

Improving Blood Pressure Control Through a Clinical Pharmacist Outreach Program in Patients With Diabetes Mellitus in 2 High-Performing Health Systems

The Adherence and Intensification of Medications Cluster Randomized, Controlled Pragmatic Trial

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Background—Even in high-performing health systems, some patients with diabetes mellitus have poor blood pressure (BP) control because of poor medication adherence and lack of medication intensification. We examined whether the Adherence and Intensification of Medications intervention, a pharmacist-led intervention combining elements found in efficacy studies to lower BP, improved BP among patients with diabetes mellitus with persistent hypertension and poor refill adherence or insufficient medication intensification in 2 high-performing health systems.

Methods and Results—We conducted a prospective, multisite cluster randomized pragmatic trial with randomization of 16 primary care teams at 5 medical centers (3 Veterans Affairs and 2 Kaiser Permanente) to the Adherence and Intensification of Medications intervention or usual care. The primary outcome was relative change in systolic BP (SBP), comparing 1797 intervention with 2303 control team patients, from 6 months preceding to 6 months after the 14-month intervention period. We examined shorter-term changes in SBP as a secondary outcome. The mean SBP decrease from 6 months before to 6 months after the intervention period was ≈ 9 mm Hg in both arms. Mean SBPs of eligible intervention patients were 2.4 mm Hg lower (95% CI: -3.4 to -1.5 ; $P < 0.001$) immediately after the intervention than those achieved by control patients.

Conclusions—The Adherence and Intensification of Medications program more rapidly lowered SBPs among intervention patients, but usual-care patients achieved equally low SBP levels by 6 months after the intervention period. These findings show the importance of evaluating in different real-life clinical settings programs found in efficacy trials to be effective before urging their widespread adoption in all settings.

Clinical Trial Registration—URL: <http://clinicaltrials.gov>. Unique identifier: NCT00495794.

(Circulation. 2012;125:2863-2872.)

Key Words: adherence ■ blood pressure ■ cluster randomized trial ■ diabetes mellitus type 2 ■ clinical inertia

Good blood pressure (BP) control is an important clinical outcome in diabetes mellitus. In the UK Prospective Diabetes Study, achieving mean systolic blood pressure (SBP) levels of 144 mm Hg led to an absolute risk reduction of 11% in diabetes mellitus complications over 10 years, an effect 3.5 times greater than intensive blood glucose control.¹ Although glycemic or cholesterol control has an incremental cost-effectiveness of \$40 to \$50 000 per quality-adjusted

life-year, BP control saves almost \$2000 per quality-adjusted life-year.¹⁻⁴

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In part in response to these findings, BP control has improved in the United States among all patients⁵ and patients with diabetes mellitus.⁶ In high-performing health-

Received December 22, 2011; accepted April 10, 2012.

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The online-only Data Supplement is available with this article at <http://circ.ahajournals.org/lookup/suppl/doi:10.1161/CIRCULATIONAHA.111.089169/-/DC1>.

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Circulation is available at <http://circ.ahajournals.org>

DOI: 10.1161/CIRCULATIONAHA.111.089169

care systems like the Veterans Affairs (VA) and Kaiser Permanente Northern California (KP) that have devoted significant resources and effort to improved risk factor control, BP control (percentage <140/90) is now at least 80%^{7,8} compared with just 50% several years earlier.⁹ This achievement has been accomplished through population care management strategies, team-based programs, incentives, and performance monitoring.^{10–13} Achieving even higher thresholds of BP control will likely be more difficult and costly and will require novel and complex interventions.

Patients with poorly controlled hypertension often have poor medication adherence or other issues contributing to lack of provider intensification of their medications.^{14–20} The most effective programs evaluated by efficacy trials in selected populations of volunteer subjects have included those led by nurse care managers or clinical pharmacists authorized to adjust medications.^{11,21–31} However, the effectiveness of these interventions in routine practice, and specifically their ability to raise rates of BP control in “high-performing systems” (defined as those systems in which BP control is already $\geq 80\%$), has not been well evaluated.

Accordingly, we designed a targeted pharmacist-led care management program by using the best evidence from efficacy trials to improve BP control among patients with diabetes mellitus who have persistent hypertension. With the use of electronic pharmacy prescribing and clinical data systems, clinical pharmacists proactively reached out to patients with uncontrolled hypertension and either poor adherence or no treatment changes in response to high BPs.^{16,20,32,33} Supported by a computer application that provided up-to-date medication-specific refill information on each participant’s antihypertensive and other diabetes mellitus medications, the pharmacists delivered tailored adherence counseling by use of motivational interviewing (MI)^{34–38} and medication management tailored for complex patients,^{11,39} providing close follow-up once a behavioral or pharmacological change was initiated.^{29,40} To evaluate the benefit of implementation of this program in real-life clinic settings, we conducted a stratified multisite cluster randomized pragmatic trial^{41,42} within clinic sites in 2 high-performing integrated health systems, Kaiser Permanente Northern California and the Department of Veterans Affairs, with 2-stage cluster sampling and additional stratification of the second stage of sampling within site by BP levels.

