Counseling African Americans to Control Hypertension (CAATCH) Trial
A Multi-Level Intervention to Improve Blood Pressure Control in Hypertensive Blacks

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Abstract—Despite strong evidence of effective interventions targeted at blood pressure (BP) control, there is little evidence on the translation of these approaches to routine clinical practice in care of hypertensive blacks. The goal of this study is to evaluate the effectiveness of a multilevel, multicomponent, evidence-based intervention compared with usual care in improving BP control among hypertensive blacks who receive care in community health centers. The primary outcomes are BP control rate at 12 months and maintenance of intervention 1 year after the trial. The secondary outcomes are within-patient change in BP from baseline to 12 months and cost-effectiveness of the intervention. Counseling African Americans to Control Hypertension (CAATCH) is a group randomized clinical trial with 2 conditions: intervention condition and usual care. Thirty community health centers were randomly assigned equally to the intervention condition group (n=15) or the usual care group (n=15). The intervention comprises 3 components targeted at patients (interactive computerized hypertension education, home BP monitoring, and monthly behavioral counseling on lifestyle modification) and 2 components targeted at physicians (monthly case rounds based on Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure guidelines, chart audit and provision of feedback on clinical performance and patients’ home BP readings). All outcomes are assessed at quarterly study visits for 1 year. Chart review is conducted at 24 months to evaluate maintenance of intervention effects and sustainability of the intervention. Poor BP control is one of the major reasons for the mortality gap between blacks and whites. Findings from this study, if successful, will provide salient information needed for translation and dissemination of evidence-based interventions targeted at BP control into clinical practice for this high-risk population. (Circ Cardiovasc Qual Outcomes. 2009;2:249-256.)

Key Words: hypertension ■ clinical trial ■ blacks ■ research

Blacks have the highest prevalence of hypertension (HTN), making it a major contributor to cardiovascular morbidity and mortality in this population.1,2 Blacks have a disproportionately higher rate of fatal stroke, death from heart disease, congestive heart failure, and a greater rate of HTN-related end-stage kidney disease than whites.1,3 Thus, it is not surprising that HTN accounts for most of the difference in mortality between blacks and whites.2

Fortunately, adequate blood pressure (BP) control can reduce mortality and produce significant cardiovascular benefits in all patients regardless of race.4,5 However, translation into clinical practice of advances in management of HTN is suboptimal, largely because of barriers that exist at the levels of the patient, the health care provider, and the health care system. Whereas systems-level barriers (eg, lack of access, medication costs, high copayments) adversely affect BP control, most cases of uncontrolled HTN occur in patients with access to care.6–8 Data from the third National Health and Nutrition Examination Survey (NHANES) suggest that most patients with uncontrolled HTN have seen a physician at least 3 times in the prior year.9 This issue may be more prevalent in blacks, whose BP remained largely uncontrolled, despite access to free or low-cost primary care, as well as free or low-cost medications and regular follow-ups.10,11 This suggests
significant barriers to poor BP still occur at the patient and physician levels.

Patient-Level Barriers and Interventions
Poor adherence to prescribed antihypertensive medications is a major barrier to BP control,\textsuperscript{12} and it may explain the racial disparity in health outcomes between blacks and whites.\textsuperscript{13} Other important patient-level barriers include poor knowledge about HTN, medication side effects, patients' health beliefs, and their reluctance to engage in lifestyle modification.\textsuperscript{14,15} Common strategies targeted at patient level barriers include patient education,\textsuperscript{16} self-monitoring approaches such as home BP monitoring,\textsuperscript{17} behavioral counseling targeted at medications,\textsuperscript{10,26} especially in patients with isolated systolic hypertension.\textsuperscript{32} For example, the effectiveness of patient education in improving BP control has been demonstrated.\textsuperscript{21} Behavioral counseling interventions in practice-based settings can improve medication adherence and reduce BP.\textsuperscript{22,23} The effect of self-monitoring on BP control is also well documented.\textsuperscript{24}

