A multicomponent quality improvement intervention to improve blood pressure and reduce racial disparities in rural primary care practices

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The Southeastern United States has the highest prevalence of hypertension and African Americans have disproportionately worse blood pressure control. The authors sought to evaluate the effect of a multicomponent practice-based quality improvement intervention on lowering mean systolic blood pressure (SBP) at 12 and 24 months compared with baseline among 525 patients, and to assess for a differential effect of the intervention by race (African Americans vs white). At 12 months, both African Americans (−5.0 mm Hg) and whites (−7.8 mm Hg) had a significant decrease in mean SBP compared with baseline, with no significant between-group difference. Similarly, at 24 months, mean SBP decreased in both African Americans (−6.0 mm Hg) and whites (−7.2 mm Hg), with no significant difference between groups. Notably, no significant racial disparity in mean SBP at baseline was shown. The intervention was effective in lowering mean SBP in both African Americans and whites but there was no differential effect of the intervention by race.

1 | BACKGROUND

Hypertension (HTN) affects more than 80 million persons in the United States[1] and increases the risk of all-cause mortality and mortality due to coronary heart disease, stroke, end-stage renal disease, and heart failure.[2] The Southeastern United States has the highest prevalence of HTN.[3] Racial differences in HTN prevalence and control are persistent,[4] with African Americans (AAs) having among the highest prevalence of HTN in the world and poor rates of control.[5] Given the excess morbidity and mortality associated with poorly controlled HTN in AAs, it is imperative to identify interventions that improve blood pressure (BP) control among this population, particularly those in the Southeast.

Contributors to BP control exist at multiple levels along the socioecological framework,[6] including the individual level (eg, literacy, medication adherence), the patient-provider interaction level (eg, communication), and the organizational/practice level (eg, clinical decision support). Therefore, interventions to improve BP control should be designed and implemented with attention to addressing multilevel determinants, including using strategies that have been shown to improve BP control in racial/ethnic minorities.[6–9] In particular, team-based care, patient education, facilitated relay of clinical data, supported self-management, home BP monitoring, and health coaching have demonstrated effectiveness in controlling BP.[7,10]

This study evaluated the effect of a multicomponent practice-based quality improvement (QI) intervention on lowering systolic BP (SBP) in a cohort of patients selected on having uncontrolled HTN as measured at their practice. We also aimed to determine whether the intervention would have a differential effect by race. We hypothesized that the intervention would reduce mean SBP at both 12 and 24 months overall and that AA patients would have greater improvement in lowering SBP compared with white patients, based on our inclusion of strategies that have been shown to be particularly effective in racial/ethnic minorities.

2 | METHODS

2.1 | Study design and setting

We conducted a prospective cohort study (2010–2015) involving 525 adults with HTN across six primary care practices in Lenoir County, a poor, economically distressed county in eastern North Carolina. Lenoir County has more residents living below the federal poverty level than the rest of the state and, in 2007, 23% of the residents were eligible for Medicaid, compared with 15% for the state.[11]

The sites included three private practices, a hospital-owned practice, and two community health centers. The practices varied in size from single-provider practices to multispecialty group practices. Study recruitment occurred from October 2011 to October 2012 with follow-up completed in October 2014. We used a nonrandomized observational trial design to maximize feasibility and acceptability for conducting this research in busy rural primary care practices unaccustomed to participating in research and to facilitate broad community participation.[12] Detailed information on the study design and methods has been previously published in a study protocol paper.[13,14] Briefly, the study included a formative phase, where we collected data from 41 in-depth interviews with patients, providers, and staff (68.5% were AA, 7.3% were American Indian, and 7.3% were mixed race) to assess their perceptions of resources and barriers that influence HTN control in their region.[14] During the implementation phase of this study, we conducted a practice-based intervention using a QI approach, with strategies designed to change practice and patient behavior (outlined in Table 1).

2.2 | Participants

Working collaboratively with practice staff, we identified and recruited potentially eligible patients. Inclusion criteria were English-speaking patients from participating practices with an established HTN diagnosis and at least one visit in the last year with an office measurement of SBP ≥150 mm Hg. For most of the practices, BP was measured by medical assistants or licensed practical nurses. To attempt to optimize our ability to find participants with uncontrolled BP when measured using guideline-supported techniques (the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure), we selected a study referral SBP cutoff value of 150 mm Hg, based on data suggesting that BP readings obtained using guideline-recommended techniques are lower, on average by 12.4 mm Hg systolic, than those obtained in using usual care processes.[15] For enrolled study participants, BP measurement was obtained by trained research staff at a community-based data collection site. We did not assess for or exclude individuals with white-coat HTN. Eligible participants provided written informed consent.

This study was funded by the National Institutes of Health (NIH)/National Heart, Lung, and Blood Institute as part of the Centers for Population Health and Health Disparities. This study was approved by the institutional review board at the University of North Carolina at Chapel Hill and is registered on clinicaltrials.gov (NIH study registry number NCT01425515).