Methods

Setting and Identification of Eligible Patients

The study protocol and methods are described in depth elsewhere.⁴³ The study took place in the outpatient primary care clinics at 3 urban VA facilities in the Midwest and 2 KP facilities in California. All sites’ institutional review boards approved the study. Patients with diabetes mellitus were identified from electronic medical record data by using a well-validated algorithm.^{43–45} Eligible patients with diabetes mellitus had persistent poor BP control and poor refill adherence or insufficient medication intensification as defined in online-only Data Supplement Appendix A and in the published protocol.^{32,43,46–48}

The 14-month intervention period during which eligible subjects were identified and offered pharmacist encounters at 3-month intervals (time 0, 3, 6, 9, and 12 months) extended from August 2008

through September 2009. A subject could be eligible at just one or at all time periods (analyses corrected for clustering by patient).

Randomization of Primary Care Teams and Stratification and Randomization of Intervention Team Patients

We used 2-stage cluster sampling, whereby we first selected team clusters at each site and randomly assigned primary care teams within the 5 sites to treatment versus control. Sixteen primary care teams were randomly assigned for a total of 8 intervention and 8 control teams (2 intervention and 2 usual-care teams at 3 sites and 1 intervention team and 1 usual-care team at 2 sites).

Each team consisted of 5 to 28 primary care providers, their staff, and patients. Cluster randomization afforded a better opportunity than individual randomization to evaluate the real-world effectiveness of pharmacist-team interactions as they would occur with full implementation. Team-level randomization also minimized cross-over contamination due to pharmacist contact within teams. Randomization within site was done to allow us to stratify analyses by site, thus reducing the major source of cluster variation attributable to site of care.

In the second stage, we randomly sampled subjects within each team for activation by assigning a priority order. First, patients were randomly selected from those patients with the highest SBPs (≥ 160 mm Hg) during the sample selection period, then from SBP 150 to 159 strata, and then from 140 to 149 strata. The highest SBP strata received first priority for patient outreach. The randomly ordered list of names was loaded into the computerized tool the pharmacists used (the Medications Management Tool). Pharmacists were instructed to contact patients in the order they appeared on their list. Any patient who the pharmacist attempted to contact, regardless of whether they were contacted or enrolled, was considered activated and included in the intervention group in intention-to-treat analyses. Thus, the activated subjects represented a stratified random sample of the eligible population on the intervention teams with the size of the sample determined by the capacity of the pharmacist resources at that site. All eligible patients in the control group were included in the analysis sample.

We used stratified 2-stage sampling because we were not sure how many patients would be eligible on each team each quarter of the 14-month period the Adherence and Intensification of Medications (AIM) pharmacists were in place, and the team sizes varied substantially across sites. If the pharmacists were able to activate all of the patients on some teams and not on others at different sites, our results would be affected not only by the intervention itself, but also by the balance between capacity and number of eligible patients at any given site. By randomly prioritizing patients from the eligible pool for activation on the intervention team, we ensured that we maintained comparability between the intervention sample and the control subjects under conditions of adequate capacity to deliver the intervention, and this comparability enabled us to perform intention-to-treat analyses.

Usual Care

Patients assigned to the usual-care teams received standard health-care services through their primary care provider, which in all sites included access to care manager and other non-AIM program clinical pharmacist services targeting patients with diabetes mellitus with poor risk factor control. The study team had no contact with the usual care teams, nor did the AIM clinical pharmacists who worked exclusively with intervention team patients. At VA sites, providers on both intervention and usual-care teams received quarterly reports of their patients with diabetes mellitus who had poor BP control and adherence or intensification issues. At KP sites, these reports were not required. Instead, patients were eligible for contact by clinical pharmacists as part of KP’s PHASE (Preventing Heart Attacks and Strokes Everyday) program for patients at high risk for cardiovascular disease events (www.permanente.net/healthyheart/). PHASE pharmacists and VA care managers received no training in MI, did not have access to the Medications Management Tool or other IT

tools providing adherence or intensification data, and provided briefer contacts with patients with less sustained follow-up (usually just 1 or 2 contacts lasting 5–10 minutes on average).

