Hypertension currently affects >80 million people in the United States and is a major risk factor for cardiovascular disease, stroke, and heart failure. Numerous epidemiological and clinical studies have demonstrated that lowering systolic blood pressure (BP) by as little as 10 mm Hg results in a 30% to 40% reduction in cardiovascular and cerebrovascular mortality. Given that hypertension is a silent disease and its treatment requires long-term lifestyle changes, both patient and provider engagement present challenges in controlling BP. Furthermore, traditional clinic-based models of care create further delays in achieving and maintaining evidence-based BP targets.

Recent evidence has shown that ≈60% of patients with hypertension fail to reach guideline-based BP targets despite decades of progress in improving BP awareness and treatment of individuals with high BP. To address this major health problem, the Institute of Medicine suggested using population-based systems to reduce the morbidity and mortality associated with uncontrolled BP. The consequent IOM report focused on the integration of several key components targeted at improving community-based BP management: (1) an integrated information technology system for data exchange, (2) community health workers linked to primary care services, and (3) behavioral and lifestyle modifications at a population or community level.

Following the framework of the chronic care model, we propose integrating remote and home BP monitoring, a web-based personal health record, and use of community health workers and physician assistants to improve the BP of a diverse group of residents in Durham County, NC, through a program called Check It, Change It: The Durham Blood Pressure Challenge (CICI).

Challenges to BP Control
Understanding the problem is often the key to understanding the solution. We recognize that failure to control BP is a multifactorial issue involving patients, providers, and the
There are several unique challenges for both patients and providers in ambulatory BP control. First, many individuals with hypertension struggle with BP self-management, which results in inadequate BP control.4,13 This struggle may be because of the fact that patients are often given little counseling on the importance of lifestyle modifications and medication adherence. Furthermore, patients are not often provided with tools that promote adequate self-management of hypertension. Second, physicians may have limited information on patients’ ambulatory BP values and are consequently dependent on ambulatory clinic visits for decision making. Third, when these BP measurements are available or when providers detect elevated BPs during a clinic visit, clinical inertia may prevent the initiation or intensification of appropriate antihypertensive therapy.4 Fourth, data on BP measures from various provider visits and other clinical sources are often not aggregated to simplify clinical decision making. Fifth, numerous patient barriers exist for traditional face-to-face interactions with providers, including the difficulty in making routine office visits because of job or childcare responsibilities, transportation issues, or financial issues related to inadequate health coverage for routine provider visits. Sixth, providers are often reluctant to increase the frequency of BP monitoring visits, given limited office patient capacity, unfavorable reimbursement models for secondary prevention office visits, or absent health coverage. Finally, limited coordination occurs among providers and healthcare settings that measure and monitor BP, leading to fragmented patient care, confusion among patients regarding the appropriate course of action, and, at times, conflicting advice and interventions.

**CICI Program for Improving Community-Level BP Control**

We propose to test multimodality interventions in a community setting that includes home BP monitoring, remote BP monitoring, web-based health records, and the use of nonphysician healthcare providers and coaches.

**Home BP Monitoring and Web-Based Portal**

Critical to improving control of BP is empowering patients to actively monitor their BP and communicate these results to their healthcare team. One mechanism that showed improvement in patient engagement, medication adherence, and BP control is ambulatory BP monitoring.3,14–16 In an effort to further engage patients in self-monitoring and self-engagement, the American Heart Association has developed a web-based interactive health portal, Heart360 (http://www.heart360.org), based on Microsoft’s HealthVault (http://www.healthvault.com) personal health record platform. Heart360 is a patient-controlled monitoring tool where individuals can input and record their health parameters, such as BP, heart rate, blood glucose, weight, medications, and lipid measurements.
Heart360 is designed to facilitate the exchange of health information between patients and their providers, as well as to provide access to a vast array of educational tools to improve cardiovascular health. Randomized controlled studies are currently underway to determine whether this novel web-based tool has been successful in controlling BP.\textsuperscript{17}