2.3 | Intervention components

We used a participatory approach to intervention development, engaging the providers and staff of the participating practices. Briefly, our multicomponent, theory-driven intervention included strategies at the practice/organization and the patient levels. We adapted the Promoting Action on Research Implementation in Health Services (PARIHS) model for the practice-level intervention, to conceptualize practice change.[16] The practices and the community-based health coach were taught communication and behavior change strategies based on social cognitive theory,[17] the transtheoretical model of behavior change, and motivational interviewing.[18,19] Table 1 summarizes the intervention components. The telephone coaching part of our

TABLE 1 Intervention Components

	Topics Covered/Description	Frequency
Practice-level strategies		
Regional dinner meetings	• Use of population-level hypertension (HTN) data to drive change and enhance quality • Strategies for systematizing care for all HTN patients (eg, identifying blood pressure [BP] goals, assessing BP knowledge, and using and reviewing home BP monitoring readings) • Medication adherence • Case study presentations—challenging cases and treatment options • Phone coaching, motivational interviewing techniques, and goal setting • Importance of health literacy for BP control, including explanation and demonstration of strategies (eg, videos and role play) to support patients with low literacy (eg, teach back and care coordination)	Quarterly (in person)
General quality improvement activities	• Define HTN population and abstract and review HTN control data from the EHR • Instruction on accurate BP measurement • Design and use of visit planners • Design and use of HTN medication algorithm	Throughout study with assistance from practice facilitators (ie, members of the research team) who visited practices regularly and via monthly "design team" conference calls with practice providers, staff, and research team
Patient-level strategies (for all 525 patients in the cohort)		
Phone coaching	• Benefits of BP medication, medication adherence, side effects, strategies to enhance adherence • Strategies to enhance communication with healthcare providers • Strategies for incorporating physical activity into one's lifestyle and mitigating barriers to physical activity • Healthy eating: reading food labels, understanding salt reduction, Dietary Approaches to Stop Hypertension (DASH) diet, portion control • Home BP measurement: accurate measurement technique, reviewing recent BP readings, addressing BP goals/targets • Weight: discussion of relationship between weight and HTN control	Monthly
Home BP monitoring	• All patients were given automated, oscillometric home blood pressure monitors at study enrollment. • Patients were instructed to measure and record their BP three times per week and to bring their records to every primary care and research clinic visit. • Primary care physicians were encouraged to review and reinforce the value of home monitoring.	Throughout study

intervention was informed by components of Bosworth's Take Care of Your Blood Pressure (TCBY) study,[20] which included telephone case management. Investigators from Bosworth's study helped our team develop the phone coaching software and train our coaches. We used two trained health coaches (non-nurses) who were external to the practice and were trained in motivational interviewing.[19] The lead coach was a certified integrative health coach. He also received a 4-hour training session on the telephone management program and participated in follow-up phone calls to discuss challenges with implementation. The lead coach trained the second coach. Additional details on the health coaching, including our assessment of fidelity to the health coaching intervention, is in press.[21] The coaches delivered the intervention via 12 monthly phone calls that lasted 15 to 20 minutes each. The coaches helped participants set care goals, reviewed appropriate BP measurement techniques, and discussed BP target values on each phone call. Participants were also mailed educational materials to correspond to the topics of each upcoming phone coaching session. A manuscript with additional descriptions of and lessons learned from implementing the phone coaching component of this intervention is currently in press.[21]

2.4 | Data sources/measurement

We collected data at baseline and at 6, 12, 18, and 24 months post-enrollment. Instruments used for data collection have been outlined in a previous publication.[13] All outcomes measure assessment was done by trained research staff using measurements obtained at research study visits, not part of routine clinical care.

2.5 | BP and race

BP was measured by trained research staff using the Omron HEM-907 automated BP monitor (Omron Healthcare, Inc, Vernon Hills, IL). A research assistant (RA) recorded the average of three sequential measurements obtained at 60-second intervals after the participant was seated for 5 minutes with both feet on the floor.[22,23]

Race was self-reported with categories consistent with the US Census.

2.6 | Covariates

Other self-reported covariates of interest included age, sex, educational level, employment status, health insurance coverage (including Medicare, Medicaid, commercial insurance), annual household income, current cigarette smoking, taking antihypertensive medications, antihypertensive medication nonadherence (assessed using the 8-item Morisky Medication Adherence Scale),[24] and comorbidities. We assessed diabetes based on self-report of physician-diagnosed diabetes or hemoglobin A_{1c} ≥6.5. We also measured literacy level using the Short Test of Functional Health Literacy Assessment (STOFHLA)[25] and measured height and weight (to calculate body mass index).

2.7 | Lifestyle study

Thirty-eight percent of study participants were simultaneously enrolled in a community-based lifestyle and weight loss intervention given that individuals with HTN are at increased risk for cardiovascular disease and may benefit from receiving a lifestyle intervention. Briefly, the lifestyle study began with a 4-month intervention phase focused on improving dietary fat and carbohydrate quality and increasing physical activity. During the remainder of the 2-year intervention, participants with a body mass index ≥25 kg/m^2 were invited to take part in a weight loss intervention. Findings from that study, including effects of the lifestyle intervention on SBP, have been published.[26]

2.8 | Analyses

The primary aim of the study was to evaluate the effectiveness of the intervention on average SBP at 12 and 24 months overall and by race (AAs vs whites). Seven participants were excluded from the race-stratified analysis because they were categorized as "other" race. We also examined the proportion of the sample that achieved BP control (BP <140/90 mm Hg) at each time point (Figure 2). Our sample size calculation was based on detecting a difference in mean SBP of 3.5 mm Hg between AAs and white patients using a one-sided .05 *t* test, assuming a baseline mean difference in SBP between AAs and whites of approximately 5 mm Hg.