Physician-Level Barriers
Perhaps the most important physician-level barrier to BP control is the lack of adherence to treatment guidelines. In a national survey of 500 primary care practitioners, recommendations of the sixth report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-6) were not followed when initiating treatment for blacks, older patients, and those with comorbid conditions including renal disease.\textsuperscript{25} Further, physicians often lack appropriate aggressiveness in the use of antihypertensive medications,\textsuperscript{10,26} especially in patients with isolated systolic HTN.\textsuperscript{10,27} Finally, there is evidence that physicians are not recommending lifestyle modifications to patients despite proven efficacy of these approaches.\textsuperscript{28} The poor adherence to evidence-based treatment guidelines may reflect physicians' lack of awareness of the guidelines, disagreement with their content, lack of expectation that adherence to recommendations will achieve the desired effect, clinical uncertainty, lack of support systems at the practice level, or lack of motivation to change previous practice.\textsuperscript{29,30} Common strategies targeted at physician level barriers include physician education and chart audit feedback to physicians. A recent review of interventions to improve BP control found that these strategies used in isolation produced small to modest effects on physician behavior or BP, compared to multi-component strategies (with 2 or more strategies) which yielded a larger effect.\textsuperscript{31} A recent multi-component intervention, which included academic detailing and feedback to providers, substantially led to within group improvement in BP control rates.\textsuperscript{32}

Study Objectives
To address the multilevel barriers to HTN control described above, we designed the Counseling African Americans to Control Hypertension (CAATCH) project. The goal of this study was to test, in cluster randomized trial, the effectiveness of a multi-level, multi-component, evidence-based intervention compared to usual care in improving BP control among hypertensive blacks who receive care in community health centers (CHCs). We hypothesize that patients randomized to the intervention condition (IC) will have, compared with those in usual care (UC) condition, a higher BP control rate at 12 months, greater reduction in both systolic BP (SBP) and diastolic BP (DBP) at 12 months, and a higher rate of maintenance of intervention effect 1 year after completion of the trial. In addition, the intervention will be more cost-effective in improving BP control rate at 12 months compared to usual care. CAATCH is designed to be feasible for adoption, implementation, and long-term maintenance, and thus is more likely to improve standard clinical practice.

Conceptual Framework
The overarching conceptual framework for CAATCH is the Chronic Care Model (CCM), which was developed for care of patients with chronic diseases in primary care settings.\textsuperscript{33} CCM uses a variety of Continuous Quality Improvement (CQI) strategies to improve care integration. As shown in Figure 1, 2 important elements that are relevant to CAATCH include patient self-management and decision support. Patient self-management helps patients to understand the nature of HTN, provides them with self-management tools such as home BP monitors, and teaches them to set goals and monitor their progress via behavioral counseling on lifestyle modification. Decision support gives health care providers access to disease-specific evidence-based guidelines to facilitate optimal HTN management. Components of the CAATCH intervention are organized around these elements to promote patient self-management skills and provider adherence to established guidelines for HTN treatment.

The rationale for selecting CCM as the conceptual framework is 3-fold. First, HTN is a chronic disease, which is treated largely in primary care settings. Second, CCM entails elements of health care delivery that involve the health care provider, the patient, and the environment in which patient care occurs, thus addressing the multilevel nature of HTN control. Finally, the existence of numerous training tools and manuals on the essential elements of CCM, including clinical decision-support, will ensure the diffusion and sustainability of the CAATCH intervention at the CHCs.
WHAT IS KNOWN

• Barriers to blood pressure control exist at multiple levels of care including the patients and health care providers.
• Many interventions targeted, separately, at each of these levels have been proven efficacious.
• There is little evidence on the combined effectiveness of these approaches or their translation to clinical practices in hypertensive African Americans who receive care in community-based primary care practices.

WHAT THE STUDY ADDS

• Using the Chronic Care Model as a framework, this study evaluates the effectiveness of a multicomponent intervention targeted at physicians and patients in a cluster randomized trial.
• Findings from this study will provide much-needed information on the effectiveness of empirically proven strategies when used as a package, as opposed to the effect of any one component in low-resource settings serving low-income minority populations.

