The global prevalence of hypertension, and the associated morbidity and mortality rates, is among the highest for blacks in the United States. Barriers to hypertension control in blacks have been identified at multiple levels, including: patient nonadherence to regimens; suboptimal prescribing; and ineffective health systems. A recent review of quality improvement strategies suggests that a team change involving pharmacists may be one of the most effective quality improvement strategies for improving blood pressure control. However, it is not known whether pharmacy interventions can be implemented successfully in corporately owned pharmacies, where most Americans now obtain their prescriptions.

Barriers to Adherence in Black Patients
Although nonadherence with antihypertensive regimens is found in all groups, blacks often have higher nonadherence according to objective measures. Studies show that minority populations experience more barriers to adherence, even after controlling for socioeconomic status. For example, blacks are more likely than whites to experience the "core" barriers to adherence, including: problematic side effects, difficulty remembering, doubts or concerns about drug efficacy, and difficulty paying for drugs. Higher priority must be placed on better tools or models of care for detecting and reducing these modifiable barriers to adherence in blacks.

Lack of Provider Tools, Training, and Confidence
Reviews of adherence-enhancing interventions suggest that many educational and behavioral interventions are efficacious; however, practitioners generally lack formal training in these techniques and lack user-friendly tools for assessing and changing patient behavior in busy practices. As a result, they often lack confidence in changing patient
behavior and view evidence-based interventions as too complicated, labor-intensive, or expensive to be implemented widely.\(^8\)\(^-\)\(^9\) Higher priority must be placed on the design of user-friendly tools and strategies that require minimal training and start-up costs and are easy to implement in busy settings. We designed our interventions with these issues in mind.

Involvement of Community Pharmacists: Need for Randomized Controlled Trials

Over the past 10 to 15 years, pharmacy education has emphasized pharmacists’ role in patient care and disease management, including hypertension.\(^10\) Pilot studies generally show that pharmacists who provide patient education and monitoring of BP can have significant effects on patient adherence (range, 28% to 95%) and BP control (range, 38% to 70%).\(^11\)\(^-\)\(^17\) Studies also show that physicians frequently change therapy based on pharmacist recommendations.\(^18\)\(^-\)\(^21\) Zillich and others\(^21\) conducted a trial that randomized 12 Iowa pharmacies to high-intensity versus low-intensity pharmacist intervention in predominantly white patients. Their results showed that 75% of the pharmacist’s recommendations were accepted by physicians.

Although these trends are promising, past studies examining the effects of pharmacist intervention have limitations. First, many studies have been conducted by pharmacy faculty or residents in university-affiliated sites, raising questions about generalizability. Especially needed are studies in corporately owned pharmacies, which now account for more than 50% of the prescriptions dispensed in the United States.\(^22\) Second, most studies have involved a small number of patients referred by physicians, resulting in biased samples. Third, studies suggest that pharmacist interventions can be cost-effective in hypertension clinics\(^23\) and Canadian pharmacies.\(^24\) It is unknown whether similar results can be obtained in the community, where a larger number of people could be reached. Our study therefore evaluates a team approach to hypertension management for black patients in corporately-owned pharmacies.

The Team Education and Adherence Monitoring (TEAM) Trial evaluates the outcomes of a team-oriented intervention that is evidence-based, patient-centered, and designed to be relatively brief and easy to implement in a community pharmacy. The interventions are focused on pharmacists and pharmacy technicians working with patients and physicians to improve BP control, the primary outcome. Secondary outcomes are changes in pharmacy-based adherence monitoring and intervention, patient adherence, and barriers to adherence, prescribing, and cost-effectiveness. The cost-effectiveness results can be compared to findings from other settings to identify the potential role of community pharmacy-based interventions in optimizing BP control. It is possible that a community pharmacy-based program may be less expensive than previously evaluated settings, offering a wider scale of intervention for fewer resources.

