean reductions in SBP and DBP and with a higher percentage of patients at BP goal at 6 months. The group of patients who continued to see the MTM pharmacist at 9 months continued to have significantly better BP control compared with the usual-care group. At least 1 drug-therapy problem was identified in almost half of the patients, the 2 most common being the needs for additional therapy and a dosage increase. Approximately one third of patients had a medication change at the initial MTM pharmacist visit. Patients' satisfaction with the pharmacists was high. Also, patients who continued to see the MTM pharmacist had better outcomes than did those who did not. The mean change in SBP was almost 10 mm Hg greater, and ~30% more of these patients were at BP goal at 9 months. In the subgroup of patients who were at BP goal at the initial visit (index visit in the usual-care group), the percentage remaining at goal at 9 months was almost 20% higher in those in the PharmD-PCP MTM group versus usual care.

These results are consistent with those identified in a recent literature review that found that 84% of published studies regarding pharmacists involved with

Table III. Pharmacists' actions for antihypertensive medication-therapy management.* Data are given as numbers (%) of patients.

Action	Baseline (n = 73)	6 Mo (n = 60)	9 Mo (n = 51)
Drug-therapy problem identified	33 (45.2)	12 (20.0)	4 (7.8)
Need for additional therapy	14/33 (42.4)	7/12 (58.3)	1/4 (25.0)
Need for dose increase	11/33 (33.3)	3/12 (25.0)	1/4 (25.0)
Nonadherence	5/33 (15.2)	1/12 (8.3)	1/4 (25.0)
Adverse drug reaction	2/33 (6.1)	2/12 (16.7)	0
Medication change at visit	25 (34.2)	7 (11.7)	2 (3.9)
Increased dosage	15/25 (60.0)	3/7 (42.9)	2/2 (100)
Added medication	8/25 (32.0)	2/7 (28.6)	0
Changed medication	3/25 (12.0)	1/7 (14.3)	0
Decreased dose	2/25 (8.0)	1/7 (14.3)	0

*Some patients may have had multiple drug-therapy problems or medication changes.

hypertension management showed favorable results.[4] However, that finding was from across studies with various study designs, few of which were RCTs, most of which provided MTM recommendations only, and very few of which used an integrated team model. Our finding of a greater percentage of patients with controlled hypertension in the PharmD-PCP MTM group was consistent with those from RCTs of this team model in hypertensive patients.[5–14] For example, in a study in 179 patients with uncontrolled hypertension (101 MTM vs 78 control), with pharmacists making recommendations to the physician (96% accepted), 89.1% of the MTM group was at goal at 9 months versus 52.9% in the control group.[9] Similarly, in a trial more closely aligned with the present study, in which the pharmacist was able to initiate and change treatment with medications under a collaborative protocol, 62% of the MTM group versus 44% of the control group were treated to goal at 12 months.[13]

In the present study, the clinical collaborative-practice protocol allowed the pharmacist to initiate, adjust, or discontinue treatment with antihypertensive medications independently, and the pharmacist saw patients independently of the PCP visit, as opposed to the design used in many studies in which the pharmacist makes only recommendations for therapy changes and/or sees a patient as a part of a PCP visit. The PharmD-PCP MTM group had fewer PCP visits than did the usual-care group, and there was no difference in total visits between groups. This finding suggests that the intervention was cost-effective via 2 mechanisms: (1) the effect of substituting the PCP with a less costly resource—the pharmacist; and (2) the achievement of better BP control. The value of a pharmacist's saving the PCP time by providing MTM services in this type of collaborative-care model to an increasing number of insured patients warrants further investigation in larger patient populations with a wide range of disease states. However, an essential component of this type of collaborative-care model is for the pharmacist and PCP to have access to a patient's complete EMR, regardless of the location or timing of the visit. Given a shared EMR, implementing the same type of collaborative protocol agreement in nonclinical settings (eg, community pharmacies) could be pursued, with appropriate communication channels, PCP availability, and adherence to patients' privacy requirements.