Remote BP Monitoring Sites

For efficient and rapid deployment of our community-based intervention for patients with hypertension, we relied on a robust informatics system enabled by the Duke University Health System’s electronic data repository that links clinical information, laboratory and diagnostic data, and financial data on all patients seen within the health system. Out of a total of 273,392 residents in Durham County in 2011, we identified 244,317 unique patients with \( \geq 1 \) encounter at Duke between January 1, 2007, and December 31, 2011, suggesting that through this data repository we could obtain clinical information of \( \approx 90\% \) of the county’s population.

Linking these data to a novel geospatially referenced repository of environmental and community resources allowed the application of powerful informatics tools, including a new suite of Google applications for information and analytics. Initial data and interventions from this informatics system have been well received by the community to assist in the feedback of the needs of their community and a data-driven ability to monitor and implement targeted interventions that achieve enhanced care delivery processes and improved health outcomes.

Recognizing that many patients may have difficulty in reliably measuring their BP at home, CICI placed BP machines in key community locations to promote self-engagement in BP monitoring. Using geospatially informed analytics to locate areas containing a high prevalence of hypertension, we positioned computer-based BP portals as well as web-connected kiosks at places where participants frequent for their daily or weekly activities, including places of worship, beauty salons and barbershops, community centers, libraries, safety net health centers, and the county health department (Figure 2).

These stations allow participants to log in to their Heart360 accounts and record their BP, heart rate, and weight, which are instantly available for review. Previous studies have shown that this strategy can enhance awareness for BP control.\textsuperscript{18,19}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{Duke_Hospital_and_Durham_Region.pdf}
\caption{Geospatial map of density of patients with hypertension in Durham County, NC (patient data are provided by Duke University Health System from January 1, 2006, to May 1, 2009). Map demonstrates the prevalence of Durham County residents with a diagnosis of hypertension. The darker the color, the higher the concentration of individuals with hypertension in the zip code represented.}
\end{figure}
Advanced Practice Providers
Numerous studies have consistently shown that well-coordinated, team-based care with physician assistants, nurse practitioners, or pharmacists can significantly lower BP and increase medication adherence.20,21 Teams involving pharmacists or nurses in patient management can significantly improve BP control by 4 to 10 mmHg over usual care.22 Some reasons for the success of these care teams are that they are more likely to (1) adhere to evidence-based protocols for BP management, (2) have more time to provide behavioral and lifestyle counseling because they often only focus on 1 or a few chronic conditions, and (3) see patients more frequently in ambulatory settings for rapid assessment of biometric parameters such as BP. In our program, the use of physician assistants was to allow dedicated providers to be available to manage complex barriers and overcome clinical inertia associated with managing BP control in a large population. The physician assistants were to serve as a link between the participant and his/her primary provider to update progress on the participant’s BP control.

Community Health Coaches
Community health coaches (CHCs) are lay people with skills in providing basic medical needs and education. The role of CHCs is to strengthen the link between healthcare providers and community members.23–28 Over the past 30 years, the concept of CHCs working with healthcare providers to improve health outcomes has gained more prominence in the United States; CHC programs have particularly proliferated in the past 10 years.29 CHCs are also referred to as community health advocates, lay health educators, community health promoters, community health outreach workers, and promoter de salud.23

A national survey of CHCs highlighted their 7 fundamental roles: cultural mediation, informal counseling and social support, providing culturally appropriate health education, advocating for individual and community needs, ensuring that people get the services they need, building individual and community capacity, and providing direct services.29 The benefits of these activities include decreasing healthcare costs, improving healthcare access, enhancing the local economy, and strengthening family and community ties. These individuals work almost exclusively in community settings and facilitate health promotion among community residents who lack access or are disenfranchised from adequate healthcare. Historically, CHCs have been used in populations with diabetes mellitus to help improve the quality of education and care in communities by bridging their ethnic, cultural, and geographic communities though self-care, social support, and community engagement.30 Many communities have provided training programs for these unique individuals and have demonstrated improved outcomes in prenatal care,31 screening behaviors,32,33 and chronic disease management23,30,34,35 (specifically for cardiovascular risk factors).36,37 The Seattle Hypertension Intervention Project demonstrated 39.4% improvement in follow-up of BP measurements among hypertensive patients with the assistance of CHCs.38