Conceptual Framework

The proposed intervention builds on 2 models which help us predict and address barriers to patient adherence and changes in pharmacy practice. First, the intervention builds on Svarstad and Bultman’s Health Collaboration Model (HCM).\(^25\)\(^-\)\(^27\) The HCM identifies 5 “core” adherence barriers amenable to change by pharmacists. These “core barriers” include: regimen knowledge barriers (poor understanding of the drug regimen and its elements such as dosage schedule, treatment duration, purpose), recall barriers (difficulty remembering multiple drugs and doses), motivational barriers (doubts regarding drug efficacy, benefits, or need for therapy), side effect barriers (bothersome side effects or concerns about long-term effects), and access barriers (difficulty paying or obtaining refills). The HCM posits that these “core barriers” can be detected and reduced by using certain tools for (1) monitoring adherence and barriers to adherence, (2) eliciting patient involvement, (3) “tailoring” interventions to address patient-specific concerns and barriers, and (4) providing regular follow-up and support to patients and physicians.

Second, the intervention builds on organizational strategies recommended in Rogers’ Diffusion of Innovation Model.\(^28\) His work suggests several strategies for promoting the adoption of
new tools and practices. First, the change agent (researcher) must seek input from users (pharmacists) to make sure that the proposed innovations (BP program and tools) are “compatible” with existing routines and work flow in the user’s organization (pharmacy). The change agent also must recognize the influence of other stakeholders (pharmacy district managers or supervisors) who can facilitate change and provide the support needed to achieve changes in practice. The change agent also must make sure that the new tools and practices are relatively simple, easy to use, and viewed by stakeholders as having relative advantages or benefits for them, their clients, and the larger organization (corporation). It is for these reasons that we developed a pharmacy-based BP program that is relatively short (6 months), involves pharmacists and pharmacy technicians, requires minimal training (8 hours), and includes time-saving tools for more rapid adherence monitoring and intervention. In addition, we established a management advisory group to facilitate collaboration between researchers and pharmacy district managers and supervisors to make sure our TEAM program and tools were compatible with pharmacy routines, resources, corporate missions, and plans. Rogers’ work also helped identify potential barriers to change such as workload, turnover, staff beliefs, and perceived barriers to change. These variables have been added to the study model to guide our analysis of intervention fidelity and outcomes (Figure 1).

WHAT IS KNOWN

- Involving pharmacists may be an effective strategy for monitoring and improving patient adherence and blood pressure (BP) control, but few controlled studies have been done in corporately owned pharmacies, where most Americans now obtain their prescriptions.

WHAT THE STUDY ADDS

- This article describes the Team Education and Adherence Monitoring (TEAM) Trial, the first randomized controlled trial (RCT) examining the cost-effectiveness of a team-oriented intervention to improve patient adherence and BP control in corporately owned community pharmacies.
- The TEAM Trial is unique because researchers recruited 28 pharmacies, screened 1,250 patients, and targeted a high-risk group of 597 treated African American patients with uncontrolled BP.
- This article is the first report describing the researchers’ conceptual model, how they selected and randomized pharmacies, how they designed their innovative BP clinics and tools, how they trained intervention pharmacists and pharmacy technicians, and how they will evaluate their interventions using blinded interviewers and other data sources.
- This work is important because community pharmacists are in an excellent position to monitor patient adherence and BP control between clinic visits and to provide useful information to hypertensive patients and their physicians.

Study Design

This study evaluates the outcomes of TEAM care (TC) versus usual care (UC) in a randomized controlled trial approved by each investigator’s institutional review board (IRB), with the University of Wisconsin IRB assuming primary responsibility. The study involves 28 community pharmacies owned by Walgreens and Aurora Pharmacy Inc. Walgreens is the nation’s largest drugstore chain with more than 5000 pharmacies nationwide, and Aurora Pharmacy Inc is a regional chain with more than 100 pharmacies in Wisconsin. The study statistician used computer software to randomize the 28 sites into an intervention group (TC) and a control group (UC; see Figure 2). Data collectors screened patients, obtained consents, and collected baseline patient and staff surveys. Researchers also reviewed pharmacy records at baseline. The goal was to enroll 25 hypertensive black patients, 1 pharmacist, and 1 to 2 pharmacy technicians per site. Primary and secondary outcomes were assessed 6 and 12 months after enrollment using blinded data collectors, prescription profiles, and program records.

