Hypertension affects 1 in 3 Americans and is one of the leading causes of morbidity and mortality in the United States. Among persons <80 years of age, controlling hypertension could avoid an estimated 46,000 deaths annually, making it the single most effective medical service for reducing mortality. As a result, the Institute of Medicine has underscored the need for population-based strategies that can reach large numbers of people with hypertension and improve the well-being of entire communities.

To date, the most successful blood pressure (BP) interventions have been pharmacist- or nurse-led home BP monitoring programs using web-based technology and automated provider alerts. However, these strategies have generally been implemented in selected populations, such as a single healthcare system or payer population, with full healthcare insurance, and among technologically savvy individuals. Thus, it remains unclear whether the efficacy seen with such programs can translate into effective BP control in socioeconomically diverse community settings.

The goal of our community-based hypertension initiative, Check It, Change It, was to develop a tiered multifaceted intervention to lower BP in a heterogeneous community setting. We hypothesized that our program that included the American Heart Association’s Heart360 (http://www.heart360.org) web-enabled personal health record platform, remote BP monitoring, physician assistant guidance, and community health coaches could lower BP in patients with hypertension in Durham County, NC, an ethnically and socioeconomically diverse setting.

**Background**—Although home blood pressure (BP) monitoring interventions have shown potential in selected populations, it is unclear whether such strategies can be generalized. We sought to determine whether a multifaceted BP control program that uses a web-based health portal (Heart360), community health coaches, and physician assistant guidance could improve hypertension control in a diverse community setting.

**Methods and Results**—Between September 12, 2010, and November 11, 2011, Check It, Change It, a community-based hypertension quality improvement program, enrolled 1756 patients with hypertension from 8 clinics in Durham County, NC. The Check It, Change It community intervention was evaluated using a prepost study design without a concurrent control. Participants were stratified into 3 tiers according to their initial BP: tier 0 (BP <140/90 mm Hg)=51% of population, tier 1 (BP=140/90–159/99 mm Hg)=30% of total, and tier 2 (BP ≥159/99 mm Hg)=19% of total. Overall, median age was 59 years (interquartile range, 49–69), 67% were female, and 76% black. After 6 months, the mean overall systolic BP declined 4.7 mm Hg. Rates of achieving target BP control (<140/90) increased overall from 51% at baseline to 63% by 6 months, and 69% had either reached their BP target or had reduced their baseline systolic BP by 10 mm Hg or more.

**Conclusions**—A multicomponent-tiered hypertension program was associated with improved BP control in a diverse community-based population.

**Key Words:** blood pressure  ■  hypertension  ■  quality improvement  ■  residence characteristics  ■  self blood pressure monitoring

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828
WHAT IS KNOWN

- Prior studies using multiple interventions including remote blood pressure monitoring programs have exhibited improvements in blood pressure control.
- However, the generalizability of previous studies programs to diverse real world communities may be limited by the exclusion of socioeconomically heterogeneous populations.

WHAT THE STUDY ADDS

- This large multicomponent community-based quality improvement program that used physician assistants, community health coaches, Heart360, and remote blood pressure monitoring was associated with population blood pressure reduction.
- The programmatic impact was consistent across important subgroups including the uninsured/underinsured and racial and ethnic minorities.
- This program demonstrates the potential success of community-based participatory research in managing chronic disease.

improvement program that enrolled participants from 8 diverse, ambulatory clinics. The evaluation component of the program used a pre-postobservational study design without a concurrent control. The CICI program included the following 5 major components: (1) longitudinal BP monitoring incorporating a web-based portal (Heart360), (2) remote BP monitoring sites with kiosks or computer terminals, (3) PAs, (4) CHC’s, and (5) the participant’s provider (Figure 1). We used geospatially informed analytics to locate areas containing a high prevalence of hypertension. Based on these findings, we placed 13 computer-based BP portals and 4 web-connected kiosks where participants frequented routinely, including places of worship, beauty salons and barbershops, community centers, libraries, safety net health centers, and the county health department (Figure 2). These sites were made available to CICI program participants at no cost. The kiosks contained integrated BP cuffs and the computer portals had universal serial bus-connected BP cuffs (Omron HEM-712-C) for measurement and direct uploading of BP and heart rate to Heart360.