Description of the AIM Intervention

Each site had 2 full-time clinical pharmacist equivalents, 3 pharmacists at KP (2 were half-time) and 2 in VA who worked exclusively with patients on intervention teams. All pharmacists participated in an initial 3-day MI training on patient-centered approaches to achieving health goals.^{49,50} Pharmacists were provided with an outline (or road map) as a guide for structuring the flow of an intake encounter and as a tool to reinforce MI approaches. Booster training was provided during biweekly webinars. At 6 months, an expert assessment of pharmacists' MI techniques concluded that all pharmacists met or exceeded MI proficiency standards.⁵¹

Interactions Between AIM Pharmacists and Intervention Team Primary Care Providers

Before the beginning of the intervention period, primary care providers (PCPs) on the intervention teams agreed that AIM pharmacists assigned to their teams could proactively reach out to eligible patients. Although the AIM pharmacists were authorized to make medication changes, the clinical pharmacists copied the participating patient's assigned PCP on all of that patient's clinical notes and alerted the PCP when one of that PCP's patients declined participation in the program, entered the program, or was discharged. Once a patient was on 3 antihypertensive medications, the clinical pharmacists were instructed to consult with the assigned PCP about, or refer the patient back to the PCP, for any additional antihypertensive medications.

Initial Contact by the Pharmacist

Before calling eligible intervention subjects, the pharmacist reviewed each patient's electronic medical record and information on medication-specific refill gaps and previous provider intensification supplied in the Medications Management Tool, key components of which are described in detail in online-only Data Supplement Appendix B and elsewhere.⁴³ If a patient agreed to participate, a phone or in-person intake encounter was scheduled, and a welcome packet was mailed with educational materials, including instructions for home monitoring and documents to record BPs and action plans. A patient was considered unreachable after 5 unsuccessful attempts. Once the pharmacists tried to call a patient on the list (activated them), whether or not the patient was reached or agreed to participate, that patient was considered a study participant and included in all analyses.⁵² Because the AIM program was considered a standard clinical program at all sites, participants received no participation incentives and did not provide informed consent for participation.⁴³

Encounters With the Pharmacist

Encounters took place at the clinics and by phone. Office encounters ranged from 15% of encounters at 1 site to >60% at another site. Participants were encouraged to self-monitor and aided in obtaining home BP monitors. At the intake encounter, the pharmacist, supported by the road map and the Medications Management Tool, assessed adherence to each prescribed BP, lipid, and antihyperglycemic medication, explored barriers to adherence, and discussed recent BP, hemoglobin A1c, and low-density lipoprotein levels. At in-person encounters, BP was measured by the pharmacist (or medical assistant at KP) as per Joint National Committee 7 protocols.⁵³ Laboratory tests were ordered according to provided treatment algorithms.⁴³ The pharmacist then explored with the patient their goals and values and how taking medications affected these. If the patient faced barriers to adherence, the pharmacist worked with the patient to set a short-term action step.^{54,55} If the patient reported no adherence problems, the pharmacist recommended and was authorized to make BP medication changes by using the site-approved treatment algorithms. At the end of the encounter, the pharmacist summarized agreed-on next steps and scheduled a

follow-up encounter. All encounters were documented in the electronic medical record, and patients' PCPs were copied. Follow-up encounters focused on assessing medication adherence, progress on previous action plans, additional action planning, and, when appropriate, intensification of medications.

A patient was eligible for discharge when all medication adherence issues had been addressed; home or clinic BPs were at target (average <135/80 for VA and <130/80 for KP patients per each institution's guidelines) or diastolic BP <60⁵⁶; or the patient was on maximum tolerated medications. In addition, patients were discharged if lost to follow-up (eg, no show for 3 scheduled encounters), enrolled for 6 months without achieving BP target with no progress, or declined further participation.

Patients who had been previously discharged but met eligibility criteria in subsequent quarters could reenter the program after a 3-month window. Thirty-five participants reentered over the 14-month intervention period.

Outcomes and Analysis

The primary outcome was the relative change in SBP measurements between the 6 months preceding and the 6 months following the 14-month intervention period among all eligible control and intervention subjects regardless of participation in the intervention (ie, an intention-to-treat analysis) (online-only Data Supplement Appendix C). SBP measures came from the sites' usual clinical care electronic databases, excluding BPs measured by the AIM pharmacists. BP values obtained in the emergency department, urgent care, inpatient, and surgery departments were also excluded.

In addition to 6-month follow-up, prespecified secondary analyses examined shorter-term changes in SBP. The sample selection period comprised the 9-month window used to determine a patient's eligibility. The 1-month preparation period extended from the day the patient was determined to be eligible to the quarter start date (ie, the first date of possible activation). The activation period extended for 3 months after the quarter start date. During this period, pharmacists were activating eligible patients sequentially from the provided stratified random-sample list. The short-term follow-up periods, quarters 1, 2, and 3, followed the activation period. Each of these periods was also 3 months in length. The final period, also known as the long-term follow-up period, comprised BPs from the end of quarter 3 to March 31, 2010 (6 months after the intervention ended). Thus, patients eligible in later quarters had fewer short-term follow-up periods, although the length of follow-up remained balanced across the intervention and control groups (online-only Data Supplement Appendix D). Control participants were assigned random activation dates by strata for analysis purposes to match the distribution of activation dates in the intervention group, although no specific actions resulted from activation.

