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Improving Blood Pressure Control through Provider Education, Provider Alerts, and Patient Education

A Cluster Randomized Trial

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Background: Inadequate blood pressure control is a persistent gap in quality care.

Objective: To evaluate provider and patient interventions to improve blood pressure control.

Design: Cluster randomized, controlled trial.

Setting: 2 hospital-based and 8 community-based clinics in the Veterans Affairs Tennessee Valley Healthcare System.

Patients: 1341 veterans with essential hypertension cared for by 182 providers. Eligible patients had 2 or more blood pressure measurements greater than 140/90 mm Hg in a 6-month period and were taking a single antihypertensive agent.

Intervention: Providers who cared for eligible patients were randomly assigned to receive an e-mail with a Web-based link to the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7) guidelines (provider education); provider education and a patient-specific hypertension computerized alert (provider education and alert); or provider education, hypertension alert, and patient education, in which patients were sent a letter advocating drug adherence, lifestyle modification, and conversations with providers (patient education).

Measurements: Proportion of patients with a systolic blood pressure less than 140 mm Hg at 6 months; intensification of antihypertensive medication.

Results: Mean baseline blood pressure was 157/83 mm Hg with no differences between groups ($P = 0.105$). Six-month follow-up data were available for 975 patients (73%). Patients of providers who were randomly assigned to the patient education group had better blood pressure control (138/75 mm Hg) than those in the provider education and alert or provider education alone groups (146/76 mm Hg and 145/78 mm Hg, respectively). More patients in the patient education group had a systolic blood pressure of 140 mm Hg or less compared with those in the provider education or provider education and alert groups (adjusted relative risk for the patient education group compared with the provider education alone group, 1.31 [95% CI, 1.06 to 1.62]; $P = 0.012$).

Limitations: Follow-up blood pressure measurements were missing for 27% of study patients. The study could not detect a mechanism by which patient education improved blood pressure control.

Conclusions: A multifactorial intervention including patient education improved blood pressure control compared with provider education alone.

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Currently, more than 50 million persons in the United States have hypertension (1). The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) promotes blood pressure goals of less than 140/90 mm Hg (2–5). Providers, however, often delay changes in therapy or use higher blood pressure thresholds for the treatment of hypertension (2, 4, 6, 7), which leads to a variance in guideline adherence that contributes to a quality gap in care. Despite widespread guideline promotion, 65% of persons in the United States have poorly controlled hypertension (1, 6, 8, 9).

Factors contributing to the achievement of hypertension goals include provider decision making and patient adherence to antihypertensive treatment. These factors can be influenced by other factors, such as patient interactions with clinicians, commercial influences, and patient participation in treatment decisions (6, 10–17). A review of hypertension goal attainment in primary care (18) found that interventions with the largest positive change were complex, multifactorial, and involved 4 areas: activities directed at changing clinician behavior, changes to the organization, information enhancement, and educational programs directed at patients. Although these findings suggest opportunities to achieve effective intervention by directing a change at each component (2, 17, 19–23), the impact of each component is less well known.

Our aim was 1) to improve the quality of care of patients with hypertension at our facility while examining the relative contribution of each aspect of a multifactorial intervention designed to improve care and 2) to show the effects of physician-level clustering on quality assessment.

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Context

Despite evidence showing that even mild elevation of blood pressure above 140/90 mm Hg puts patients at risk for cardiovascular complications, many patients who are treated for hypertension still have high blood pressure.

Contribution

The authors sought to improve the blood pressure of patients using a health systems approach. They randomly assigned providers caring for hypertensive patients to receive a Web link to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; the Web link and a computer alert notifying them of the patient's blood pressure; or the Web link, computer alert, and a letter educating the patient about ways to control his or her blood pressure. Patients of providers randomly assigned to the third group had greater decreases in blood pressure and were more likely to have a systolic blood pressure less than 140 mm Hg.

Cautions

The study took place in a Veterans Affairs setting, follow-up blood pressure measures were missing for many patients, and the study was not designed to detect a mechanism for any observed changes.

Implications

A health systems approach that gave providers feedback about their patients' blood pressure and that gave patients information about ways to control it improved blood pressure control compared with provider education alone.

—The Editors

We conducted a cluster randomized, controlled study to evaluate common components of a multifactorial intervention in veterans with essential hypertension.

METHODS

Study Design and Setting

This project was a cluster randomized, controlled trial designed to examine the relative contribution of 3 quality improvement interventions of increasing intensity in improving blood pressure control in veterans. This study was the evaluation component of a Veterans Integrated Service Network campaign to improve blood pressure control in patients who are treated in the Tennessee Valley Healthcare System. The health care system comprises 2 teaching hospitals, 2 large community-based outpatient clinics, and 6 small community-based outpatient clinics. There were 523 659 outpatient visits made by 69 928 veterans during fiscal year 2004. The institutional review board of Vanderbilt University and the VA Tennessee Valley Healthcare System research and development committee for human subjects protection approved this study.