We used descriptive statistics to summarize the sample characteristics overall and by race and compared participant characteristics by race using chi-square test for categorical variables and *t* test for continuous variables. The overall effect of the intervention on reducing SBP at 12 and 24 months was tested using a paired *t* test. We compared mean changes in SBP between AAs and white patients using simple linear regression and multivariable regression controlling for age, sex, co-enrollment in the lifestyle study, and other covariates that were imbalanced between the races (educational level, diabetes, and weight). We did not adjust for household income as it was highly correlated with educational level and was not reported by 15% of study participants.

We conducted the analyses with the intent-to-treat (ITT) principle by imputing missing SBP data using the last-observation-carried-forward approach, as well as conducting the analyses on only participants with nonmissing outcome data for the time period of interest. As results were qualitatively the same, we report outcomes for returnees only in the main text but results for ITT analyses are included as Supporting Information.

We also conducted longitudinal analyses using generalized linear mixed models that included a random intercept to account for within-subject correlation over time and with race and time as fixed effects, to examine changes over time and to assess changes in SBP at 12 and 24 months. Because the results were similar to results obtained using paired *t* tests and linear regressions at single time points, we do not present the results from longitudinal models. Analyses were conducted using SAS software, version 9.3 (SAS Institute Inc, Cary, NC).

Finally, we conducted sensitivity analyses, including stratifying our primary analyses based on: (1) co-enrollment in a lifestyle study (Tables S5 and S6), and (2) having an SBP at baseline of ≥140 mm Hg.

Because we did not find significant differences in SBP by race when comparing practice as a fixed vs a random effect (*P*=.08), we did not adjust for clustering of patients within practices in the results we present.

3 | RESULTS

3.1 | Participant characteristics

We enrolled 525 participants across six practices. Figure 1 shows the participant flow diagram for the study. Overall, the mean age of our sample was 58 years, and the majority of participants were female with a high school or less education (Table 2). Twenty-three percent of the sample had an STOFHLA score in the "low literacy" category. Most of the participants (75%) had health insurance. Forty-three percent of the overall sample had diabetes, based on either self-report or hemoglobin A_{1c} ≥6.5. Twenty-three percent were current smokers. At baseline, mean systolic and diastolic BP was 139 mm Hg and 82 mm Hg, respectively. Notably, there was no significant racial difference in SBP at baseline, with AAs having a mean SBP of 140 mm Hg and whites having a mean SBP of 137 mm Hg (*P*=.25). Most participants (89%) reported taking antihypertensive medications (mean of 1.9 medication classes) at baseline. Thirty-eight percent of the overall sample was also concurrently enrolled in a lifestyle intervention study.

3.2 | Effect of intervention on mean change in SBP at 12 and 24 months

After examining the differences in baseline characteristics between attendees and nonattendees at 12- and 24-month follow-up visits, we found that attendees were more likely than nonattendees to be older, AA, and have moderate-high medication adherence.

At 12 months compared with baseline, mean SBP was 6 mm Hg lower for the overall sample in unadjusted analyses (Table 3). Both AAs (−5.0 mm Hg) and whites (−7.8 mm Hg) had a significant decrease

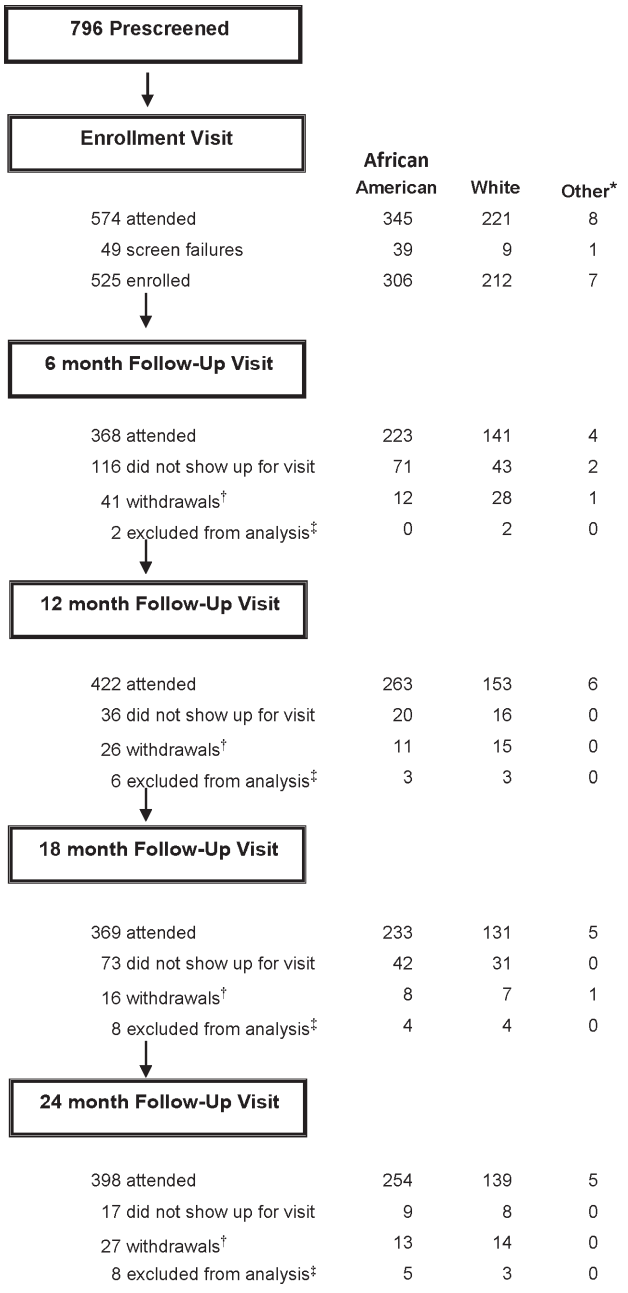

FIGURE 1 Study flow diagram. *Other race included mixed race, those who identified race as Hispanic or human, and those who refused to identify. †Withdrawals were due to death, medical reasons, moved out of area, requested to stop participation, personal reasons, lost to follow-up, or other reason. ‡Exclusions for analysis were due to diagnosis of cancer, gastric bypass surgery, gastric sleeve surgery, and pregnancy

in mean SBP (both *P* values <.001), but the unadjusted difference in the changes in SBP between the races was not statistically significant (−2.7 mm Hg, *P*=.26). After multivariable adjustment, the difference in the changes in mean SBP between race groups remained small and not statistically significant.