All analyses were intention-to-treat and were done with a 3-level multiple linear regression, with SBP measurements nested within subject within team to account for clustering of patients within teams and the precision of BP measurement given differing numbers of BP measurements per subject.⁴³ The analysis further accounted for the sampling design by including site and the BP eligibility strata in all models.⁴³ All analyses were done by use of STATA 11.1 (Stata, College Station, TX, 2010). As described in detail elsewhere,⁴³ this study was powered to detect a 4-mm Hg difference with a power of 0.8 with only 2 observed BPs per person in the pre- and postintervention measurement windows, under an assumption of an interclass correlation coefficient of 0.02. We had an average of 4 observed BPs per person for each window, and the observed interclass correlation coefficient at the team level after stratification by site was considerably <0.02. The target sample size for the power calculation was achieved.

Of the 4100 patients in the analyses, 3313 had one or more BPs in the period before the start of the study, 3080 also had one or more in the poststudy period. 543 only had a BP in the post period. Two hundred forty-five patients had no measurements in either the pre- or poststudy periods (they were from some of the latter parts of the year and had not been under VA care or had not been seeking care during the 6 months preceding the start of the study). All patients were

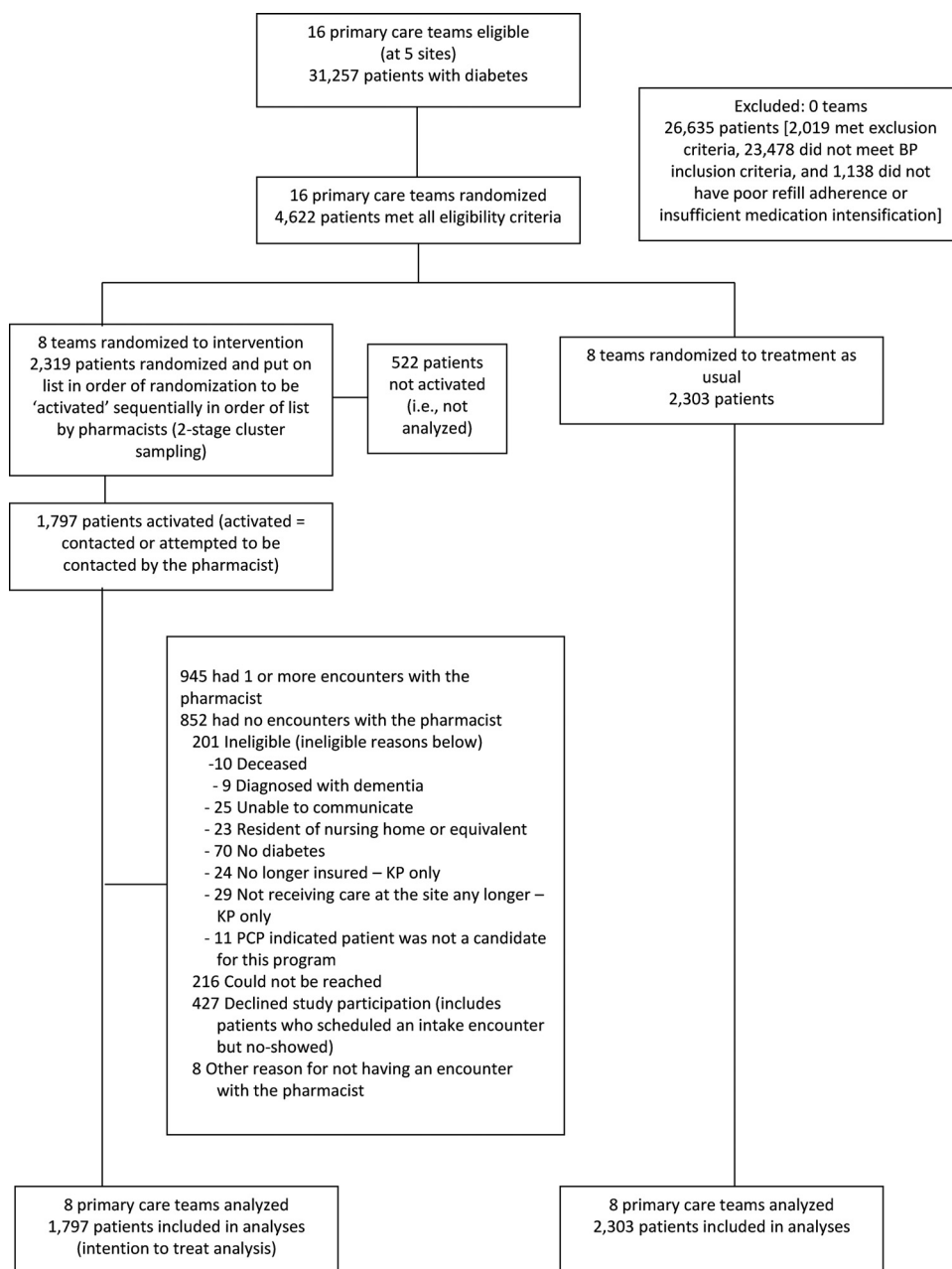


Figure 1. CONSORT diagram. PCP indicates primary care providers; KP, Kaiser Permanente Northern California.

included in the primary outcome analysis, with the exception of the 245 who had no BPs in either pre- or poststudy period. The multilevel model allows including subjects with incomplete outcome data under an assumption of missing at random conditional on the covariates. Our secondary analysis was a longitudinal analysis able to take advantage of all BPs collected during usual care of the patients and not only those during the 6 months before study start and the 6 months after the program's end.