Three PAs and 8 CHCs were hired to work on CICI. The PAs and CHCs were provided specific training on evidence-based BP measurement techniques and encouraged to provide this training to all participants with whom they interacted. For patients with stage 2 hypertension and patients with limited transportation, the program provided free BP cuffs for home use, along with both written and verbal education regarding obtaining guideline-based BP measurements at home.

All program and intervention materials were provided in Spanish and English at seventh grade reading levels, and bilingual CHCs were hired to enroll and follow Spanish-speaking participants.

Sites and Participants

Durham is a community of 240,000 citizens in North Carolina with nearly equal numbers of white and black residents. To recruit participants for the program, we selected 6 primary care and 2 specialty clinics in Durham County, NC. Clinic choices were based on heterogeneity of patient and payer mix, socioeconomic status, mixture of clinic models (including hospital-based, free or safety net, and subspecialty), and their location (targeting areas with high concentrations of individuals with hypertension). Five of the clinics (4 primary care and 1 cardiology) that participated were affiliated with Duke University Health System and had a traditional outpatient continuity clinic infrastructure. The remaining clinics included a private

DOTATION

Figure 1. A description of the Check It, Change It program components. HTN indicates hypertension; and PA, physician assistant.
Tiered Intervention

**Intervention Protocol**

After enrollment, there was a 6-week period in which participant’s were asked to enter BP measurements into Heart360 at least once every 2 weeks. Patients were stratified into 1 of 3 groups: tier 0 (mean BP <140/90 mm Hg), tier 1 (mean BP=140–159/90–99 mm Hg), and tier 2 (mean BP >159/99 mm Hg). After stratification, all participants were asked to continue entering BP data in Heart360 at least every 2 weeks and received automated email reminders if they did not. Patients were to be enrolled in the program for ≤26 weeks.

The intervention was tiered to BP. Tier 0 participants received bi-monthly automated reminders to enter their BP measurements into Heart360. Tier 1 patients were additionally supported by PA’s who provided ongoing behavioral and lifestyle counseling, detailed medication assessments, and intensification of medical therapy as needed. Tier 2 patients received these interventions and were assigned a CHC who conducted ≥1 home visit to identify nonmedical barriers to achieve BP control via a structured assessment. If barriers(s) were identified, a plan for more optimal BP control was constructed between the patient, PA, and CHC.

**Outcomes**

The primary outcomes included (1) difference in systolic and diastolic BP from enrollment (BP obtained in the clinic at enrollment) to the last BP as measured in clinic within 6 months after enrollment; (2) proportion of participants that achieved BP <140/90 mm Hg by last clinic visit within 6 months; and (3) proportion of participants who’s BP was <140/90 mm Hg or who had a ≥10 mm Hg drop in systolic BP by last visit relative to their enrollment BP. The patients’ clinic BP measurement was considered the gold standard measurement for the purposes of this program’s analysis and was used for the final assessment of the program’s impact on BP control. The intervention period for all participants was 6 months from enrollment. If no follow-up BP measurements were available in the ambulatory medical record after the initial enrollment, then the enrollment BP was carried forward and the patient was assumed to have had no improvement in BP (0 mm Hg change).

In addition to BP measurements, program assessment included administrative and process measures related to care delivery. Relevant metrics included PA interactions with patients, number of CHC home visits, remote BP site use, and Heart360 usage. Our program evaluation also encompassed qualitative surveys at the end of the program to determine participants’ acceptance and feasibility of community-based interventions.