Table 4 presents the differences in mean SBP from baseline to 24 months overall and by race. Mean SBP decreased by 6.4 mm Hg overall. Similar to the baseline to 12 month comparisons, mean SBP decreased in both AAs and whites, but the unadjusted between-race difference in mean SBP change was small and not statistically significant (−1.3 mm Hg, *P*=.61). The adjusted differences in mean SBP change by race remained nonsignificant after multivariable adjustment.

The corresponding results based on ITT analysis are presented in Tables S1 and S2.

We also conducted a longitudinal analysis examining SBP changes from 0 to 6, 6 to 12, 12 to 18, and 18 to 24 months (data not shown). This analysis demonstrated that the greatest reduction in SBP occurred during the first 12 months (*P*<.01 for both the 0 to 6 months and 6 to 12 months time periods) and the trend was similar in AAs and whites.

3.3 | Effect of intervention on changes in SBP among those co-enrolled in a lifestyle study

Tables S3 and S4 in the Supporting Information present data on racial differences in SBP from baseline to 12 months and baseline to 24 months within strata of co-enrollment in the lifestyle study. Among those not co-enrolled in the lifestyle study, the racial difference in SBP change was −5.7 (−11.1 to −0.2), slightly favoring whites (*P*=.04) in the unadjusted analysis. Among those who were co-enrolled in the lifestyle study, the racial difference in SBP change was 1.5 (−7.5 to 10.4) in the unadjusted analysis. The data on racial differences in SBP from baseline to 24 months within strata of co-enrollment in the lifestyle study were similar to the data for 12 months.

Corresponding results based on ITT analysis are presented in Tables S3 and S4.

3.4 | Effect of intervention on changes in SBP among those with baseline SBP ≥140 mm Hg

Among participants who returned for 12-month follow-up, 183 participants (66 whites, 117 AAs) had a baseline SBP ≥140 mm Hg, with an overall mean SBP of 158 mm Hg (156 to 159 mm Hg). At 12 months, the mean SBP for the overall sample was 141 mm Hg (138 to 144 mm Hg). While both AAs and whites had highly significant reductions in mean SBP from baseline to 12 months (mean for AAs, 15.3 mm Hg; mean SBP for whites, 17.4; both *P* values <.0001), the between-race difference in mean BP change was not statistically significant (*P*=.6). Among participants who returned for 24-month follow-up (175 participants; 62 whites, 113 AAs) the results were similar (data not shown).

3.5 | Effect of intervention on achieving BP control (<140/90 mm Hg) at 12 and 24 months

Figure 2 presents the percentage of patients with controlled BP at each time period. At baseline, 55% of the overall sample had controlled BP (54% AAs and 56% whites). At 12 months, 70% of the overall sample had controlled BP. Of those who were uncontrolled at baseline (n=183), 56% were controlled at 12 months and this

TABLE 2 Baseline Participant Characteristics

Demographics	Overall N=525[a]	African American n=306	White n=212	*P* Value
Age, mean (range)	58 (20–93)	57 (25–93)	60 (22–91)	.02
Female sex	356 (68)	218 (71)	134 (63)	.05
Education: high school or less	382 (73)	246 (80)	132 (62)	<.001
Low literacy				
STOFHLA score=0–22 (6% missing)	111 (23)	85 (30)	25 (12)	<.001
Currently have health insurance	394 (75)	218 (71)	170 (80)	.02
Employment status				
Working full or part time	199 (38)	120 (39)	74 (35)	.32
Household income ≤$40,000 (15% missing)	350 (78)	224 (88)	121 (66)	<.001
Self-rated health (good–excellent)	322 (61)	187 (61)	130 (61)	.96
CVD and risk factors for CVD				
CVD	122 (23)	69 (23)	52 (25)	.60
Diabetes	227 (43)	154 (50)	70 (33)	<.001
Current cigarette smoker	118 (23)	69 (23)	47 (22)	.54
Systolic BP, mean (SE), mm Hg	139 (1.0)	140 (1.3)	137 (1.4)	.25
Diastolic BP, mean (SE), mm Hg	82 (0.6)	83 (0.8)	80 (0.8)	.01
Systolic BP ≥140 mm Hg	231 (44)	138 (45)	89 (42)	.48
Medication class count, mean (SE) (4% missing)	1.9 (.01)	2.1 (0.1)	1.6 (0.1)	<.001
Antihypertensive medication adherence				
Low (Morisky score <6) (11% missing)	187 (40)	128 (42)	58 (34)	.05
Lifestyle				
Lifestyle study participant	200 (38)	130 (42)	72 (34)	.07
Physiologic mean (SE)				
Weight, kg (1% missing)	98 (1.2)	102 (1.5)	93 (1.8)	<.001
BMI (2% missing)	36 (0.4)	37 (0.6)	34 (0.6)	<.001
No. of comorbidities, mean (SE)[b]	3.5 (0.1)	3.4 (0.1)	3.7 (0.2)	.04

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure; CVD, cardiovascular disease; HbA_{1c}, hemoglobin A_{1c}; SE, standard error; STOFHLA, Short Test of Functional Health Literacy Assessment.