Program Sites and Population
To identity participants for this program, we chose 6 primary care and 2 specialty clinics in Durham County, NC. These clinics were chosen given their heterogeneous patient mix of race, socioeconomic status, diversity of clinic models (including hospital-based, free, and subspecialty clinics), and location (targeting areas with high concentrations of individuals with hypertension), which were identified through our geospatial analysis. Eligible participants at the participating clinics included individuals >18 years of age and a previous diagnosis of hypertension (International Classification of Diseases, Ninth Revision code 401.X) or a previous hypertension diagnosis in the medical record. Individuals were excluded if they did not reside in Durham County, refused to enroll in the program, or had a neurocognitive disorder that prevented enrollment. We did not limit recruitment to those solely with uncontrolled BP at their enrollment visit because, sometimes, patients who have controlled BP during clinic visits may have poorly controlled BP at subsequent ambulatory follow-up.

Each site had a minimum of a 3-month enrollment period and up to 6 months if the site offered participation to all eligible individuals. Program staff provided participants with information about the CICI program, assisted in setting up email addresses as required for Heart360 (if a participant did not already have one), and helped participants to create accounts in Heart360. Additionally, a brief patient assessment was administered to obtain the participant’s demographics, basic health status and health literacy, and current medical, behavioral, and lifestyle management for his/her BP.

Each site had its own institutional review board or equivalent, and the Duke University Health System Institutional Review Board approved CICI as a clinical quality improvement program and approved all research-related activities.

Intervention Protocol
Enrolled participants received a tiered intervention of numerous integrated resources based on the mean of their 2 most recent BPs entered into Heart360. The components that comprised the tiered interventions included: (1) AHA’s Heart360 web-based tool for recording and sharing BP measurements, (2) 3 physician assistants shared among the 8 clinics whose sole focus was BP management for enrolled participants, (3) 8 CHCs, (4) 17 remote BP-monitoring stations throughout Durham County linked to Heart360, and (5) the patient’s clinic provider.

The physician assistants and CHCs received 4 weeks of training with a curriculum focused on high-BP behavioral and lifestyle techniques for cardiovascular disease risk factor management.39,40 Additionally, they were provided specific training on evidence-based BP measurement techniques and were encouraged to provide this training to all participants with whom they interacted. For the highest-risk patients with uncontrolled BP, we also provided free BP cuffs (Omron HEM-712-C) for home use, along with both written and verbal education regarding guideline-based home BP measurements.41 For a 6-week period after enrollment, participants uploaded BP measurements into Heart360 via the web or through 1 of
the remote BP stations. During this period, participants were required to upload ≥1 BP every 2 weeks. If no measurements were recorded in Heart360 during the third week, reminders were sent via email, short message service, or telephone. This 6-week period allowed participants to become familiar with Heart360, thereby initiating and fostering self-monitoring.

After the initial 6-week run-in period, participants were stratified into risk tiers based on their mean BPs recorded in Heart360: tier 0, BP <140/90 mm Hg; tier 1, BP ≥140/90 and <160/100 mm Hg; and tier 2, BP ≥160/100 mm Hg. The clinic-based physician assistants reviewed BP recordings of participants in Heart360 daily, and all participants were encouraged to continue Heart360 BP uploads at least every 2 weeks, with reminders in the third week if noncompliant with BP recording. Using the mean of the 2 most recent BP recordings in Heart360 in the 2-week intervals, participants were reassigned to a different tier based on whether they did or did not meet BP goals.