The American Heart Association sponsored the implementation of the CICI program, and Novartis Pharmaceuticals supported the statistical analysis. The American Heart Association, Duke Clinical Research Institute, and CAARE, Inc collaboratively developed program concepts, design, and marketing strategies and materials. The Duke Clinical Research Institute coordinated and implemented the program, collected and managed the data, and conducted the primary analyses independent from sponsors.

**Statistical Analysis**

Baseline characteristics were reported as means, medians, and standard deviations (SDs) for interval- and ratio-level variables (eg, age) and proportions for nominal- and ordinal-level data (eg, sex, comorbidities). To assess the improvement in BP control, we examined our 3 outcome variables in the overall population, and according to BP at enrollment. Specifically, 3 analytic tiers were defined according to initial BP: tier 0 (initial mean BP <140/90 mm Hg), tier 1 (initial mean BP=140–159/90–99 mm Hg), and tier 2 (initial mean BP >159/99 mm Hg). Given random fluctuation in BP measurements, patients with initially high BPs may be expected to change because of regression to the mean. To estimate the magnitude of regression to the mean in those with initially high BP, we looked at the complimentary change in BP among those with initial BP <140/90 mm Hg at enrollment. Because the mean BP in the overall population was near 140, these groups would be expected to regress similarly, in the absence of systematic changes.

Subgroup analyses were included, stratifying outcomes by baseline clinical factors such as race and insurance status. Given the disproportionately high burden of hypertension among black patients and the uninsured and underinsured, we paid particular attention to the change in BP in these groups.

**Results**

**Participant Characteristics**

From December 9, 2010, to November 1, 2011, a total of 1756 participants were enrolled. Demographic and clinical characteristics of the program participants are shown in Table 1. The median age was 60 years (interquartile range, 50–69), 65.6% were female, and 76.1% were black. Relative to tier 0 patients, those in tiers 1 and 2 were older, less likely married, and had more coexisting comorbid illness. Overall 16% of participants...
Table 1. Check It, Change It Program Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (N=1756)</th>
<th>Tier 0 (N=889)</th>
<th>Tier 1 (N=534)</th>
<th>Tier 2 (N=333)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
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<td>59 (49, 68)</td>
<td>57 (46, 67)</td>
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<td>34.5</td>
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<td>4.9</td>
<td>4.2</td>
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<tr>
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<td>10.9</td>
<td>17.0</td>
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<tr>
<td>Other</td>
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<td>20.9</td>
<td>13.7</td>
<td>9.0</td>
</tr>
</tbody>
</table>

Values are presented as % or median (25th, 75th percentiles). HMO indicates Health Maintenance Organization.

In patients who had a BP ≥140/90 mmHg at program enrollment (N=867), the mean decrease in systolic BP and diastolic BP was 14.5 mmHg (SD 21.5) and 6.9 mmHg (SD 12.1) respectively, whereas the patients with controlled BP (<140/90) at enrollment saw increases of 4.9 mmHg (SD 16.1) and 1.9 mmHg (SD 10), respectively. Assuming that the latter increase reflects regression to the mean, then a more conservative estimate of BP improvement among hypertensive patients (BP ≥140/90 mmHg) may have been ≈10 mmHg for systolic BP and 5 mmHg for diastolic BP.

Last, 44% of individuals with BP >140/90 mmHg initially reached goal BP and 58% reached a BP <140/90 mmHg or had a ≥10 mmHg decrease in systolic BP at program completion (Table 2).

Two hundred sixty-four (15%) of enrolled CICI patients did not return for a clinic visit during the 6-month intervention period. Demographics of those patients include the following: median age, 53 years; 63.6% female, 81% black, 35% self-pay, 13% Medicaid, and 26% had private insurance. Their mean systolic BP was 137.1 (SD, 20.2) and 52.3% had a BP <140/90 mmHg. Removing those 264 patients from the primary analysis revealed slightly more substantial BP effects for all 3 outcomes. The mean decrease in systolic BP increased from 4.7 mm Hg to 5.5 mm Hg. The number of patients with a BP <140/90 mmHg at program conclusion increased slightly from 63% to 64%. Finally, at program conclusion, the proportion of participants who either reached a BP <140/90 mmHg or had a SBP decrease of ≥10 mmHg increased from 69% to 72%.