Data are reported as number (percentage) of participants unless otherwise indicated.

[a]Seven not categorized (one mixed race, two erroneous, four refused).

[b]Comorbidities include heart failure, high blood pressure or hypertension, high cholesterol, chronic obstructive pulmonary disease, kidney disease, lung disease, stroke or mini-stroke, depression, chronic back pain, cancer, diabetes, arthritis, fibromyalgia, and obstructive sleep apnea.

significantly differed by race (62% of whites vs 52% of AAs, *P*<.0001). At 24 months, 54% of the overall sample had controlled BP. Of those who were uncontrolled at baseline (n=175), 59% had controlled BP at 24 months and this was significantly different by race (56% of whites vs 61% of AAs, *P*<.0001).

4 | DISCUSSION

Our study suggests that a multicomponent, multilevel intervention delivered in rural primary care practice can lower SBP over a 2-year period among AA and white patients with HTN. Although our intervention included both practice- and individual-level strategies that have been shown to improve BP control in racial/ethnic minority groups, our intervention was not differentially more effective in AAs than whites.

Contrary to what we expected based on most extant data, we did not see a racial disparity in SBP at baseline. On the contrary, BP was fairly well-controlled (mean SBP 139 mm Hg overall) with no significant differences in mean SBP by race, using standard BP measurements obtained at study visits by trained research staff. Similar studies have also shown fairly high levels of controlled BP at baseline among

TABLE 3 Mean Change in SBP at 12 Months, Overall and By Race

Group	No.	Baseline	12 Months	Change in SBP: Baseline Minus 12 Months	Unadjusted Racial Difference (AAs minus Whites) in SBP Change	Model 1: Adjusted Racial Difference in SBP Change[a]	Model 2: Adjusted Racial Difference in SBP Change[b]	Model 3: Adjusted Racial Difference in SBP Change[c]
SBP, mm Hg (95% CI)								
Overall	408	139 (137–141)	133 (131–135)	6.0 (4.1–8.0) *P*<.01				
AAs	257	139 (137–142)	134 (132–137)	5.0 (7.6–2.5) *P*<.01	−2.7 (−7.5 to 2.0)	−1.7 (−6.5 to 3.0)	−2.1 (−6.8 to 2.6)	−3.4 (−7.7 to 0.9)
Whites	151	138 (135–140)	130 (127–133)	7.8 (10.6–4.9) *P*<.001				

Abbreviations: AAs, African Americans; CI, confidence interval; SBP, systolic blood pressure.
[a]Model adjusted for age and sex.
[b]Model adjusted for age, sex, and co-enrollment in the lifestyle study.
[c]Model adjusted for age, sex, co-enrollment in the lifestyle study, education level, diabetes, weight, and health insurance.

TABLE 4 Mean Change in SBP at 24 Months, Overall and By Race

Group	No.	Baseline	24 Months	Change in SBP: Baseline Minus 24 Months	Unadjusted Racial Difference (AAs Minus Whites) in SBP Change	Model 1: Adjusted Racial Difference in SBP Change[a]	Model 2: Adjusted Racial Difference in SBP Change[b]	Model 3: Adjusted Racial Difference in SBP Change[c]
SBP, mm Hg (95% CI)								
Overall	383	139 (137–141)	133 (131–135)	−6.4 (8.3–4.4) *P*<.001				
AAs	246	140 (137–142)	134 (132–136)	6.0 (8.5–3.3) *P*<.001	−1.3 (−6.1 to 3.6)	0 (−4.8 to 4.8)	−0.5 (−5.3 to 4.4)	−2.0 (−6.1 to 2.0)
Whites	137	138 (136–141)	131 (129–134)	7.2 (10.0–4.3) *P*<.001				

Abbreviations: AAs, African Americans; CI, confidence interval; SBP, systolic blood pressure.
[a]Model adjusted for age and sex.
[b]Model adjusted for age, sex, and co-enrollment in the lifestyle study.
[c]Model adjusted for age, sex, co-enrollment in the lifestyle study, education level, diabetes, weight, and health insurance.

hypertensive patients when measured by trained research staff.[27] There is a very plausible reason for these findings. We targeted patients for enrollment who had a previously documented in-clinic SBP ≥150 mm Hg, as measured by clinic staff. It is likely that this level of BP was an overestimate of the patient's "true" SBP given that prior studies have noted limitations of office BP measurement, including low reproducibility and difficulty in obtaining high-quality and accurate measurement.[28,29] Together, these factors resulted in our enrolling a sample with much better BP control than we expected. Moreover, the near-normal BP readings at baseline limited our ability to demonstrate effectiveness of the intervention and show superior outcomes among AAs. Although we did not see a differential effect of the intervention in AAs, the fact that we successfully engaged AAs is, in and of itself, a success. Fifty-eight percent of the sample was AA, with almost 30% being AA men—a group that generally has less physician contact than other groups, lower rates of HTN treatment and control, and are often felt to be more difficult to engage and enroll in research studies.[1,30,31]