Results

Baseline Attributes of Eligible Subjects

The CONSORT diagram in Figure 1 shows participant flow. Table 1 shows that baseline characteristics of eligible intervention and control patients were similar. Fifteen percent of patients with diabetes mellitus were eligible for the intervention. Most of those excluded did not have persistent hyper-

tension. There were no differences in age, race/ethnicity, sex, documented medication adherence, number of primary care visits in the previous 12 months, being on insulin or a moderate-dose statin at baseline between the 1797 intervention team patients whom the pharmacists tried to contact and the 522 whom they did not have time to try to contact. Activated patients had higher mean SBPs (154 versus 149 mm Hg) and were on average on slightly more classes of BP medications (2.4 versus 2.2) than nonactivated patients.

Healthcare Utilization and Intervention Engagement During Study Period

Table 2 shows that there were no differences in health services utilization between eligible intervention and control patients during the 14-month intervention period. Interven-

Table 1. Baseline Characteristics of Intervention and Control Team Patients

Characteristics	Intervention (N=1797)	Control (N=2303)
Age (years) on August 1, 2008	65.3±11.7	65.3±12.1
Male	1250 (70)	1582 (69)
Race		
White	928 (52)	1128 (49)
Black	275 (15)	353 (15)
Hispanic	174 (10)	257 (11)
Asian	115 (6)	180 (8)
Other	61 (3)	83 (4)
Unknown	244 (14)	302 (13)
Identified with adherence gap(s) ≥20%	1059 (59)	1361 (59)
Most recent systolic BP in the last 3 mo (mm Hg)*	157±12	156±13
Mean systolic BP over last 9 mo (mm Hg)*	154±10	153±12
Most recent diastolic BP in the last 3 mo (mm Hg)*	79±11	79±12
Mean diastolic BP over last 9 mo (mm Hg)*	79±9	78±11
Most recent hemoglobin A1c in the last 12 mo (%)	7.4±1.6	7.4±1.6
Most recent LDL cholesterol in the last 12 mo (mg/dL)	94±33	95±34
On insulin†	479 (27)	614 (27)
On a statin†	1134 (63)	1478 (64)
On a moderate or higher dose statin†	992 (55)	1257 (55)
Moderate or higher doses BP classes†	1.8±1.4	1.8±1.3
Classes of antihypertensive medications†	2.4±1.5	2.3±1.5
Primary care visits in the past 12 mo	4.9±4.9	4.9±5.3

Values presented are n (%) or mean±SD. BP indicates blood pressure; LDL, low-density lipoprotein.

*Weighting based on BP strata groups (140–149, 150–159, and 160+). A greater proportion of participants in the intervention group were in the higher stratas because of our activation protocol. We weighted the participants in the lower stratas of the intervention so that the distribution for intervention and control would be similar.

†Refill documented within 120 d of eligible date.

tion patients were more likely than control patients to undergo medication changes during the 6-month period following the quarter start date, although both groups had high rates of medication changes.

Table 3 presents information on mean and median number and frequency of pharmacist encounters among the 945 eligible intervention team patients who had at least 1 encounter with AIM pharmacists. Participants had a median of 3.8 pharmacist encounters and a median of 9 weeks of follow-up during their enrollment in the program. Their intake encounter averaged 50 minutes, and follow-up encounters averaged 27 minutes; 60.8% of all encounters took place by phone, and 69% of all patients were discharged with a target BP.

Team-Level Changes in SBP Over the 14-Month Intervention Period and 6 Months After

In our primary analysis, the intervention group SBP change from the 6 months before versus 6 months after the 14-month

Table 2. Other Resource Use During the 14-Month Intervention Period (July 2008 to August 2009)

	Intervention (N=1797)	Control (N=2303)	P
Hospitalized in VA or KP facility	227 (13)	300 (13)	0.71
Primary care visits	4.6±5.9	4.3±6.1	0.10
Had ER visit	434 (24)	532 (23)	0.43
Proportion of patients with BP medication changes*	69.7%	63.0%	<0.01

Values presented are n (%) or mean±SD. VA indicates Veterans Affairs; KP, Kaiser Permanente Northern California; ER, emergency room; and BP, blood pressure.