Methods

Study Design

As shown in Figure 2, CAATCH is a group randomized clinical trial with 2 conditions: IC and UC. Using a balanced design, 30 CHCs were randomly assigned equally to the IC (n = 15) or the UC (n = 15). CHCs were matched on the size of the practices before randomization. Assessments are conducted at baseline, 2 weeks postbaseline (visit 1), and every 3 months thereafter for 12 months (visits 2 to 5). The primary and secondary outcomes are assessed at 12 months. Chart review is conducted at 24 months to evaluate maintenance of intervention effects in both groups.

Study Sites and Population

The CHCs were eligible for the study if at least 25% of their patient population are self-identified as black or African-American. To be eligible, patients must be self-identified as black or African-American, be at least 18 years old, be receiving care at the participating CHC for a period of at least 6 months, have a diagnosis of HTN and uncontrolled BP at the last office visit (BP >140/90), be taking at least 1 antihypertensive medication. In addition, all patients must have had uncontrolled BP (SBP ≥140 mm Hg or DBP ≥90 mm Hg) at the time of the consent visit, as measured by BPTu (VSM Medtech, Model BPM-300), an automated oscillometric validated BP monitor. Patients are excluded if they are non-English speaking, have an arm circumference of ≥42 cm, participate in other HTN-related trials, currently use home BP monitoring, have cognitive impairment with Mini Mental Status Examination (MMSE) score <24 for patients with >8th grade education, or MMSE <17 for those with an ≤eighth grade education, are unwilling or unable to complete screening or baseline assessments, or unwilling/unable to provide informed consent.

Description of the Interventions

The intervention comprises 3 components targeted at patients and 2 components targeted at physicians. The patient components include (1) interactive computerized self-paced programmed instruction for educating patients about the causes, complications, and treatment of HTN; expected side effects of medications, and methods for adoption of lifestyle changes; (2) home BP monitoring; and (3) individual and group behavioral counseling sessions on the adoption of lifestyle modifications conducted by trained study staff, CHC dieticians, and health educators. The physician intervention includes 2 components: (1) monthly case-rounds with continuing medical education based on JNC-7 HTN treatment guidelines; and (2) provision of feedback using CQI process measures (obtained from chart reviews of patient office encounters) and provision of feedback on patients’ home BP readings.

Plans to Promote Intervention Treatment Fidelity

Treatment fidelity includes 6 core components: (1) ensuring a fixed number of intervention “dose” across the patient and provider groups and tracking of dosage delivery; (2) use of standardized intervention materials (eg, manualized group materials, slides for continuing medical education [CME]) that include built-in checks for participant and provider comprehension and skills acquisition; (3) use of teach-back methodology to ensure patient comprehension and ability to use skills and equipment (home blood pressure monitors); (4) standardized training for interventionists (role-play techniques to ensure skills acquisition); (5) intervention “booster training” for study staff and site providers (eg, nutritionists) on a monthly to quarterly basis; and (6) observation of intervention delivery and feedback to interventionists.

Patient-Level Interventions

The patient education component (SPPI) and documentation of home BP monitor use occurs every 3 months during scheduled study visits, whereas the behavioral counseling sessions on lifestyle modification occur monthly for 6 months. The components are described in detail below.

Computerized Interactive Patient Education Using SPPI

This component is designed to increase patients’ HTN knowledge. The content of the SPPI tutorial is based on 2 National Heart, Lung, and Blood Institute publications, “Your Guide to Lowering Blood Pressure” and “Facts about the DASH Eating Plan.” The tutorial is broken down into several modules that are written at an appropriate reading level. The computer program gives patients control of the pace of learning, and they are asked questions on the material and given feedback to verify their understanding of the material.