The overall effect sizes noted in our study (−6.0 mm Hg at 12 months and −6.4 mm Hg at 24 months) are consistent with published estimates from a systematic review of QI strategies for HTN management.[7] In that review, intervention groups experienced median reductions in SBP that were 4.5 mm Hg (interquartile range, 1.5 to 11.0) greater than control groups. We can directly compare our findings with those from two other multilevel, multicomponent interventions that have examined intervention effects on reducing racial disparities in BP.[32,33] Jackson and colleagues[32] conducted a post hoc analysis of data from a randomized clinical trial conducted in the Veterans Affairs healthcare system, which tested interventions consisting of home BP monitoring plus medication management with clinical decision support, home BP monitoring plus a behavioral management intervention, or a combined medication management and behavioral management intervention against usual care. This study demonstrated differential intervention effects on SBP over time for AAs and whites, with AAs benefiting from the intervention while whites observed no

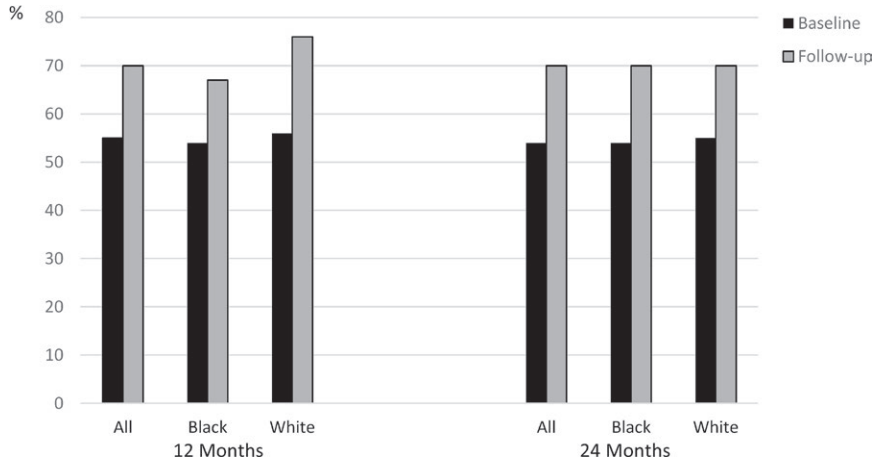

FIGURE 2 Percentage of patients with controlled blood pressure (<140/90 mm Hg), overall and by race, at baseline and at 12- and 24-month follow-up

benefit. AAs in the combined intervention group, compared with the usual care group, had significantly lower SBP at 12 months (−6.6 mm Hg; 95% confidence interval, −12.5 to −0.7) and 18 months (−9.7 mm Hg; 95% confidence interval, −16.0 to −3.4).

In another post hoc analysis, Bosworth and colleagues[33] compared the effects of several interventions (home BP monitoring, behavioral phone calls without medication management, and a combination of the two) with usual care among white and predominantly AA (95%) patients. The race by time by treatment effect suggested likely differential intervention effects over time in SBP for whites and nonwhite patients (P=.08). At 12 months, nonwhite participants in all three intervention groups had SBP decreases of 5.3 mm Hg to 5.7 mm Hg compared with usual care (all P<.05). At 24 months, nonwhite patients in the combined intervention arm continued to have lower SBP compared with the usual care group (7.5 mm Hg, P<.02). Among whites, mean SBP was not significantly different at 12 and 24 months for intervention arm patients compared with usual care patients.

Other studies have also tested practice-based interventions with intervention strategies primarily targeted at patients and physicians.[20,34–36] The effects on BP of these multicomponent interventions is mixed. Unlike our study, all of these studies except for one[35] used a randomized trial design, most enrolled a majority or exclusively racial minority population, and therefore did not examine differential intervention effects by race.

We propose two possible explanations for why our intervention was not differentially more effective in AAs than whites. First, our intervention was a practice-level QI intervention that employed strategies that have been associated with BP improvement in racial minority populations, such as supported self-management, home BP monitoring, continuing medical education, practice facilitation, and team-based HTN care[7,10,37–41]; however, we did not *culturally tailor* our intervention to AAs. Previous research has shown that QI strategies can be effective in improving SBP[42,43]; however, the effects of generalized QI programs on disparities reduction have found mixed results.[44,45] Some studies have shown a reduction in disparities in processes of care with little effect on disparities in clinical outcomes. Second, our patient-level intervention may not have sufficiently addressed the unique factors that influence BP in AAs. Studies have demonstrated that there may be racial differences in patterns of interaction within the healthcare system,[46] psychosocial and cultural factors,[46] and disease-perception issues (eg, beliefs about HTN).[47] These factors may have differential effects on SBP in AAs compared with whites and our intervention did not target these contributors to BP control.

5 | STUDY LIMITATIONS AND STRENGTHS

Our study's findings should be considered in light of its limitations. First, as a cohort study reporting pre-post measures, observed changes could be due to secular trends or other factors and not the intervention per se. Second, our missing data rate of about 25% at each time period may have biased our results. However, we were more likely to retain AAs—a population that many researchers have deemed "hard to recruit and retain"—than whites. Third, the QI nature of our study was a limitation and a strength. We designed and implemented the intervention with broad stakeholder input to maximize feasibility and sustainability.[14] However, the level of engagement with the intervention was inconsistent and variable across the six practices. Issues such as staff turnover and practices' novelty in participating in research may have adversely impacted intervention delivery. Fourth, we have several limitations with respect to BP assessment. We used only a single elevated SBP as the enrollment criteria. We did not use ambulatory BP monitoring to screen participants for HTN, as this was not a US Preventive Task Force Grade A recommendation at the time this study was designed and implemented. Last, the "bundled" nature of our intervention makes it difficult to discern which components of the intervention were the most beneficial.