*Calculated as a change (increase in dose, decrease in dose, adding of a class, dropping of a class, or switching of a medication within the same class) in BP medications during the 6-month period following the quarter start date.

intervention was not different from control group, declining 8.9 mm Hg in the intervention group in comparison with a 9.0 mm Hg decrease for the control group (difference of 0.18 [−0.77, 1.13]). There were no differences in mean A1c and low-density lipoprotein levels between intervention and control teams after the end of the intervention period (examining a 12-month period): low-density lipoprotein mean values of 89.1 mg/dL (31.1) on intervention teams versus 87.8 mg/dL (32.9) on control teams and A1c mean of 7.4% (1.4) and 7.6% (1.6) on control teams.

Figure 2 reports the results of secondary analyses of short-term SBP changes, examining 3-month intervals through the study period calculated before and after the first date of the quarter in which each participant was activated (online-only Data Supplement Appendix D). Control participants improved at a slower rate. By the end of quarter 1, the period after the quarter in which patients were activated, mean SBPs had dropped 7.2 mm Hg in the control group in comparison with 9.7 mm Hg in the intervention group (difference of 2.4 mm Hg [1.5, 3.4]; $P<0.001$). By 6 months and throughout the remainder of follow-up, eligible control team patients' mean SBPs were indistinguishable from those of intervention group participants.

Table 4 illustrates the observational cohort results comparing those who agreed to participate (ie, activated intervention patients who had at least 1 encounter with a pharmacist) with those who did not get the intervention (ie, activated intervention patients who did not have an encounter with the pharmacist AND all control patients). There were more medication changes among those who participated in the intervention than among those in the nontreated group. The intervention participants who had at least 1 encounter achieved a maximal SBP improvement ≈4 mm Hg greater than the intervention participants with no encounters. This difference also disappeared as the control group approached the same level of control over time.

Discussion

In this team-level pragmatic randomized trial providing targeted adherence counseling and medication management to patients with diabetes mellitus with persistent hypertension in 2 high-performing integrated healthcare systems, we

Table 3. Description of Intervention Processes

Pharmacist level	
Patients activated over the entire intervention period	1797
Patients having at least 1 encounter with the pharmacist	945 (52.6% of activated)
Patient level	
Encounters during first enrollment, n (median)	3.8±3.2 (3)
Days enrolled during first enrollment, n (median)	62±71 (41)
Enrolled in the program >1 time during intervention	35 (3.7)
Encounters over entire intervention period, n (median)	3.9±3.3 (3)
Days enrolled over entire intervention period, n (median)	64±71 (42)
Discharged at the first encounter	184 (19.5)
Reasons for discharge (examining a patient's first discharge in the program)	
Had a target BP (clinic or home)	650 (68.8)
Lost to follow-up (eg, no-showed for 3 encounters) or enrolled for 6+ months and no further progress was being made	97 (10.3)
Program ended (ie, 14-mo intervention ended)	74 (7.8)
Declined further participation	50 (5.3)
DBP <60	46 (4.9)
On maximum medications	22 (2.3)
DBP <60 and on maximum medications	2 (0.2)
Other	4 (0.4)
Encounter level	
Length of intake encounters, minutes (median)*	50.2±7.9 (52)
Length of follow-up encounters, minutes (median)*	26.9±4.7 (28)
Phone encounters (not office)	2241 (60.8)

Values presented are n (%) or mean±SD. BP indicates blood pressure; DBP, diastolic blood pressure.

*From pharmacist daily logs; collected during 4 different weeks over the intervention period.

sought to respond to the Institute of Medicine's call to evaluate state-of-the-art approaches to improve quality of care in real-life clinical practice.^{42,57} Integrated delivery systems provide health care to >40 million Americans, and with the spread of Accountable Care Organizations, increasing numbers of patients will receive care in systems that have virtual integration.^{58,59} We designed AIM to incorporate elements of successful interventions and apply them to a high-risk population with diabetes mellitus, hypertension, and presumed medication adherence or management problems.⁶⁰ We used evidence-based algorithms for medication intensification and provided pharmacists with objective data on participants' refill gaps and training in evidence-based MI approaches to assist their adherence assessments, yet found

similar levels of SBP reduction among intervention and usual-care patients 6 months after the end of the intervention period. Therefore, the answer to our primary question is that, at least within higher-performing healthcare systems, additional monetary and staff resources devoted to state-of-the-art interventions cannot be counted on to improve BP control beyond usual care and may simply add to greater polypharmacy in intervention subjects.

Intervention implementation was successful. Participants had an average of 4 encounters totaling several hours over 9 weeks. Patients who met with AIM pharmacists had more rapid intensification of their medications. The intervention was effective in reducing BP, because, both during and immediately after receiving the intervention, activated intervention team patients on average had clinically and statistically significant 2.4 mm Hg lower SBPs than control team patients. Furthermore, this average decline in BP includes the 47% of activated team patients who did not participate at all in the program. A 2.4 mm Hg difference in SBP if sustained could translate to a 6% to 8% reduction in stroke mortality and a 4% to 5% reduction in coronary heart disease mortality.⁶¹ Despite this earlier and more rapid decline in BP among the intervention patients, patients on the control teams experienced a similar decline ≈3 months after the intervention group.