Inclusion Criteria

We first identified eligible patients and then randomly assigned providers caring for at least 1 of those patients to receive study interventions. Patients were eligible for inclusion in the study if they were 21 to 90 years of age, filled their medications at Veterans Administration (VA) pharmacies, had at least 2 uncontrolled blood pressure measurements in the 6-month baseline period (systolic blood pressure >140 mm Hg or diastolic blood pressure ≥90 mm Hg), and were only taking 1 antihypertensive medication. We restricted our study sample to patients with uncontrolled hypertension who were only taking 1 antihypertensive medication because the JNC 7 guidelines propose that most patients with hypertension will require 2 or more medications to achieve their blood pressure goals (5, 12). Therefore, this sample includes patients for whom the quality of hypertension care could be improved. Eligible patients were identified between July and December 2003 by searching data from the Mid-South Quality Improvement Data warehouse, which are downloaded monthly from Veterans Health Information System and Technology Architecture.

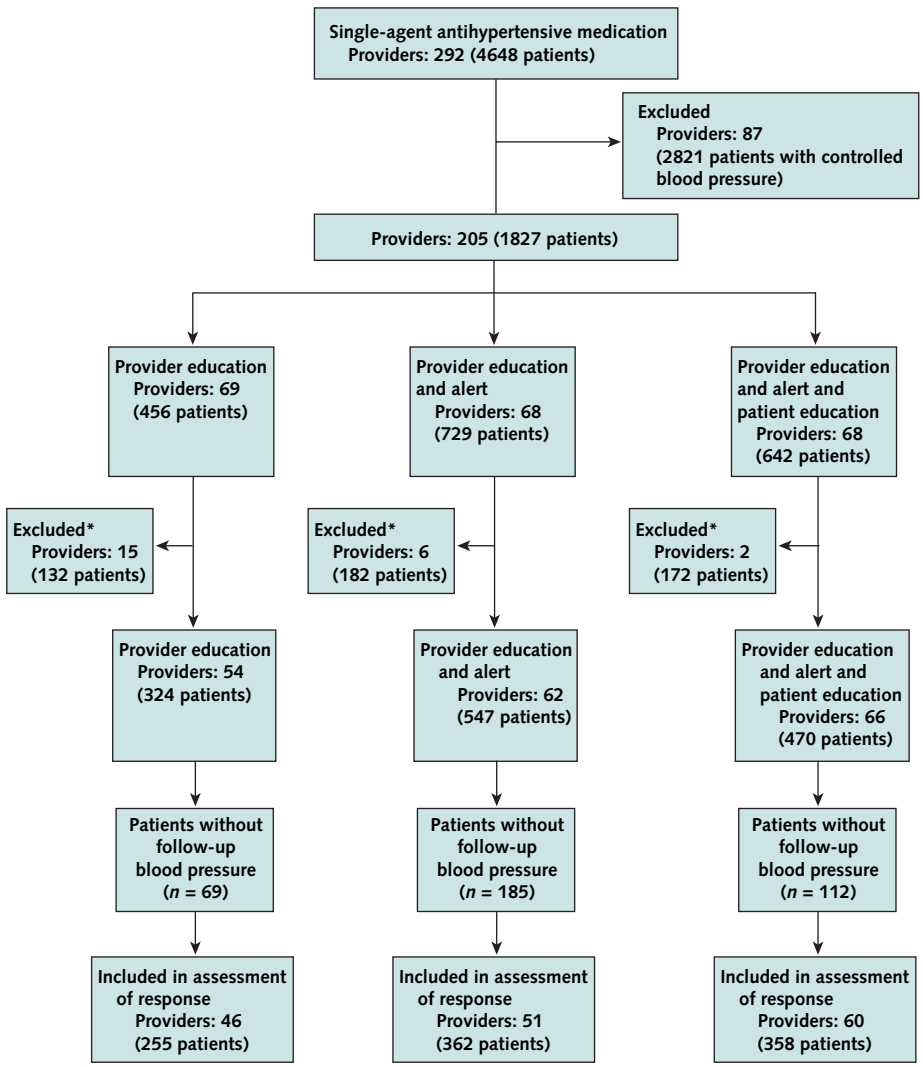
The search initially identified 4648 patients with a primary care visit who had a diagnosis of hypertension indicated by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes 401.1 or 401.9 and who were prescribed only 1 antihypertensive medication (**Figure**). We excluded 2821 (60%) patients because they had at least 1 recorded blood pressure reading between July and December 2003 that was at goal (systolic blood pressure ≤140 mm Hg and diastolic blood pressure <90 mm Hg). We mailed an assent letter to the remaining 1827 patients in January 2004 asking permission to review their electronic medical record and indicating that their primary provider would potentially receive suggestions to improve their hypertension care. Another 486 patients were excluded after randomization because they declined chart review ($n = 222$) or were taking more than 1 antihypertensive medication at the time of chart review ($n = 264$).

Providers were eligible for randomization if they provided care for at least 1 patient who fulfilled the eligibility criteria. Providers were classified as attending physicians, resident physicians, or nonphysician clinicians (nurse practitioner or physician assistant) and were stratified into providers with at least 30 eligible patients and those with less than 30 eligible patients to help balance the number of patients in each study group. One hundred eighty-two providers were randomly assigned to study interventions; after randomization, 23 providers were additionally excluded because the patients they cared for declined chart review or were taking more than 1 antihypertensive medication at the time of chart review (**Figure**).