Home BP Monitoring

Patients receive an automated home BP monitor (Microlife USA Inc, Model BP 3AC1-1 PC). This monitor uses an oscillometric algorithm, which has been validated using the American Association of Medical Instrumentation and the British Hypertension Society criteria. All patients receive instructions on the use of their home BP monitoring and are encouraged to record their weekly BP readings (twice daily, 3 days a week), in a diary that was provided to them by the research assistants (RAs). They are asked to bring the diary to each study visit.

Behavioral Counseling on Lifestyle Modifications

Patients receive 6 group behavioral counseling sessions (monthly) on adoption of recommended lifestyle modifications conducted by trained CHC staff or study staff. The specific behavior change strategies adopted at these sessions include motivational interviewing, goal setting, problem solving, stimulus control, cognitive strategies, and self-monitoring. The target behavior goals set in collaboration with the patients include dietary changes, weight loss, reduction of sodium intake, increased physical activity, moderation of alcohol intake, and adherence to prescribed BP medications. The behavioral counseling sessions are delivered by study and clinical staff at the CHCs, including nutritionists, nurses, and health educators, who are all trained by the project director (S.F.). The training addresses motivational interviewing counseling strategies for improving nutrition, physical activity, weight loss, and promoting...
medication adherence. Professional educational credits are provided for dieticians and health educators.

**Physician-Level Interventions**

Physicians enrolled in the intervention sites receive monthly CME accredited lectures either live or via telephone and webcasts. These lectures provide information in 2 domains: core HTN knowledge and practice guidelines based on the JNC-7 report, and HTN case conferences plus expert consultation. The physicians are also provided CQI feedback every 3 months on their patients’ office (obtained from chart reviews) and home BP readings with recommendations on the appropriate medication adjustments for each patient. The lectures are conducted by 3 HTN specialists (G.O., T.P., and J.R.).

Core HTN knowledge and practice guidelines include 2 live 1-hour lectures presented at the beginning of the study at each intervention site. These lectures address the major highlights of JNC-7 guidelines with particular emphasis on their relevance to blacks. The format is a standard 45-minute lecture followed by a 15-minute Question and Answer session (see Webcast Library at www.cdnetwork.org).

HTN case conferences and expert consultation involves a strategy of combining CME with academic detailing and peer-to-peer collaborative management. It uses case rounds format to provide real-time specialty consultation on HTN management. These sessions occur monthly for 12 months. Each CHC has the opportunity to present a single clinical case using a standardized format. The HTN specialists (G.O., J.R., and T.P.) provide feedback on the adequacy of current treatment strategies based on JNC-7 recommendations. The case presentations are followed by an open discussion among the participating physicians and the HTN specialist who delivers the lecture.

**Provision of Feedback to Physicians on CQI Process Measures**

These reports inform physicians concerning the degree to which they effectively implement JNC-7 guidelines. Study staff extracts the CQI process measures from patients’ medical records after each study visit using a chart extraction tool developed for this study. These data are used to create a clinician flow sheet on the patient’s BP level, comorbid condition, home BP readings since the last study visit, and the patient’s BP medications. The HTN specialist makes treatment recommendations to the physicians based on the clinician flow sheet. Such recommendations can be any of the following: stop a given medication, start a given medication, increase or decrease the dosage, or make no medication changes/continue current medication. The flow sheets are placed in patients’ charts for the physicians to review.

**UC Condition**

Patients at the UC sites receive print versions of the National, Heart, Lung, and Blood Institute publications “Your Guide to Lowering Blood Pressure,” “Facts about the DASH Eating Plan,” and 4 educational group sessions on the benefits of mineral and vitamin supplementations. Physicians are given the print version of JNC-7 guidelines and a laminated reference card of the JNC-7 treatment algorithm. The physicians also receive CME-accredited webcasts on topics unrelated to HTN, such as asthma and vitamin supplements.

Regardless of the randomization assignments, all sites receive identical compensation to offset the costs of the time their physicians and other clinical staff spend in these training sessions. All patients receive up to $170 over the 12-month study duration as compensation for their time.
Outcomes, Measures, and Data Analysis

Primary Outcome
The primary outcome is the proportion of patients with adequate BP control (BP < 140/90 for all patients or BP < 130/80 for those with comorbid diabetes or kidney disease) at 12 months and the maintenance of intervention effects 1 year after the trial.