Tier 0 participants were encouraged to upload their BP recordings into Heart360, which were being monitored via the provider portal of Heart360 by physician assistants. These participants continued to receive reminders to upload their BP recordings into Heart360 but did not receive any other active intervention unless their average BP increased ≥140/90 mm Hg. For tier 1 participants, physician assistants provided ongoing behavioral and lifestyle counseling, medication intensification, medical adherence assessments and interventions, laboratory and BP follow-up assessments, and consultation with clinic provider, if necessary. All participants were educated on the proper techniques for measuring BP.

In addition to the intervention by physician assistants as received by tier 1 participants, tier 2 participants received intense intervention through the assignment of a CHC who provided ≥1 home visit to identify nonmedical barriers to achieving BP control. Through a structured assessment process, the CHC documented social, psychological, transportation, mental health, health literacy, or financial barriers that may have impeded BP control and communicated these findings to the participant’s physician assistant and primary provider. Tier 2 patients were also provided access to hospital- and community-based programs to address any other identified issues, as well as other cardiovascular disease risk factors such as diabetes mellitus, hyperlipidemia, and tobacco use. In addition to providing home visits, the CHCs served as educators and hypertension management facilitators to participants enrolled in the program. Those CHCs who were bilingual (Spanish and English) were used to provide language concordance for Spanish-speaking participants, and all intervention materials were available in both Spanish and English at seventh-grade reading levels.

A tiered approach was used for the intervention in order to direct limited resources toward those individuals at the greatest risk for cardiovascular disease morbidity and mortality, as well as to those with the most uncontrolled BP. We used <140/90 mm Hg for BP control based on the most recent Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) guidelines. For specific subpopulations (eg, renal dysfunction, diabetes mellitus), we recognized that a lower BP threshold was to be recommended. Nevertheless, the goal of our program was to demonstrate that a community-based program could improve population-level BP. Because data supported that just reducing BP from elevated levels (regardless of how high) could improve outcomes, we wanted to provide a consistent threshold for all participants.

Community and home BP measurements were used to assess the relative control of ambulatory BP and to identify movement among the 3 tiers, impact of interventions (behavioral, lifestyle, and medications), and adherence to the treatment plan. When there were large discrepancies between the last clinical BP measurement and ambulatory readings, the participants were contacted to ensure that they understood how to properly measure their BP and use BP cuffs, and that they had been adherent to their BP control medications. Any continuous discrepancy led to arranging a clinic visit for the participant to review the BP measurement technique, to calibrate the BP cuff if required, and to review the medication and behavioral interventions to help the participant with better BP control. Additionally, clinical, home, or Heart360 BP values that fell outside prespecified safety parameters (systolic BP ≥180 mm Hg or diastolic BP ≥110 mm Hg) triggered a protocol contact to study investigators for assessment of additional medical interventions.

**Outcomes Assessment**

Clinical BP measurements have been considered the gold standard for the purposes of this program’s analysis and were used for the final assessment of the program’s impact on BP control. Three primary outcomes for our quality improvement initiative were assessed: (1) difference in systolic and diastolic BP from enrollment to the last BP measured in clinic within 6 months after enrollment (defined as last BP), (2) proportion of participants with either a last BP <140/90 mm Hg or who achieved a ≥10 mm Hg drop in systolic BP (when comparing enrollment BP to last BP), and (3) proportion of participants who achieved last BP <140/90 mm Hg. The intervention period for all participants was 6 months from enrollment time. Enrollment and final BP measurements were obtained from ambulatory medical records. If no follow-up BP measurements were available in the ambulatory medical records after the initial enrollment, then the initial BP was used as both BP measurement at enrollment and last BP; therefore, the change in BP for these participants was 0 mm Hg.