Interventions

Providers were randomly assigned to 1 of 3 study groups: provider education only; provider education and

Figure. **Study flow diagram.**



*Excluded providers cared for patients who declined chart review or those who were taking more than 1 medication at the time of chart review after randomization.

alert; or provider education, alert, and patient education. All interventions were performed during the week of 14 June through 18 June 2004, and follow-up continued through 31 December 2004.

Provider Education

All providers in the 3 study groups received an e-mail message that explained the planned intervention. Providers who received only the e-mail message were controls for those who received the other 2 more intensive interventions. The e-mail informed providers that they might receive electronic alerts in the computerized patient record requesting reevaluation of a patient's antihypertensive regimen. It also reported that a letter was being sent to selected patients advocating medication adherence and lifestyle modification to lower blood pressure. The e-mail message included a Web link to the JNC 7 guidelines for the treatment of hypertension (www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf). The message was sent by the supervisory pharmacist at the VA Tennessee Valley Healthcare System and was signed by the medical director of the network.

Provider Education and Alert

In the second study group, an alert was added to provider education. The alert was a 1-time patient-specific electronic notification that was sent by the pharmacy to the prescribing provider through each eligible patient's electronic medical record over a 1-week period in June 2004. Each time providers signed on to a computer, any medical record that contained an alert was brought to their attention. The alert gave a brief outline of the JNC 7 recom-

mendations (5) and reminded providers that goal blood pressure should be 140/90 mm Hg or less. It included dates and values of the patient's last 3 recorded blood pressure measurements and offered the following options: addition of a thiazide or thiazide combination diuretic, addition of another antihypertensive medication, or continuation of current medications and dosages. The alert reminded providers of the available thiazides on the VA formulary and stated that thiazides were contraindicated in patients with renal insufficiency or allergies to sulfa medications.

Provider Education, Alert, and Patient Education

The third study group combined the provider education and alert described previously with a patient education component. We sent a personalized letter that contained educational information concerning hypertension to each eligible patient in this study group. The letter was labeled "Notice: To Veterans with High Blood Pressure" and was designed at an eighth-grade reading level. The letter recommended the use of behavioral strategies, such as medication adherence, low-sodium diet, and exercise, to improve blood pressure control. It noted that many patients need more than 1 medication to control their blood pressure and that all medication changes should be discussed with their VA provider. The letter mentioned that more information on hypertension was available at the VA patient education library and online at the American Heart Association's Web site (www.americanheart.org). This patient education letter was also signed by the network medical director.

Randomization

The randomization sequence was computer-generated and was assigned by a member of the study team who was blinded to patient and provider assignment until the intervention. Once the providers had been assigned to 1 of 3 potential groups, the list was given to the study coordinator, who mailed patient assent letters, unlinked provider numbers to provider name, and delivered the intervention to each randomly assigned provider. All investigators, providers, and patients were unaware of group assignments until the intervention. Because randomization occurred before chart review confirmation, there was some disequilibrium in the number of providers in each group.

Measurements

The primary outcome measure was the proportion of patients clustered by provider who reached the systolic blood pressure goal of 140 mm Hg or less. If more than 1 blood pressure reading was available for a patient, we used the last available reading to determine whether the patient reached his or her blood pressure goal. The secondary outcome measure was the proportion of patients clustered by provider who reached a diastolic blood pressure goal of less than 90 mm Hg. We chose systolic blood pressure as the primary outcome measure because the National High Blood Pressure Education Program (24, 25) has recommended that systolic blood pressure be the principal measure for diagnosing and managing hypertension.

The primary process measure was intensification of the patient's antihypertensive medication regimen. Intensification was defined as the addition of another antihypertensive medication, titration of the original antihypertensive medication, or both. Switching from a single agent to a different single agent did not qualify as intensification.

Data on blood pressure readings and intensification of antihypertensive regimen were collected through the Mid-South Quality Improvement Data warehouse. Other important patient data, including age, sex, and comorbid conditions, were collected to be used as covariates in the analysis. The Charlson–Deyo comorbidity score was calculated on the basis of all ICD-9-CM codes for outpatient visits during 2003.

Patient medication adherence was assessed as a potential mediator of changes in blood pressure by using medication refills and a modification of Steiner and colleagues' method (26–28). The time between each filled prescription was estimated by dividing the minimum number of days dispensed by the number of days between fills (range of adherence score, 0 to 1). We then took a weighted average of those estimates, weighting by the number of days between fills. A patient who always refilled medications within the expected time had an adherence score of 1.

Through this database, we also collected provider characteristics, including age, sex, provider type (staff physician, resident physician, or midlevel provider [nurse practitioner or physician assistant]), and location of care (teaching hospital, large community-based clinic [$\geq$5 providers], or small community-based clinic [$<$5 providers]).

Statistical Analysis

Our planned sample size of 1300 patients assigned to 200 providers was based on the assumption that by using a simple logistic regression model, 1300 patients were required to detect an odds ratio of 1.5 for providers in the provider education and alert group and an odds ratio of 1.8 for those in the provider education, alert, and patient education group (α value, 0.05; power, 0.90 [SamplePower, version 2.0, SPSS Inc., Chicago, Illinois]). This estimate did not adjust for the observed 73% follow-up rate or the observed intracluster correlation coefficient of approximately 0.05.