BP Outcomes in Special Populations
Black patients with poorly controlled hypertension (tiers 1 and 2) at baseline had a decline in their mean changes in systolic BP of 15.0 mmHg (SD±22.5) and diastolic BP 7.2 mmHg (SD±12.5) from enrollment to program completion while the overall proportion of black patients with a BP <140/90 mmHg increased from 49.2% to 62.2%. Similarly Medicaid (n=284) and self-pay patients (n=174) with poorly controlled BP at the beginning of the program had declines in systolic BP of 13.2 mm Hg (SD±24.0) and 15.2 mm Hg (SD±21.3), respectively. Additionally, the overall proportion of Medicaid and uninsured patients with a BP <140/90 mmHg increased from 37.4% to 51.2% and 34.2% to 51.3% (Table 2).

Healthcare Utilization
Among patients who participated in the CICI program, 58% entered ≥2 BP’s in Heart360. A total of 14 401 BP measurements were entered in Heart360 during the program. The mean number of BP’s entered per person was 6.5 (SD, 18). Of patients that entered BP’s in Heart360, 42% entered only 1 BP, 30% entered 2 to 4 BP’s, 17% had 5 to 12, and 11% entered >12 BP readings. Of note, there was an association between greater use of Heart360 and systolic BP decrease (Table 3).

PAs interacted directly with 396 program participants and another 50 in collaboration with the CHC. Less than 10% of these encounters were in person at clinic visits. The majority of the interactions were phone consultations (94%). As a result of these communications, a total of 181 new prescriptions were written that included medication adjustments or
new medications. CHCs held 100 health programs aimed at promoting diet and exercise, proper BP measurement technique, and assistance with Heart360. CHCs conducted home visits in over 70% (184 of 260) of tier 2 patients.

All program participants were surveyed at program conclusion, and responses were obtained for 352 (20%). Respondents noted the time spent by CHC’s and PA’s outlining plans for controlled BP, 31% indicated the BP educational materials from Heart360 and the American Heart Association written materials were somewhat easy or easy to use. Patients identified multiple aspects of the program as most helpful; 35% noted the time spent by CHC’s and PA’s outlining plans for BP control, 31% indicated the educational materials from Heart360 and the American Heart Association written materials, and 72% valued most that the program made them more aware about hypertension and its effects on their health.

Discussion
The multifaceted, community-based, Heart360 supported, CICI hypertension program demonstrated several important findings: (1) we were able to engage, a diverse group of patients, including a large portion of traditionally underserved and otherwise challenging individuals in a hypertension quality improvement program; (2) overall population mean BP declined over the course of 6 months, and there was a corresponding overall increase in rates of achieving target BP control; (3) among individuals with elevated BP at baseline, systolic BP declined by 14.5 mm Hg while BP control rates increased by 12%; and (4) these changes in BP control rates were of similar or greater magnitude in black, Medicaid and uninsured patients than their counterparts.

The findings from our program are consistent with prior research demonstrating the success of multifaceted BP treatment strategies in improving BP control.6,14–20 Other hypertension programs have implemented strategies using remote monitoring and care management to target patients with hypertension not at goal. Kaiser Permanente Colorado researchers in Denver randomized 350 individuals with uncontrolled hypertension to a pharmacists-led, Heart360 assisted, home monitoring and care management to target patients with hypertension not at goal. Kaiser Permanente Colorado researchers in Denver randomized 350 individuals with uncontrolled hypertension to a pharmacists-led, Heart360 assisted, home BP monitoring program. At 6 months, 54% of the intervention group had reached their goal BP, compared with 35% in the control group.12 Similarly, researchers from Group Health, a large integrated practice in Washington State, found that adding Web-based pharmacist care to home BP monitoring and Web training significantly increased the percentage of patients with controlled BP compared with usual care.6 Although each were well-conducted trials, both were implemented in integrated health systems with seamless medication and laboratory test ordering, and the ability to review patient encounter