Despite these limitations, our study has strengths. We focused exclusively on a rural impoverished community where the burden of HTN is high, whereas other studies have focused on more urban populations.[32,33] Second, our study was specifically powered to assess effect modification by race, unlike other studies that conducted post

hoc analyses by race[32,33] or that did not examine race differences in intervention effects.[48]

6 | CONCLUSIONS

Our study demonstrates that we can reduce mean SBP and improve BP control among AA and white patients with HTN from rural underserved communities through a systematic practice-based QI intervention. However, our intervention is not more effective in AAs compared with whites. Surprisingly, we did not show a racial disparity in SBP at baseline and baseline SBP of the sample was fairly well controlled when measured by trained research staff outside of the clinical encounter. This highlights well-known issues with approaches to BP measurement and the disparity of HTN control in daily practice compared with clinical trials.[49,50]

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CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest to disclose.

REFERENCES

1. Mozaffarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics-2016 update: a report from the American Heart Association. *Circulation*. 2016;133:e38–e360.
2. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA*. 2003;289:2560–2572.
3. Howard G, Prineas R, Moy C, et al. Racial and geographic differences in awareness, treatment, and control of hypertension: the reasons for geographic and racial differences in stroke study. *Stroke*. 2006;37:1171–1178.
4. Centers for Disease Control and Prevention (CDC). Racial/ethnic disparities in awareness, treatment, and control of Hypertension—United States, 2003-2010. *MMWR Morb Mortal Wkly Rep*. 2013;2:351–355.
5. Mozaffarian D, Benjamin EJ, Go AS, et al. Executive summary: heart disease and stroke statistics-2016 update: a report from the American Heart Association. *Circulation*. 2016;133:447–454.
6. Mueller M, Purnell TS, Mensah GA, Cooper LA. Reducing racial and ethnic disparities in hypertension prevention and control: what will it take to translate research into practice and policy? *Am J Hypertens*. 2015;28:699–716.
7. Walsh JM, McDonald KM, Shojania KG, et al. Quality improvement strategies for hypertension management: a systematic review. *Med Care*. 2006;44:646–657.
8. Dennison CR, Post WS, Kim MT, et al. Underserved urban African American men: hypertension trial outcomes and mortality during 5 years. *Am J Hypertens*. 2007;20:164–171.
9. Connell P, Wolfe C, McKevitt C. Preventing stroke: a narrative review of community interventions for improving hypertension control in black adults. *Health Soc Care Community*. 2008;16:165–187.
10. Glynn LG, Murphy AW, Smith SM, Schroeder K, Fahey T. Interventions used to improve control of blood pressure in patients with hypertension. *Cochrane Database Syst Rev*. 2010;Cd005182.
11. Lenoir County Health Department. Community Health Assessment of Lenoir County. 2007 report www.co.lenoir.nc.us. Accessed June 3, 2010.
12. Handley MA, Schillinger D, Shiboski S. Quasi-experimental designs in practice-based research settings: design and implementation considerations. *J Am Board Fam Med*. 2011;24:589–596.
13. Halladay JR, Donahue KE, Hinderliter AL, et al. The Heart Healthy Lenoir project—an intervention to reduce disparities in hypertension control: study protocol. *BMC Health Serv Res*. 2013;13:441.
14. Donahue KE, Vu MB, Halladay JR, et al. Patient and practice perspectives on strategies for controlling blood pressure, North Carolina, 2010-2012. *Prev Chronic Dis*. 2014;11:E69; quiz E69.
15. Burgess SE, MacLaughlin EJ, Smith PA, Salcido A, Benton TJ. Blood pressure rising: differences between current clinical and recommended measurement techniques. *J Am Soc Hypertens*. 2011;5:484–488.
16. Kitson AL, Rycroft-Malone J, Harvey G, McCormack B, Seers K, Titchen A. Evaluating the successful implementation of evidence into practice using the PARiHS framework: theoretical and practical challenges. *Implement Sci*. 2008;3:1.
17. Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory*. Englewood Cliffs, NJ: Prentice Hall; 1986.
18. Rollnick S, Miller WR. What is motivational interviewing? *Behav Cogn Psychother*. 1995;23:325–334.
19. Miller W, Rollnick S. *Motivational interviewing: preparing people to change addictive behavior*. New York, NY: Guilford Press; 1991.
20. Bosworth HB, Olsen MK, Neary A, et al. Take Control of Your Blood Pressure (TCYB) study: a multifactorial tailored behavioral and educational intervention for achieving blood pressure control. *Patient Educ Couns*. 2008;70:338–347.
21. Donahue KE, Halladay JR, Cene C, et al. Lessons learned from implementing health coaching in the Heart Healthy Lenoir Hypertension Study. *Prog Community Health Partnersh*. 2016. In Press.
22. El Assaad MA, Topouchian JA, Darne BM, Asmar RG. Validation of the Omron HEM-907 device for blood pressure measurement. *Am J Hypertens*. 2002;15:87A.
23. White WB, Anwar YA. Evaluation of the overall efficacy of the Omron office digital blood pressure HEM-907 monitor in adults. *Blood Press Monit*. 2001;6:107–110.
24. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care*. 1986;24:67–74.
25. Baker DW, Williams MV, Parker RM, Gazmararian JA, Nurss J. Development of a brief test to measure functional health literacy. *Patient Educ Couns*. 1999;38:33–42.
26. Keyserling TC, Samuel-Hodge CD, Pitts SJ, et al. A community-based lifestyle and weight loss intervention promoting a Mediterranean-style diet pattern evaluated in the stroke belt of North Carolina: the Heart Healthy Lenoir Program. *BMC Public Health*. 2016;16:732.
27. Bosworth HB, Olsen MK, Grubber JM, et al. Two self-management interventions to improve hypertension control: a randomized trial. *Ann Intern Med*. 2009;151:687–695.
28. Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans: an AHA scientific statement from the Council on High Blood Pressure Research Professional and Public Education Subcommittee. *J Clin Hypertens (Greenwich)*. 2005;7:102–109.