Using descriptive statistics, proportions, means, standard deviations, and ranges, we examined demographic characteristics of the patients and providers. A patient's success in achieving his or her systolic blood pressure goal of 140 mm Hg or less was coded as a binary variable. We derived the model by determining a priori covariates for inclusion based on clinical significance. To estimate the relative risk for blood pressure control between treatment groups, we used a log risk binomial regression model with the provider as a random effect while adjusting for prein-

Table 1. **Provider Characteristics**

Variable	Provider Education Only ($n = 54$)	Provider Education and Alert ($n = 62$)	Provider Education, Alert, and Patient Education ($n = 66$)	*P* Value
Men, *n (%)*	27 (50.0)	38 (61.3)	42 (63.6)	0.28
Mean age (SD), *y*	47.5 (8.3)	47.0 (11.0)	46.5 (11.8)	0.89
Provider type, *n (%)*				
Staff physician	27 (50.0)	33 (53.2)	41 (62.1)	0.32
Resident physician	9 (16.7)	13 (20.9)	14 (21.2)	
Nonphysician clinician	18 (33.3)	16 (25.8)	11 (16.7)	
Practice location, *n (%)**				0.57
Teaching hospitals	35 (64.8)	33 (53.2)	36 (54.5)	
Large community-based clinic (≥5 staff physicians)	8 (14.8)	12 (19.4)	10 (15.2)	
Small community-based clinic (<5 staff physicians)	7 (13.0)	10 (16.2)	15 (22.8)	

* The location of care was unknown for 16 providers.

tervention systolic blood pressure, patient age, Charlson–Deyo comorbidity score, baseline medication adherence, provider type, and the provider stratification variable (<30 eligible patients vs. ≥30 eligible patients). We tested for interactions between intervention groups and each of the baseline covariates. None of these interactions were statistically significant; therefore, they were not included in the final model.

We conducted intention-to-treat analysis such that clinicians were considered exposed to the intervention assigned to them, regardless of changes in patient panels. Similarly, all patients with available follow-up blood pressure readings were analyzed within the intervention group to which their provider was assigned. We conducted 2 analyses on the primary outcome of interest: the principal analysis on patients with available follow-up blood pressure readings and an alternative analysis assuming that those missing follow-up blood pressure readings never reached their goal. We report relative risks and 95% CIs for reaching systolic goal. Statistical analyses were conducted by using Stata, version 8.0 (Stata Corp., College Station, Texas), R Statistical Program (R Foundation, available at www.r-project.org), and SAS for Windows, version 11.0 (SAS Institute, Cary, North Carolina).

Role of the Funding Source

This study was sponsored by the U.S. Department of Veterans Affairs (Veterans Integrated Service Network [VISN] Implementation grant), Clinical Research Center of Excellence, and Center for Patient Healthcare Behavior. The principal investigators and coinvestigators had full access to the data and were responsible for the study protocol, statistical analysis plan, study progress, analysis, study reporting, and the decision to publish the paper. The U.S. Department of Veterans Affairs–VISN 9 had the opportunity to comment on the manuscript before submission.

RESULTS

Study Flow

Two hundred five providers caring for 1827 patients were randomly assigned to 1 of the 3 study groups. Of the 205 providers, 23 were subsequently excluded after randomization because patients did not consent ($n = 222$) or because chart review showed that a patient was taking more than 1 medication ($n = 264$). Providers who were excluded did not differ from those who were included in sex (14 of 23 [60.8%] were men; $P = 0.85$) or mean age (48 years [SD, 23]; $P = 0.96$). All 23 providers practiced at teaching hospitals. Eleven of the 23 were staff physicians (47.8%), 10 were resident physicians (43.5%), and 2 were nonphysician clinicians (8.7%). More excluded providers were residents ($P = 0.022$) compared with those who were included.

The remaining 182 providers included in the study cared for 1341 eligible patients with uncontrolled hypertension who were taking 1 medication and consented to have their charts reviewed (**Figure**). The control group (provider education) consisted of 324 patients cared for by 54 providers, the second group (provider education and alert) consisted of 547 patients cared for by 62 providers, and the third group (provider education, alert, and patient education) consisted of 470 patients cared for by 66 providers.

Provider Characteristics

Provider characteristics are detailed by study group in **Table 1**. One hundred seven of the 182 providers (58.8%) were men, with a mean age of 47 years (SD, 10). Forty-five of the 182 providers (24.7%) were nurse practitioners or physician assistants; the remaining patients received care from a staff physician (101 of 182 [55.5%]) or from a resident physician (36 of 182 [19.8%]). One hundred four of 182 providers (57.1%) practiced in 1 of the 2 teaching hospitals; 62 of 182 (34.1%) providers cared for patients in 1 of the 8 community-based outpatient clinics.