To assess the impact of intervention, we evaluated the primary outcomes against 2 control groups: (1) concurrent controls: individuals within the participating clinics with hypertension and meeting all eligibility criteria (age >18 years, residing in Durham County, and hypertension diagnosis by ICD-9 coding before start of study) but not yet enrolled in the program; and (2) historical controls: individuals from the participating clinics who met all eligibility criteria for enrollment at a scheduled visit from 2 years to 6 months before the start of the program.

Baseline characteristics and outcomes were compared between control and intervention groups. In assessment of outcomes, differences in measured characteristics between groups were accounted for by propensity matching. Similarly,
differences in outcomes between study participants and historical controls (2 years to 6 months before start of program) were quantified for participating clinics and compared against nonparticipating sites by a test of interaction using propensity matching to account for differences in case mix. Both concurrent and historical controls were identified for each participating clinic using the local electronic health record system.

Subgroup analyses were included, stratifying outcomes by baseline clinical factors, such as age, sex, race, other relevant clinical risk factors, and the enrolling clinic site. We studied the 3 outcome variables stratified by enrollment tier and examined only the subgroup of participants with BP >140/90 at enrollment. Other measures considered for analysis included medication adherence (as self-reported using the modified Morisky scale), 43 employment status, insurance status, education level, social and environmental characteristics, health beliefs, use of Heart360 (frequency, persistence), and number of follow-up clinic visits during the study period.

In addition to clinical outcomes, program assessment involved administrative and process measures related to care delivery. Relevant metrics included number of home visits per month, telephone contacts, clinical assessments, use of remote BP monitoring site, etc (Table). Assessment of these metrics provided information on the use of individual components of the program in an effort to build a business case for progressive scalability and sustainability. Given the disproportionately high burden of hypertension among low-income and black patients, we paid particular attention to the impact of this program on these 2 groups. Our analysis used qualitative surveys to determine participants’ acceptance and feasibility of community-based interventions at the end of the program. We also examined providers’ perceptions of the intervention through a separate survey at the conclusion of the program. Finally, a cost analysis was performed to demonstrate the value of hiring additional staff (program management, physician assistants, and health coaches), building infrastructure, and technology support relative to BP control.

**Sample Size Considerations**

Our goal was to have a sufficient sample size to detect an improvement in the proportion of participants who achieved last BP <140/90 mm Hg. A sample size of 2000 participants was required to have >90% power to detect a 5% increase in the proportion of patients reaching the goal and >99% power to detect a 10% increase, given a type-I error rate (α) of 0.05. These estimates of BP control were determined from previous studies of self-management trials conducted in our community and were felt achievable with the proposed interventions. We considered it feasible to achieve this sample size based on an estimated total of 6000 eligible participants in the selected clinics during the intervention period. Other end points included continuous data and were expected to have greater power.

**Potential Study Challenges**

Our study had limitations in the community, county, and program levels. With regard to limitations at the community level, our challenges were as follows. First, the design of our study was intended to augment and enhance traditional clinic-based care for BP control. However, this model of care could be viewed by traditional providers as redundant or cannibalizing their care. As a result, we had to spend time educating physicians in clinics on the goals of the CICI program and how achieving these goals will enhance existing patient care. Second, several persons communicated with participants, and hence documentation of such interactions to facilitate information transfer among these persons was critical. We used standardized note templates to ensure documentation was available in the medical record. We also provided real-time intervention to effectively reduce BP in poorly controlled participants through the program’s physician assistants. In turn, these physician assistants actively communicated with the participants’ primary care providers. It remains to be determined whether this community-based program could be replicated beyond our county.

With regard to limitations at the county level, our challenges were as follows. First, Durham County presents unique challenges in providing care to patients with uncontrolled BP, given that it has a wide diversity of patients in terms of ethnicity, socioeconomic status, educational attainment, insurance, and access to care. Second, although Duke University Health System provides 80% of healthcare to this community, numerous independent practices, safety net and free clinics, and community health centers exist to provide care. This variety of healthcare sources creates complexity when trying to integrate these providers around a common goal—namely, to reduce BP in the community.