Almost half of the PharmD-PCP MTM collaborative-care patients had a drug-therapy problem identified at the initial pharmacist visit, with one third requiring a medication change. This finding highlights the value of an MTM collaborative-practice model that allows pharmacists to make medication changes, per protocol, as opposed to making only recommendations to the patient and/or physician. If the pharmacists in the present study were limited to making only recommendations for

changes in medication therapy, it would have required contacting the PCP, the PCP's assessing each recommendation, and the PCP's taking action to change the medication. Reduced time and expense on the part of the physician may be achieved in well-thought-out and -planned collaborative-practice protocols with pharmacists providing MTM services.

We attempted to make the present study an in-practice, pragmatic trial of integrating a new provider, the clinical pharmacist, into a clinic to build a PharmD-PCP MTM team. Two key points regarding enrolling and retaining patients may inform future implementation efforts. First, to minimize the involvement and time commitment of the clinic's staff for this new service, we chose to use retrospective data collected from the institution's registry of EMRs to identify patients for the intervention and control groups and to enroll patients in the intervention group. However, we learned that a more current BP measure may be needed because almost 50% of our patients (in both groups) were at goal at the initial pharmacist visit (index visit in the usual-care group). Although none of the other randomized MTM trials in hypertensive patients have done so, we elected to include these patients in the study because BP measures fluctuate in clinical practice. This decision proved to be important because BP measures in many of these patients were above targeted goals at 6 and 9 months (PharmD-PCP MTM group, 15% and 18%, respectively; usual-care group, 46% and 37%). Thus, in future studies, the selection of patients for antihypertensive intervention may be better based on multiple BP measures over time or on BP measures in combination with other indicators, such as the complexity and cost of the medication regimen and evidence of poor adherence. Second, retaining patients was somewhat problematic; for example, 19% of patients (12 of 64 patients with data available from the month-6 visit) did not return to the pharmacist after the month-6 pharmacist visit. Achieving BP goal did not account for all of these patients because more than one third of these patients were not at goal at the month-6 pharmacist visit. Although there are likely many reasons for dropout, having providers and staff more involved in reinforcing the pharmacist's role and benefits, and/or improving the convenience of pharmacist visits, may improve patients' engagement and retention.

Study Limitations

Study patients were from a single, university-based general internal medicine practice; therefore, the results are not generalizable to patients from different practice settings or to all patients with hypertension. Because this study was a randomized pragmatic trial, our results may not be representative of those achieved in usual practice. However, we allowed much of the trial conduct to be as naturalistic as possible. In addition, eligible patients were able to speak, read, and write in English, so our study population may have been more English literate than some other populations. Patients received a small payment for each clinic visit, which may have influenced their behavior (eg, medication adherence). Randomization at the patient level may have allowed for contamination of the usual-care group because physicians had patients in both the PharmD-PCP MTM intervention group and the usual-care group. However, physicians did not know which patients would be randomly selected for the usual-care group because the sample was drawn after the intervention was complete.

In the present trial, patients were randomly selected to be offered participation in the PharmD-PCP MTM group, but because a portion declined participation after randomization, it is likely that selection accounts for the few observed differences in patients' characteristics between those who ultimately chose to participate and the usual-care group for which there was no offer of participation. Because patients in the PharmD-PCP MTM group knew that they were participating in a trial, whereas those in the usual-care group did not, our results may have been affected by a Hawthorne effect, or participation bias. In the PharmD-PCP MTM group, BP was measured by the 2 clinical pharmacists, whereas in the usual-care group, BP was measured by licensed vocational nurses, which could have affected group comparisons. Although the pharmacists' training before the study start may have helped to ensure that they were using the same method as in other clinic patients, it is possible that there was bias in the pharmacists' assessments because they were aware of the study. This study examined data from pharmacists managing patients' antihypertensive medications. The outcomes achieved, as well as the numbers of drug-therapy problems identified and medication changes made, would likely have differed if the pharmacists had also managed medications for patients' comorbid conditions.

CONCLUSIONS

In this study in hypertensive patients, a pharmacist–physician collaborative MTM service was more effective in lowering BP at 6 and 9 months than was usual care in patients who continued to see the pharmacist. Given the shortages of PCPs and the aging population, recognizing a pharmacist's potential contribution to improving MTM in collaboration with physicians and incorporating pharmacists in the primary care team to provide MTM services may be a successful strategy for managing medication therapy, improving patient outcomes, and possibly extending the capacity of primary care.

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CONFLICTS OF INTEREST

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