Patient Characteristics

Patients in each study group had similar baseline characteristics (**Table 2**). The cohort of 1341 veterans had a mean age of 65 years (SD, 12), and 97% were men. There were no differences between groups in initial mean preintervention blood pressure (157/82 mm Hg). Five hundred fifty-five of the 1341 patients (41.4%) had stage 2 hyper-

Table 2. **Patients' Baseline Characteristics***

Variable	Provider Education Only (n = 324)	Provider Education and Alert (n = 547)	Provider Education Alert, and Patient Education (n = 470)	P Value
Mean patient age (SD), *y*	65.1 (11.9)	65.5 (12.0)	64.6 (12.6)	0.54
Men, %	96.6	97.3	96.0	0.52
Blood pressure				
Mean systolic blood pressure (SD), *mm Hg*	157.3 (11.9)	158.0 (12.4)	156.3 (11.4)	0.105
Mean diastolic blood pressure (SD), *mm Hg*	82.8 (10.3)	82.1 (11.9)	83.1 (10.5)	0.41
Stage 2 hypertension, %†	38.9	45.2	38.7	0.067
Antihypertensive drug, %				0.145
ACE inhibitor or ARB	41.4	37.8	40.0	
Calcium-channel blocker	27.2	23.8	20.4	
β-Blocker	12.0	11.2	13.6	
Diuretics	14.8	19.5	20.0	
Others	4.6	7.7	6.0	
Mean adherence score (SD)‡	0.86 (0.2)	0.85 (0.2)	0.83 (0.2)	0.130
Charlson–Deyo score, %				0.134
0	72.8	78.4	78.3	
1 or 2	23.5	20.1	19.6	
≥3	2.1	1.5	3.7	
Comorbid conditions, %				
Diabetes	6.2	3.8	2.8	0.048
Hyperlipidemia	38.6	40.8	36.8	0.40
Tobacco use, %				0.85
Current	31.2	32.7	30.6	
Former	43.3	42.6	46.0	

* ACE = angiotensin-converting enzyme; ARB = angiotensin-receptor blocker.
† A systolic blood pressure greater than 160 mm Hg or a diastolic blood pressure greater than 100 mm Hg.
‡ Weighted average of total number of days of drug dispensed/total number of observation days. Scores range from 0 to 1, with 1 being perfect adherence.

tension (systolic blood pressure >160 mm Hg or diastolic blood pressure >100 mm Hg). Consistent with a population taking a single antihypertensive drug, most study patients (77%) were healthy and had a Charlson–Deyo comorbidity score of 0, which indicates no diabetes, heart disease, cancer, chronic pulmonary disease, connective tissue disease, cerebrovascular disease, peripheral vascular disease, renal disease, or liver disease. Our patient selection method also explains the unusually low prevalence of diabetes. Although there were similar numbers of patients with diabetes in each group (20 patients vs. 21 patients vs. 13 patients), there was a slightly higher proportion of patients with diabetes in the group receiving provider education only (P = 0.048).

The antihypertensive medication prescribed at baseline was similar among the 3 study groups. Approximately 40% of patients were using angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers; 25% were taking calcium-channel blockers; 15% were taking any diuretics; 12% were taking β-blockers; and approximately 6% were prescribed other agents, predominantly α-adrenergic antagonists. Score of adherence to baseline antihypertensive medication was similar among the 3 study groups (0.86 [SD, 0.2] vs. 0.85 [SD, 0.2] vs. 0.83 [SD, 0.2], respectively; P = 0.130).

Missing Data

At trial completion, 975 patients (73%) had at least 1 follow-up blood pressure reading, including 255 of 324 (78.7%) in the provider education only group, 362 of 547 (66.2%) in the provider education and alert group, and 358 of 470 (76.2%) in the provider education, alert, and patient education group. Six hundred eight patients had 2 or more blood pressure checks at follow-up (167 of 324 [51.5%] vs. 228 of 547 [41.7%] vs. 213 of 470 [45.3%], respectively), and 324 patients had 3 or more follow-up blood pressure measurements (98 of 324 [30.2%] vs. 125 of 547 [22.9%] vs. 101 of 470 [21.5%], respectively).

Outcome Measures: Systolic and Diastolic Blood Pressure

Systolic blood pressure after intervention averaged 145 mm Hg, 146 mm Hg, and 138 mm Hg in the provider education; provider education and alert; and provider education, alert, and patient education groups, respectively (**Table 3**). Our principal analysis examined the proportion of patients who reached their systolic blood pressure goal

(≤140 mm Hg) among 975 (73%) patients who had follow-up blood pressure readings. Four hundred sixty-eight (48%) of these patients achieved the systolic blood pressure goal of 140 mm Hg or less. However, the proportion achieving goal blood pressure differed in the 3 groups: 107 of 255 (42.0%) versus 148 of 362 (40.9%) versus 213 of 358 (59.5%) ($P = 0.003$) in the provider education; provider education and alert; and provider education, alert, and patient education groups, respectively. When we compared the provider education, alert, and patient education group with the provider education only group, there was an absolute risk reduction of 17.5%. The relative risk for reaching systolic blood pressure goal for patients in the provider education and alert group compared with the provider education only group was 1.00 (95% CI, 0.79 to 1.25) after adjusting for provider as a random effect, preintervention systolic blood pressure, patient age, Charlson–Deyo comorbidity score, baseline medication adherence,