Other existing programs contributed to BP lowering among this high-risk population on control teams. In both systems, rates of meeting BP performance measures among patients with diabetes mellitus were routinely reported, and nurse care managers were available to all PCPs for follow-up on BP control issues. In the VA physician performance bonuses were tied in part to achieving BP control goals. At the KP sites, PHASE pharmacists were also reaching out to patients with diabetes mellitus with poor risk factor control on the control teams for brief interventions. Although lower than among activated intervention team patients, high rates of treatment intensification and medication changes occurred among eligible control team patients during the study period. It is also possible that the AIM intervention caused better than usual care in the control group. At the VA, providers on the control team were also provided with quarterly reports that listed their patients who would have been eligible for AIM, along with their adherence and intensification data. However, the literature does not suggest that individual provider audit and feedback alone is particularly effective.⁶²

In the intervention arm, only 53% of subjects had a pharmacist encounter. Higher rates of participation might have led to a more substantial initial improvement and a detectable longer-term effect. However, it is hard to conceive of a way to get higher levels of participation in a real-world setting than by using proactive outreach with specially trained pharmacists who were members of the teams already providing primary care to these patients. Of potential concern, once the program ended at 14 months, all of the subjects were returned to usual care during the 6-month follow-up period used in our primary outcome analysis. Results from other recent trials have reinforced that short-term gains in risk factor control often fail to

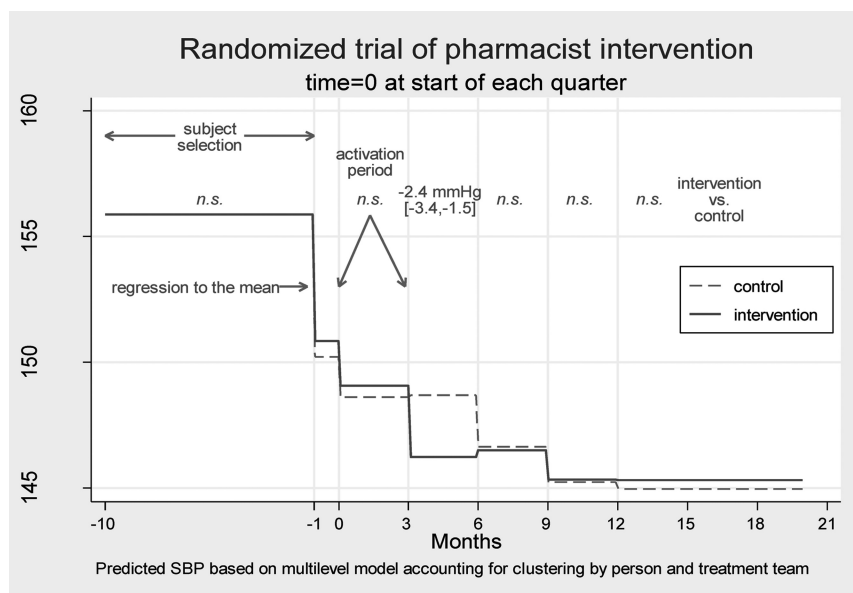


Figure 2. Predicted changes in systolic blood pressures per quarter between eligible intervention and usual-care teams in multilevel models. BP indicates blood pressure; SBP, systolic blood pressure.

persist if there is no maintenance after program completion.^{29,63} However, in our study, the lack of longer-term difference did not appear to be a result of deterioration of control in the intervention group, but rather continued improvement in the control group, suggesting that usual care or regression to the mean for a cohort of patients selected on the basis of elevated BPs accounted for the lack of effect, not the absence of maintenance.

The study findings reinforce the importance of carefully testing the effectiveness of interventions with known efficacy in real-world practice before broad implementation. It also demonstrates the fallacy of using uncontrolled prestudy/poststudy data to justify expenditures on clinical programs, because, without controls, our intervention would have seemed very successful, lowering SBP by almost 10 mm Hg. We collected qualitative information to explore in greater depth factors that influenced actual delivery of the intervention and both facilitators and barriers to success.^{52,64} Most previous evaluations of pharmacist-led interventions shown to improve BP included only volunteer clinical trial subjects, used research clinicians during the intervention, assessed BP

outcomes measured as part of the study, and compared these BP outcomes of intervention and control patients made immediately after the patient participated in the intervention. In contrast, we measured the ability to translate these findings into practice by focusing on the team level, using team-based pharmacists, assessing BP outcomes through BPs taken during routine clinic care, and evaluating the impact on the entire target population, including all those activated to receive the intervention, whether or not they were successfully reached by or ever had an encounter with the pharmacist. In this manner, we sought to provide information most relevant to health center leaders who need to decide whether to invest resources to implement interventions.