<p>| Table 2. Outcomes for Participants by Tier |
|-------------------------------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|</p>
<table>
<thead>
<tr>
<th>Participants</th>
<th>SBP First Reading</th>
<th>SBP Last Reading</th>
<th>Change (Δ)</th>
<th>BP &lt;140/90 mm Hg First Reading</th>
<th>BP &lt;140/90 mm Hg Last Reading</th>
<th>Change (Δ)</th>
<th>BP &lt;140/90 or ≥10 mm Hg Decrease in SBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (n=1756)</td>
<td>138.1±22.0</td>
<td>133.4±19.1</td>
<td>−4.7±21.4</td>
<td>50.6</td>
<td>62.5</td>
<td>11.9</td>
<td>69.4</td>
</tr>
<tr>
<td>Tier 0 (n=889)</td>
<td>122.0±10.6</td>
<td>126.8±15.4</td>
<td>4.9±16.1</td>
<td>100</td>
<td>80.2</td>
<td>−19.8</td>
<td>80.2</td>
</tr>
<tr>
<td>Tier 1 (n=534)</td>
<td>145.1±7.7</td>
<td>136.3±15.6</td>
<td>−8.8±15.8</td>
<td>0</td>
<td>48.3</td>
<td>48.3</td>
<td>53.4</td>
</tr>
<tr>
<td>Tier 2 (n=333)</td>
<td>170.1±18.8</td>
<td>146.5±24.6</td>
<td>−23.7±26.5</td>
<td>0</td>
<td>38.1</td>
<td>38.1</td>
<td>66.4</td>
</tr>
</tbody>
</table>

Values are presented as % or mean±SD, in mm Hg. Tier 0 BP <140/90 mm Hg. Tier 1 BP=140–159/90–99 mm Hg. Tier 2 BP >159/99 mm Hg. SBP indicates systolic blood pressure.

*First vs last BP entered.
notes. Moreover, essentially all patients in these study populations had prescription drug coverage and few were minorities or of lower socioeconomic status. Thus, their results while internally valid may not be applicable to less amalgamated health systems with more diverse patient composition.

Improving public health often entails moving beyond the conventional healthcare system to include integrated and innovative approaches. Community-based participatory research (CBPR) is an applied collaborative approach that enables community residents to more actively participate in the full spectrum of research (from conception—design—conduct—analysis—conclusions—communication of results) with a goal of influencing change in community health, systems, programs, or policies. CBPR has emerged as an alternative research paradigm that integrates education and social action to improve health and deepen our scientific base of knowledge in the areas of health promotion and disease management. It is regarded as an effective method for transferring evidence-based research from clinical settings to communities that can most benefit thereby improving health.21,22

CICI exemplifies CBPR and is one of the largest hypertension programs successfully implemented in a racially diverse, socioeconomically heterogeneous population. The program’s multifaceted intervention simultaneously promoted home BP monitoring and addressed patient and system-level barriers. A tiered approach was used for the intervention to allocate limited resources to individuals at the greatest risk for cardiovascular disease morbidity and mortality, as well as to those with the most uncontrolled BP.

Compared with the aforementioned studies, the programmatic impact on overall population mean BP decrease was modest (systolic BP of 4.7 mm Hg). However, these results, in part, are reflective of our enrollment of patients with a history of hypertension regardless of whether they were controlled or not at baseline. In our analysis, those who had a BP <140/90 mm Hg at enrollment (50% of total) would not be expected to have further reductions in their BP as they were already at goal. For the 15% of patients who did not return for a clinic visit, during the intervention period, we conservatively recorded that they had no BP improvement. Although these lost to follow-up patients may have reduced our measured impact, they are not uncommon among community-based effectiveness studies. In contrast, among those with baseline BP ≥140/90, the decline in systolic BP was 14.5 mm Hg.