Table 3. **Primary Outcome Measures and Process Measures by Study Group***

Outcomes†	Trial Group			*P* Value‡
	Provider Education Only	Provider Education and Alert	Provider Education, Alert, and Patient Education	
Mean systolic blood pressure (SD), *mm Hg* [*n* = 975]	145 (19)	146 (19)	138 (18)	
Mean change in systolic blood pressure from baseline (SD), *mm Hg* [*n* = 902]	−12 (21)	−11 (21)	−16 (20)	
Systolic blood pressure ≤140 mm Hg, *n/n (%)* [*n* = 975]	107/255 (42.0)	148/362 (40.9)	213/358 (59.5)	
Unadjusted RR without clustering (95% CI)	Referent	0.97 (0.81 to 1.18)	1.42 (1.20 to 1.68)	<0.001
RR (95% CI)	Referent	1.00 (0.80 to 1.25)	1.37 (1.11 to 1.68)	0.003
Adjusted RR with clustering (95% CI) [*n* = 804]§	Referent	1.00 (0.79 to 1.25)	1.31 (1.06 to 1.62)	0.012
Systolic blood pressure ≤140 mm Hg assuming missing blood pressure is not controlled, *n/n (%)* [*n* = 1341]	107/324 (33.0)	148/547 (27.1)	213/470 (45.3)	
Unadjusted RR without clustering (95% CI)	Referent	0.82 (0.67 to 1.01)	1.37 (1.14 to 1.65)	<0.001
RR (95% CI)	Referent	0.84 (0.66 to 1.07)	1.33 (1.06 to 1.65)	0.013
Adjusted RR with clustering (95% CI) [*n* = 992]§	Referent	0.92 (0.57 to 1.47)	1.26 (1.00 to 1.58)	0.050
Diastolic blood pressure <90 mm Hg assuming missing blood pressure was not controlled, *n/n (%)* [*n* = 1341]	220/324 (67.9)	321/547 (58.7)	321/470 (68.3)	
RR (95% CI)	Referent	0.90 (0.79 to 1.03)	1.02 (0.90 to 1.15)	0.81
Any changes in antihypertensive drugs, *n/n (%)* [*n* = 1341]	105/324 (32.4)	156/547 (28.5)	137/470 (29.1)	
RR (95% CI)	Referent	0.88 (0.72 to 1.08)	0.90 (0.73 to 1.11)	0.33
Dose increased, *n/n (%)*	42/324 (13.0)	50/547 (9.1)	41/470 (8.7)	
RR (95% CI)	Referent	0.69 (0.46 to 1.03)	0.68 (0.44 to 1.04)	0.07
Drug added, *n/n (%)*	51/324 (15.7)	84/547 (15.4)	82/470 (17.5)	
RR (95% CI)	Referent	1.01 (0.71 to 1.44)	1.13 (0.80 to 1.60)	0.49
Diuretic, *n/n (%)*	30/324 (9.3)	49/547 (9.0)	53/470 (11.3)	
RR (95% CI)	Referent	0.99 (0.62 to 1.59)	1.22 (0.77 to 1.93)	0.41
ACE/ARB, *n/n (%)*	21/324 (6.5)	34/547 (6.2)	33/470 (7.0)	
RR (95% CI)	Referent	0.96 (0.57 to 1.63)	1.08 (0.64 to 1.84)	0.77
Calcium-channel blocker, *n/n (%)*	7/324 (2.2)	16/547 (2.9)	14/470 (3.0)	
RR (95% CI)	Referent	1.35 (0.56 to 3.26)	1.38 (0.56 to 3.38)	0.48
β-Blocker, *n/n (%)*	16/324 (4.9)	20/547 (3.7)	18/470 (3.8)	
Unadjusted RR (95% CI) ‖	Referent	0.74 (0.39 to 1.41)	0.78 (0.40 to 1.50)	NA
α-Adrenergic antagonist, *n/n (%)*	8/324 (2.5)	14/547 (2.6)	8/470 (1.7)	
RR (95% CI)	Referent	1.19 (0.51 to 3.26)	0.73 (0.29 to 1.81)	0.50
Both increased dose and drug added, *n/n (%)*	12/324 (3.7)	22/547 (4.0)	14/470 (3.0)	
RR (95% CI)	Referent	1.09 (0.54 to 2.35)	0.80 (0.38 to 1.72)	0.57
Mean medication adherence (SD) [*n* = 948]	0.89 (0.14)	0.89 (0.14)	0.88 (0.16)	
Adverse events [*n* = 1341]				
Hospitalizations, *n/n (%)*	12/324 (3.7)	16/547 (2.9)	25/470 (5.3)	
Deaths, *n/n (%)*	8/324 (2.5)	3/547 (0.6)	4/470 (0.9)	

* ACE = angiotensin-converting enzyme; ARB = angiotensin-receptor blocker; NA = not available; RR = relative risk.
† Values in square brackets are numbers of patients at risk. These numbers differ because information was missing for some patients. RRs were estimated by using the log risk binomial regression model and are unadjusted accounting for clustering unless otherwise noted. Provider was included as a random effect in the model.
‡ *P* values are for the comparison between the provider education and alert and patient education group and the provider education only group and account for clustering in the model, except when specified as a model not accounting for clustering.
§ Adjusted for preintervention systolic blood pressure, patient age, Charlson–Deyo comorbidity score, baseline medication adherence, provider type, and patient volume per provider (<30 eligible patients vs. ≥30 eligible patients).
‖ Model not stable when clustering by provider; therefore, the unadjusted RR is reported and the *P* value could not be calculated.

provider type, and provider level stratification (intracluster correlation coefficient, 0.043). For patients who received provider education, alert, and patient education, the adjusted relative risk for reaching systolic blood pressure goal was 1.31 (CI, 1.06 to 1.62; $P = 0.012$) compared with those who received provider education only (intracluster correlation coefficient, 0.043).