29. Myers MG, Godwin M, Dawes M, Kiss A, Tobe SW, Kaczorowski J. Measurement of blood pressure in the office: recognizing the problem and proposing the solution. *Hypertension*. 2010;55:195–200.
30. Victor RG, Leonard D, Hess P, et al. Factors associated with hypertension awareness, treatment, and control in Dallas County, Texas. *Arch Intern Med*. 2008;168:1285–1293.
31. Hill MN, Bone LR, Hilton SC, Roary MC, Kelen GD, Levine DM. A clinical trial to improve high blood pressure care in young urban black men: recruitment, follow-up, and outcomes. *Am J Hypertens*. 1999;12:548–554.
32. Jackson GL, Oddone EZ, Olsen MK, et al. Racial differences in the effect of a telephone-delivered hypertension disease management program. *J Gen Intern Med*. 2012;27:1682–1689.
33. Bosworth HB, Olsen MK, Grubber JM, Powers BJ, Oddone EZ. Racial differences in two self-management hypertension interventions. *Am J Med*. 2011;124:e461–e468.
34. Roumie CL, Elasy TA, Greevy R, et al. Improving blood pressure control through provider education, provider alerts, and patient education: a cluster randomized trial. *Ann Intern Med*. 2006;145:165–175.
35. Svetkey LP, Pollak KI, Yancy WS Jr, et al. Hypertension improvement project: randomized trial of quality improvement for physicians and lifestyle modification for patients. *Hypertension*. 2009;54:1226–1233.
36. Johnson W, Shaya FT, Khanna N, et al. The Baltimore Partnership to Educate and Achieve Control of Hypertension (The BPTEACH Trial): a randomized trial of the effect of education on improving blood pressure control in a largely African American population. *J Clin Hypertens (Greenwich)*. 2011;13:563–570.
37. Jenkins RG, Ornstein SM, Nietert PJ, Klockars SJ, Thiedke C. Quality improvement for prevention of cardiovascular disease and stroke in an academic family medicine center: do racial differences in outcome exist? *Ethn Dis*. 2006;16:132–137.
38. Cappuccio FP, Kerry SM, Forbes L, Donald A. Blood pressure control by home monitoring: meta-analysis of randomised trials. *BMJ*. 2004;329:145.
39. Rogers MA, Small D, Buchan DA, et al. Home monitoring service improves mean arterial pressure in patients with essential hypertension. A randomized, controlled trial. *Ann Intern Med*. 2001;134:1024–1032.
40. Hill MN, Han HR, Dennison CR, et al. Hypertension care and control in underserved urban African American men: behavioral and physiologic outcomes at 36 months. *Am J Hypertens*. 2003;16:906–913.
41. Irwin R, Stokes T, Marshall T. Practice-level quality improvement interventions in primary care: a review of systematic reviews. *Primary Health Care Res Dev*. 2015;16:556–577.
42. Walsh J, McDonald KM, Shojania KG, et al. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies (Vol. 3: Hypertension Care)*. Rockville, MD: Agency for Healthcare Research and Quality; 2005.
43. Fahey T, Schroeder K, Ebrahim S. Educational and organisational interventions used to improve the management of hypertension in primary care: a systematic review. *Br J Gen Pract*. 2005;55:875–882.
44. Trivedi AN, Zaslavsky AM, Schneider EC, Ayanian JZ. Trends in the quality of care and racial disparities in Medicare managed care. *N Engl J Med*. 2005;353:692–700.
45. Sehgal AR. Impact of quality improvement efforts on race and sex disparities in hemodialysis. *JAMA*. 2003;289:996–1000.
46. Bosworth HB, Oddone EZ. A model of psychosocial and cultural antecedents of blood pressure control. *J Natl Med Assoc*. 2002;94:236–248.
47. Kressin NR, Orner MB, Manze M, Glickman ME, Berlowitz D. Understanding contributors to racial disparities in blood pressure control. *Circ Cardiovasc Qual Outcomes*. 2010;3:173–180.
48. Ogedegbe G, Tobin JN, Fernandez S, et al. Counseling African Americans to Control Hypertension (CAATCH) trial: a multi-level intervention to improve blood pressure control in hypertensive blacks. *Circ Cardiovasc Qual Outcomes*. 2009;2:249–256.
49. Yerasi C, Baker NC, Jonnalagadda AK, et al. Assessment of hypertension control and clinical course of patients excluded from the SYMPLICITY HTN-3 trial. *J Am Soc Hypertens*. 2015;9:959–965.
50. Verberk WJ, Kroon AA, Kessels AG, de Leeuw PW. Home blood pressure measurement: a systematic review. *J Am Coll Cardiol*. 2005;46:743–751.

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