Secondary Outcomes
The secondary outcomes are within-patient change in BP from baseline to 12 months and the cost effectiveness of intervention at 12 months.

Measures
All study assessments are conducted at baseline, 2 weeks postbaseline, and quarterly thereafter with the final assessment at 12 months. All study measurements are performed by trained RAs and divided into 3 categories: (1) physiological and laboratory measures, (2) self-report measures, and (3) chart data. The Table summarizes the measures according to their timeline. A subset of data are extracted from patient charts 1 year after the trial (24 months) to evaluate the maintenance of intervention effects.

Physiological Measures
Office BP Measurements
At baseline, 3 readings are taken by trained RAs using an automated BP monitor (BPTru) with the patient seated comfortably for 5 minutes before each measurement, following AHA guidelines. The same procedure is repeated at each follow up visit (3, 6, 9, and 12 months). Average of the 3 readings is used as the measure for each visit. Blood pressure is defined as uncontrolled if the average SBP ≥ 140 mm Hg or DBP ≥ 90 mm Hg (for those without comorbidity) OR average SBP > 130 mm Hg or DBP > 80 mm Hg (for those with diabetes or kidney disease).

Height and weight are measured without shoes using a tape rule and a validated digital scale, respectively. All measurements are recorded to the nearest 0.1 cm and 0.1 kg. These data are used to compute patients’ body mass index.

Self-Report Measures
Patient Demographics
CDN has developed an instrument to collect sociodemographic data to allow us to properly describe the cohort and examine effects of these factors on BP control. Variables include age, gender, household income, education level, marital status, employment status, and health insurance status.

Medication adherence to prescribed antihypertensive medications is assessed with the widely used and well-validated 4-item scale developed by Morisky that specifically addresses adherence to prescribed medication regimen.34 In studies of inner city patients with HTN, this measure has a Cronbach α of 0.9.35 Data on medication adherence will allow us to assess the potential effect of medication adherence on BP control.

Knowledge of HTN is assessed with a 12-item questionnaire developed by the National, Heart, Lung, and Blood Institute for use among nonmedical personnel.36 It will serve as an intervention check of the patient education component. We expect that IC patients will show substantial increases in HTN knowledge compared to UC.

Dietary intake is assessed with the Rapid Eating and Activity Assessment for Patients,37 a brief diet and physical activity questionnaire that assesses frequency of adherence to US Dietary Guidelines. It measures intake of whole grains,
dairy, fruits and vegetables, fat, sugary foods and beverages, sodium, alcohol, and physical activity. It will serve as an intervention fidelity check for the behavioral counseling component of the patient intervention.

Depression is negatively associated with BP control and medication adherence.\textsuperscript{38} It will be assessed with the Patient Health Questionnaire (PHQ-9), a valid instrument for making criterion-based diagnoses of depressive disorders in primary care practices.\textsuperscript{39} A PHQ-9 score >10 had a sensitivity of 88\% for major depression, whereas PHQ-9 scores of >5, >10, and >20 represented mild, moderately severe, and severe depression, respectively.\textsuperscript{40}

Health-related quality of life is measured using the 5-item EuroQol,\textsuperscript{41} which assesses the patient’s health state in multiple areas (mobility, self-care, activities, pain/discomfort, anxiety/depression), and asks patients to rate their overall health state using a visual analog scale. This measure will be used to assess patient’s self-reported quality of life in relation to BP control.

**Chart Extraction Data**

Information extracted from the charts includes office BP readings, antihypertensive medications and dosages (this reflects the treatment intensity by participating physicians), changes in diagnosis, and medical comorbidity.