Implementation Changes

We found that there was a direct association between higher use of Heart360 and larger recorded BP declines as entered into Heart360. This provides some indirect evidence that those patients who were more engaged with their BP self-monitoring actually achieved better BP control. However, we also found that use of Heart360 presented some technical challenges for some. A significant portion of our program population had limited or no prior computer or Internet experience. This is in contrast with other studies that required patients to have a home computer or provided participants with home BP telemonitoring devices.3,12,23,24 By the end of the study, it was apparent that a digital divide existed among many of the elderly patients and those individuals with financial hardship that inhibited their ability to master the processes necessary for web-based monitoring.

Increasing marketing and advertisement of the remote monitoring stations may have improved use; however, it seemed that providing a BP cuff to high-risk participants provided the most convenience for the participant. This should be considered in future interventions.

Limitations

Our program results should be noted within the context of its limitations. The CICI program was not a randomized clinical trial but rather a quality improvement initiative conceived and implemented using the principles of CBPR. To that end, the reduction in BP observed at program conclusion may be confounded by unmeasured factors. We also did not have a specific concurrent control population to compare these changes with and our findings of lower BP in those with elevated baseline BP may reflect regression to the mean. Our analysis, however, also attempted to quantify the magnitude of this bias and to report more conservative estimates of programmatic impact. In an effort to present our findings in the perspective of the design limitations, we report as the primary outcome overall BP change in all patients including those with BPs well below guideline recommendations for hypertension. In fact, the mean baseline population systolic BP was 138.1 mm Hg, a number that would not have met inclusion criteria for most prior BP intervention studies. Moreover, a major challenge of CBPR centers on how to determine its effects on outcomes, specifically, the added value of community participation to the intervention and to the intervention’s outcomes. Yet the increasing widespread practice of CBPR points to an emerging evidence that participation makes a difference, and the science may need to adapt and expand to better uncover these differences.

We were limited in our ability to determine medication changes because of the multiple practice settings of program participants and the lack of a connected electronic medical record. Consequently, the contribution of medication intensification to our results is unknown.

In addition, we did not require home computers, Internet, or email access for participation. This would have increased compliance with remote monitoring but would have excluded a large part of our elderly, ethnic minority, and less educated county residents who are less likely to have these conveniences at their disposal. As anticipated, many participants were not comfortable using the computer, the Internet, or Heart360 and preferred providing their BP readings to their PA or CHC via the phone. As a result, an automated telephone system that participants could have used to log their BP readings might have been a worthwhile addition to the intervention.

Conclusions

CICI represents a unique partnership between a community, academic medical center, and a patient focused professional organization to collaborate successfully in creating and implementing a hypertension management program. This community-based program successfully integrated healthcare providers, Heart360, and remote monitoring to engage, empower, and assist a distinct group of community residents.
to achieve better hypertension control with the biggest impact on those with the most poorly controlled hypertension. We think multidisciplinary collaborations such as in CICI can serve as a potential model for community-based chronic disease management moving forward.

Sources of Funding

Check It, Change It was developed in collaboration with the American Heart Association and Durham Health Innovations and was completed with a sponsorship from Novartis Pharmaceuticals Corporation.

Disclosures

Dr Shah reports serving as a clinical consultant for Castlight Health. Dr Allen LaPointe reports grant support from Pfizer for a research project on medication adherence. Please see the Duke Clinical Research Institute web site http://www.dcri.duke.edu/research/coi.jsp for Drs Califf’s and Peterson’s disclosures. The other authors report no conflicts.

References


Check It, Change It: A Community-Based, Multifaceted Intervention to Improve Blood Pressure Control

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