The alternative analysis made the conservative assumption that no patients with missing follow-up blood pressure measurements reached their systolic blood pressure goals. One hundred seven of 324 (33.0%) patients in the provider education only group, 148 of 547 (27.1%) in the provider education and alert group, and 213 of 470 (45.3%) in the provider education, alert, and patient education group reached their blood pressure goals ($P = 0.013$), for an absolute risk reduction of 12.3%. For patients who received provider education, alert, and patient education, the relative risk for reaching systolic blood pressure goal compared with those who received provider education only was 1.33 (CI, 1.06 to 1.65; $P = 0.013$; intracluster correlation coefficient, 0.063).

The secondary outcome was the proportion of patients who reached a diastolic blood pressure goal of less than 90 mm Hg. There were no between-group differences in this secondary outcome ($P = 0.81$) when adjusted for covariates and clustered by provider.

Process Measures: Intensification of Antihypertensive Regimen and Adherence

Three hundred ninety-eight patients had intensification of their blood pressure regimen: 105 of 324 in the provider education only group (32.4%); 156 of 547 in the provider education and alert group (28.5%); and 137 of 470 in the provider education, alert, and patient education group (29.1%). One hundred thirty-three patients had a dose increase in their medication (42 of 324 [13.0%] vs. 50 of 547 [9.0%] vs. 41 of 470 [8.7%]), 217 had at least 1 additional antihypertensive medication prescribed (51 of 324 [15.7%] vs. 84 of 547 [15.4%] vs. 82 of 470 [17.5%]), and 48 had a dose increase and an additional antihypertensive medication prescribed (12 of 324 [3.7%] vs. 22 of 547 [4.0%] vs. 14 of 470 [3.0%]). Medication adherence (pharmacy refills) was also measured after intervention, and there were no differences in medication adherence score among study groups (0.89 [SD, 0.14] vs. 0.89 [SD, 0.14] vs. 0.88 [SD, 0.16]; $P = 0.71$).

Of the 265 patients who had at least 1 additional antihypertensive medication prescribed, the most common medication added was a diuretic (132 of 265 [49.8%]). Thirty of the 324 patients (9.3%) in the provider education only group received a new prescription for a diuretic compared with 49 of 547 patients (9.0%) assigned to the provider education and alert group and 53 of 470 (11.3%) in the provider education, alert, and patient education group. The difference between groups was not statistically significant ($P = 0.41$). The mean preintervention blood pressure among these 106 patients was 162 mm Hg (SD, 14) versus a mean systolic blood pressure of 148 mm Hg (SD, 18) after intervention. For those prescribed diuretics, the mean changes in the 3 groups were −8.6 mm Hg (SD, 13.8), −12.8 mm Hg (SD, 19.1), and −15.4 mm Hg (SD, 21.4), respectively. The unadjusted relative risk with clustering of having a diuretic added was 1.22 (CI, 0.77 to 1.93) for patients in the provider education and alert and patient education group compared with those in the provider education only group. The second most common medication addition was an angiotensin-converting enzyme or angiotensin-receptor blocker (88 new prescriptions). There were 37 new prescriptions for calcium-channel blockers, 54 for β-blockers, and 30 for α-adrenergic antagonists (**Table 3**). The addition of a diuretic was associated with improved blood pressure control when controlling for the addition of any other agent in a logistic model ($P = 0.004$; $P > 0.1$ for all other agents).

Hospitalizations and Death during Follow-up

During the study period, January to December 2004, 15 (1.1%) participants died (8 [2.5%] in the provider education only group, 3 [0.6%] in the provider education and alert group, and 4 [0.9%] in the provider education, alert, and patient education group; $P = 0.027$). Fifty-three patients (12 [3.7%] vs. 16 [3.0%] vs. 25 [5.3%]; $P = 0.143$) were hospitalized during the 6-month period after intervention The discharge diagnosis was available for 52 of the 53 patients who were hospitalized. Five, 7, and 5 patients, respectively, were hospitalized for a cardiovascular cause in each group. The remaining hospitalizations ($n = 36$) were for noncardiovascular reasons, including new diagnoses of cancer ($n = 7$); psychiatric admissions ($n = 10$); surgical or gastrointestinal admissions ($n = 6$); pneumonia or chronic obstructive pulmonary disease exacerbation ($n = 4$), arthritis or back pain ($n = 4$); kidney stone, zoster, syndrome of inappropriate antidiuretic hormone, and hematuria ($n = 1$ for each); and unknown reasons ($n = 1$).