With regard to limitations at the program level, our challenges were as follows. First, our program was not a

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**Table. Sample of Process Metrics Collected to Assess Program Sustainability and Scalability**

<table>
<thead>
<tr>
<th>Enrollment metrics</th>
<th>Number eligible</th>
<th>Number enrolled</th>
<th>Percent enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean time to complete enrollment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician assistant metrics</td>
<td>Average number of panel patients</td>
<td>Total number of clinic visits</td>
<td>Mean clinic visits per day</td>
</tr>
<tr>
<td>Community health worker metrics</td>
<td>Total number of patients in rier 2</td>
<td>Home visits, % (N)</td>
<td>Number attempted home visits, % (N)</td>
</tr>
<tr>
<td>Heart360 metrics</td>
<td>Number of uploads</td>
<td>Number of remote BP uploads</td>
<td>Number of BP uploads from home</td>
</tr>
<tr>
<td>Number of reminder automated SMS texts</td>
<td>Number of reminder automated e-mails</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BP indicates blood pressure; and SMS, short message service.
randomized controlled trial but a quality improvement initiative with a retrospective data analysis. As a result, any evidence of BP reduction may have been confounded by unmeasured factors. We tried to minimize these confounding effects with the use of historical and concurrent controls and adjusting for measured confounding, but even this did not always account for the spillover effect of the program into nonparticipating clinics, not to mention the Hawthorne effect on providers in participating clinics. Second, although public marketing of the CICI program is prudent because this effort is a public health initiative, marketing introduces the possibility of selection bias, as well as the potential use of Heart360 by individuals not in the program. Third, this selection process may have affected participants approached in clinics who are interested in BP control or disease management by introducing bias toward those who were elected to participate. Fourth, the use of a web-based monitoring tool posed challenges with regard to Internet service access, thereby limiting the benefits of this tool in our program. Nevertheless, we attempted to provide broad implementation of remote monitoring stations and program opportunities for education in the hope of limiting the impact of technology literacy and diffusion on self-monitoring. Moreover, for efficient and effective identification of patients with uncontrolled BP, we require technology and analytic infrastructure (similar to the Duke data repository). With rapid and diffuse deployment of electronic medical records as part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act 2009, these data will become more broadly accessible by health entities implementing the technology. Finally, as we look toward the future, expanding our program and making it longitudinally sustainable will require the engagement of key stakeholders to allocate resources because current insurance payment models based on traditional ambulatory care cannot fully support a novel, integrated community approach to BP control.

Summary
A community-based hypertension disease management model integrating remote BP monitoring, coordinated care teams, and a web-based disease self-management program has the potential to address critical impediments to improve BP control, thereby helping to reduce the burden of cardiovascular and cerebrovascular disease morbidity and mortality. The current model of hypertension management that is solely clinic- and provider-based has failed to improve population-level BP control. As a result, it is critical to develop new models that extend care to where people live and work. Nevertheless, the success of a community-based approach with improved patient self-engagement and self-monitoring hinges on a patient-centered coordinated approach.

Our intervention builds on previously successful strategies that have demonstrated improved BP control, such as the use of physician assistants and CHCs while providing novel opportunities for remote BP monitoring and innovative self-management tools to further engage participants. The use of remote monitoring unshackles participants and providers from the traditional office-based setting for BP monitoring. If successful, our program introduces a system where goal-directed risk factor modification can be an ongoing collaborative effort between the participant and other agents motivated toward BP control. If our paradigm is effective in BP control, it can serve as a model for broader chronic disease management including, but not limited to, diabetes mellitus, hyperlipidemia, and obesity.

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

Bimal R. Shah, Kevin L. Thomas, Sharon Elliot-Bynum, Kristin Thomas, Katrina Damon, Nancy Allen LaPointe, Sarah A. Calhoun, Laine Thomas, Robin Mathews, Robert M. Califf and Eric D. Peterson

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