**Medical Comorbidity**

Hypertensive blacks have comorbid illnesses that may affect the primary outcome. We use the Charlson Comorbidity Index to adjust for the confounding effects on BP control and their nonuniform prognostic impact on patients. The Charlson Index is a validated weighted index for prospectively classifying comorbid conditions, which takes into account the number and the seriousness of comorbid diseases.\textsuperscript{42}

**CQI Process Measures**

These measures reflect the degree to which physicians adhere to recommended JNC-7 guidelines; for instance, the proportion of patients with compelling indications such as diabetes being treated with angiotensin-converting enzyme inhibitors, or those with stage II HTN being treated with a combination of 2 drugs. For each physician appointment recorded for a participant during the study period, the following data will be extracted from the charts: dates of appointment, prescribed medications following this appointment (name, dosage, frequency), or decrease or increase of medication.

Cost effectiveness of the intervention will be assessed in an incremental analysis that will compare total ambulatory care costs and BP control in the IC to those in the UC condition. Results will be expressed in terms of incremental total costs (or savings) in relation to the difference in proportion of patients whose BP becomes controlled at 12 months. For the cost analysis, we will measure costs applicable to IC and UC conditions (eg, RA time in conducting recruitment and follow up, medications, service use such as emergency department visits or specialists’ office visits), and costs applicable to the IC group only (eg, home BP monitors, study staff time for delivery of behavioral counseling sessions, investigators’ time for delivery of intervention-related CME courses) or UC group only (eg, study staff time for delivery of CME courses on non-HTN health-related topics). Costs will be converted into dollars using average local unit costs (for both intervention and usual care costs), time diaries and salaries (for RA and investigator time), and summed across components. Cost effectiveness will be calculated as the sum incremental increases in cost (or savings) in the IC divided by the corresponding incremental decrease (or increase) in SBP and DBP.

**Study Implementation: Challenges and Lessons Learned to Date**

We have encountered several “every day” or “real world” barriers to implementation of the CAATCH study protocol. One of the most frequently occurring barriers is limited access to office space for patient screening, consent, and evaluation. CHCs operate on a limited budget, and as a result, when patient caseload is high, consistent office space may be difficult to secure for patient screening, delivery of intervention, and study follow-up visits. Fortunately, this has been the case for few CHCs, and recruitment coordinators have been flexible and quickly adapted to such situations.

A second challenge that we have encountered is the rapid staff turnover at the CHCs, hence their limited availability for conducting the group counseling on lifestyle modifications. In 1 instance, the CHC nutritionist at 1 study site slated to deliver the group behavioral counseling began maternity leave shortly before the research protocol began at the CHC. In a second instance, a CHC nurse who served as the facilitator for the behavioral counseling was unavailable due to a heavy patient schedule and limited staff. In both of these situations, alternate study staff was at hand to deliver the behavioral counseling sessions. In addition, this led us to consider and pursue the option of hiring a study nutritionist, both to coordinate and track the progress of the group sessions, and to serve as “back-up” in situations where staffing becomes an issue.

A third challenge is the unanticipated higher than expected rates of screen-failures encountered as a result of using the automated BPTru monitor as our screening tool. Although the use of BPTru more effectively standardizes the identification of patients with uncontrolled BP, its stringency may also underevaluate patients whose BP levels would have been otherwise elevated. Thus, BPTru underestimates white-coat effect with a resultant higher than anticipated rate of screen-failures. As a result, we have had to screen 5 patients for each eligible patient. Added to this factor is the recent demographic shift in the population of blacks who attend CHCs in the New York City Metropolitan Area. The combination of these factors has prolonged patient recruitment by a significant amount of time.

Finally, competing demands and priorities that primary care providers face in underresourced primary care practices pose the biggest challenge to implementation of the study protocol, given its heavy reliance on voluntary participation of the providers. As the numbers of uninsured patients continue to rise, the demand for low-cost primary care services continues to grow. The combination of increased
patient volume coupled with the relatively limited resources available to the primary care providers makes their voluntary participation and adherence to study protocol difficult or impossible. For our study, a significant proportion of the participating providers could not attend the continuous medical education HTN case rounds at the allotted time for these reasons.

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Disclosures

None.

References


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