DISCUSSION

Our cluster randomized, controlled trial shows the effectiveness of adding patient education to provider education in improving blood pressure control among veterans with uncontrolled essential hypertension. Previous studies found that a strategy of provider education alone led to inconsistent results or minimal change in provider behavior (29–31). Therefore, we used provider education only as the control group for our study. Patients in all 3 intervention groups had clinically significant and clinically meaningful reductions in systolic blood pressure. Those receiving patient education had an additional important reduction in blood pressure. The additional 6–mm Hg reduction in blood pressure in the provider education, alert, and patient education group has the potential to reduce cerebrovascular morbidity and mortality by 42%, cor-

onary heart disease by 14%, and heart failure by 50% (13, 32–39).

The magnitude of reduction of systolic blood pressure in all 3 groups was surprising because of the modest observed changes in medications and medication adherence. Regression to the mean, secular trends in the promotion of appropriate blood pressure control, or the effectiveness of the provider education component in promoting diuretics may explain part of the reduction in blood pressure in the 3 groups. The addition of a diuretic was associated with improved blood pressure control when we controlled for the addition of any other agent ($P = 0.004$), providing further evidence that diuretics are important for treating hypertension (5, 12, 40–42).

Among the 975 patients with follow-up blood pressure recorded, 59.5% of those in the group that received provider education, alert, and patient education reached their systolic blood pressure goal compared with 42% of patients in the group that received provider education only. The magnitude of this improvement is similar to results reported in a recent systematic review (43) that evaluated many quality improvement strategies designed to improve control of blood pressure in patients with essential hypertension (median, 16.2% increase in attainment of systolic blood pressure goal). The largest reductions in blood pressure were in studies that included patient education and in those that implemented an organizational change.

This patient-centered approach has been promoted in chronic disease care to achieve collaboration between patient and provider at each visit (20, 44–51). However, past efforts to improve care through the provision of information have generally proven inadequate (52–54). Two recent trials, one done in England and the other done in Oregon, tested the effectiveness of hypertension education packets that were mailed to patients in a primary care network (55, 56). For both trials, after 1 year of follow-up, there was no difference in blood pressure between groups; however, in both studies, the intervention group scored higher on a knowledge quiz. Another study by Goldstein and colleagues (57) also focused on the appropriateness of prescribing blood pressure medication among clinicians using generalized provider education versus individualized education. These investigators found that using an individualized intervention resulted in prescribing guideline-concordant antihypertensive medications at rates more than twice those seen with the generalized intervention. Similar to our study, there were no differences in blood pressure between these 2 groups. However, many of these trials used patient education only or provider education only and differed substantially from our multifactorial intervention, which may have had an additive effect of motivating both the provider and the patient to make a change. The ongoing study by Bosworth and colleagues (58) will examine the interaction between patient- and provider-based interventions. These investigators designed a 2-year, multisite trial to evaluate provider interventions, patient interventions, and the interaction between both interventions among a sample of veterans with hypertension.

The aim of our patient education intervention was to encourage behavioral changes in patients, including increased medication adherence, which could help bring about better blood pressure control. Our observed improvements in blood pressure were not related to a measurable difference in the quantity of additional antihypertensive medications or adherence as measured by pharmacy refills among the 3 groups. It is possible that these effects were achieved through differential changes in diet and exercise or through changes in adherence that were not detected by our metric. Steiner and colleagues (26, 28) reported that up to 33% of participants in their blood pressure validation study obtained substantial oversupplies of medications, thus limiting their results. The adherence measure only takes into account prescription filling and not actual use, which might then result in imprecision in our measurement of patient adherence and exclude a potentially important reason for the improvement in blood pressure control among those in the patient education group.

Study limitations may have affected the magnitude of the interventions. Provider crossover probably occurred between study groups because some alerts were forwarded to the appropriate provider if provider panels were changed and patients were reassigned. If alerts were forwarded to providers who were in the control group, we would be less likely to find differences among groups. Because 27% of the study patients did not have at least 1 recorded blood pressure reading after 6 months of follow-up, we conducted an alternative analysis, assuming that none of these patients reached their systolic blood pressure goal. Under this conservative assumption, the intensive intervention group had a relative risk of 1.26 for reaching blood pressure control compared with the provider education only group ($P = 0.050$). The consistency of these results in this conservative estimate bolsters our confidence in these findings.

Despite the well-established causal link between hypertension treatment and patient outcomes and more than 25 years of published guidelines for hypertension management, there remains a profound gap between recommended and delivered care (2–4, 6, 8, 9). In our study, approximately one third of the veterans had their antihypertensive regimens intensified when elevated blood pressure indicated the appropriateness of such intensification. At the end of the study period, our primary care providers were insufficiently aggressive, although this study was completed 18 months after the JNC 7 guidelines were published. The Institute of Medicine's report *Crossing the Quality Chasm* (59) suggested that without active interventions to disseminate new knowledge generated by randomized trials, it takes 17 years on average for that knowledge to be adopted into practice.

Comprehensive health care delivery systems aimed at

the continual improvement of blood pressure control have the potential to improve the health of millions of people in the United States. Our findings suggest that there is a 17.5% absolute increase in the number of people who reach blood pressure goals when quality improvement strategies include patient education compared with provider interventions alone. Even minimal interventions that increase collaboration between patient and provider can improve our systems of care and lead to superior patient outcomes. Future studies are needed to assess the relative benefit of variations in patient and provider interventions to create and evaluate patient-centered, effective, timely, equitable, safe, and efficient care (59).

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