If our intervention indeed successfully deployed elements found to be most consistently effective in the experimental literature then there are 4 possible conclusions. The first is that we need different interventions that translate more effectively into routine clinical practice. For example, we might move from the focus on physician clinical inertia and provider-intensive clinical redesign to empower the patient to do their own intensification as suggested by a successful recent UK clinical efficacy trial that allowed patients to make a limited number of intensification steps themselves without interaction with the healthcare system.⁶⁵ A second possibility is that we are not able to improve the control of those with persistent hypertension because we cannot identify them accurately. Emphasizing the imprecision of routine clinical BP measurement, data from the recent Perindopril Protection Against Recurrent Stroke Study showed that “Six months after BP was stabilized on treatment, if SBP was measured as having increased by >10 mm Hg, six of those measurements would be false-positives for every true increase of ≥ 10 mm Hg.”⁶⁶ Other recent studies have also highlighted the risk of misclassification based on clinic or home BPs alone.^{67,68} If using an average of recent routine clinical BP measurements to identify eligible patients results in targeting many patients who do not in fact have elevated BP, then it is not surprising to fail to find a sustained

Table 4. Medication Changes 6 mo Following the Quarter Start Date (Observational Results From “as Treated Analysis”)

	Treated (N=945), %	Nontreated (N=3155), %
Any change	81.2	61.6
Increase dose	33.6	19.6
Add class	57.3	38.1
Switch drug	6.5	3.9
Drop class	15.1	17.6
Decrease dose	6.1	3.9

These results should not be interpreted as being from the randomized trial. They are the observational cohort results comparing those accepting the intervention (treated=activated intervention patients who had an encounter) with those who did not get the intervention (Nontreated=activation intervention patients who did not have an encounter and all control patients).

improvement in BP over and above usual care. A third possibility is that the 47% of eligible patients who did not participate in the program represent the small intractable group of patients, in whom BP control is essentially impossible, owing to either biological or psychosocial factors. And finally, the greater medication intensification in the intervention teams without correspondingly greater sustained improved SBPs relative to the usual-care group suggests that the intervention was more effective in increasing medications than in improving medication adherence.

In summary, in these 2 high-performing healthcare systems that have achieved high levels of BP control, a state-of-the-art intensive pharmacist-led program did not provide sustained incremental benefit for the small target group of fall-outs. Indeed, the systems that have been put into place to achieve the impressive 80% rates of control may be demonstrating best achievable practices. Although these programs improve control for some patients during a given time period, other patients fall out of control during that same time period. As long as current usual-care practices and incentives remain in place, these systems may be nearing their near-maximal safe control rates for the population with diabetes mellitus. Our study emphasizes how difficult it is to move the control barometer once high rates of control are achieved and suggests that clinical inertia alone is not what is preventing us from reaching optimal control in all our patients.⁶⁹ Our study further reinforces the importance of rigorously evaluating in different real-life clinical settings programs found in efficacy trials to be effective before urging their widespread adoption in all settings.

Acknowledgments

The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs or the University of Michigan. Dr Selby is currently the Executive Director of PCORI. The views expressed in this article are Dr Selby's and do not necessarily reflect those of PCORI. The study team thanks our extraordinary clinical pharmacists, and their supervisors, as well, at KP and VA. Many thanks also to Rob Holleman for his meticulous data management and analysis. We also thank our advisory team members Drs Pam Reeves, Adam Tremblay, Fran Cunningham, Steven Bernstein, John Piette, and Jim Chan. Dr Rod Hayward made valuable contributions to an earlier draft of this article.

Sources of Funding

This work was supported by Department of Veterans Affairs Health Services Research and Development award SDP 06-128 and the National Institute of Diabetes and Digestive and Kidney Diseases grant 5 R18 DK076622.

Disclosures

Dr Bosworth has received honoraria (<10 k) for study review and as a speaker related to wellness and adherence. He is a member of Pfizer's medication adherence advisory board (<10 k).

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CLINICAL PERSPECTIVE

We studied the implementation and clinical outcomes of a state-of-the-art, intensive pharmacist-led intervention seeking to improve blood pressure control in a high-risk population (patients with diabetes mellitus, persistent hypertension, and documented medication adherence or management problems) in 2 high-performing healthcare systems (Kaiser Permanente and the Veterans Affairs Health System). In the short term, the program improved blood pressure control in comparison with usual care, but, by 6 months after the program's completion, patients receiving usual care had on average achieved similar systolic blood pressure improvements (mean of 10 mm Hg decrease). In such high-performing healthcare systems, the programs already put into place to achieve the impressive 80% rates of blood pressure control in these systems may be demonstrating best achievable practices. Clinical inertia alone may not be preventing the achievement of optimal control in high-risk patients. Clinicians should continue to work on improving medication management for these patients and on assisting patients with barriers to medication adherence. However, even with these strategies, it is likely that some patients with persistent hypertension will remain with poor blood pressure control.