Study Sites and Population

The study pharmacies had to be owned by Walgreens or Aurora Pharmacy Inc, located in a zip code area with a significant black population, and have 1 licensed pharmacist and 1 pharmacy technician willing to implement a BP clinic and TEAM Care program for 25 hypertensive patients over a 6-month period. The pharmacies were identified by their pharmacy supervisor or district manager in collaboration with the principal investigator (B.L.S.) and located in 5 Wisconsin cities: Milwaukee, Racine, Kenosha, Beloit, and Madison. The majority of pharmacies were located in zip code areas with ≥30% blacks.

To be eligible for the TEAM trial, patients had to: be black and 18 years or older, have an active prescription for antihypertensive medication, get their antihypertensive medication filled at the study pharmacy, have a mean screening BP ≥140/90 mm Hg and ≤210/115 mm Hg (using the second and third BP measurements), and be able to read and fill out a self-administered questionnaire and come to the study pharmacy for 6 monthly visits if needed. Patients were excluded if they reported kidney dialysis, liver disease, organ transplant, memory loss that interferes with daily activities, terminal illness, pregnancy, alcohol or substance problem, or symptoms of heart failure (short of breath or chest pain after walking one-half block, feet and legs so swollen that you can’t put on your shoes, or difficulty sleeping because of shortness of breath). Patients also were excluded if their arm circumference was larger than recommended for the available cuffs (>16.5 inches) or if their physician recommended exclusion for medical reasons. Patients were distributed across all physician practice settings.

Patients were recruited by trained data collectors using study posters, flyers, monetary incentives, and help from pharmacy staff, pharmacy students, and black health professionals who sponsored a small number of church-based screenings in 1 of the cities. The flyer included a brief study description, a toll-free number, and a tear-off section for patients to indicate interest and contact information. The data
collectors then contacted interested patients about a convenient time for screening at their pharmacy. Patients were offered a $5 gift card for completing the BP screening, a $20 card for completing enrollment questionnaires, a $25 card for the 6-month follow-up questionnaire and BP check, and up to $10 in gift cards to offset certain transportation costs. Researchers also distributed a staff information sheet and consent form to participating pharmacists and pharmacy technicians before completing a baseline and 6-month follow-up survey. Pharmacy staff received no monetary incentives or compensation for participation. Intervention staff received 7.0 hours of continuing education credit at no cost. Employers received compensation for staff retrieval of patient records and other study-related activities.

**Interventions**

**Information for All Pharmacy Staff, Patients, and Physicians (UC and TC sites)**

All pharmacists and pharmacy technicians received an oral and written description of the study, 1 copy of a reference card with JNC 7 guidelines, and copies of 2 hypertension brochures that were mailed to their patients. After the pharmacy met enrollment goals, the principal investigator (PI) mailed a packet to all patients. This packet explained the patient’s assigned group and encouraged the patient to read the enclosed brochures titled “High Blood Pressure in African Americans” (American Heart Association, 2001) and “Your Guide for Lowering Blood Pressure” (National Heart, Lung, and Blood Institute, 2003). The brochures explained the risks of high BP, how to interpret BP numbers, and ways to lower BP (tips for managing drugs, being active, cutting salt, following Dietary Approaches to Stop Hypertension (DASH) plan, losing weight). The PI also mailed a packet to the patient’s primary physician. The physician packet included a description of the study and eligibility criteria, a form for recommending patient exclusion (if needed), and a reference card with JNC 7 guidelines for treating hypertension. No additional interventions were delivered to the usual care pharmacy staff, patients, or their physicians.

**Training for Intervention Pharmacists and Pharmacy Technicians (TC Sites)**

Table 1 lists the multi-step intervention targeting pharmacy staff and patients at the TC sites. The first step involved training pharmacists and pharmacy technicians. Pharmacy staff who completed this training received 7 credit hours of continuing education for self-study (1 hour) and attending a 7-hour interactive workshop conducted by pharmacy and medical educators using diverse methods (lecture, slides, handouts, demonstration and practice, role play, case studies, break-out discussion). Three modules addressed: the rationale and guidelines for measuring and managing hypertension in blacks; the rationale and guidelines for improving patient adherence and involvement in care; and guidelines for improving patient follow-up, retention, and physician collaboration. (Although our trial targeted blacks, the TEAM mate materials and tools were designed so they can be applied in any population or pharmacy.)

**Clinical Tools Kits (TC Sites)**

The second intervention step involved the distribution of clinical tools to intervention staff at TC sites (Table 1). These user-friendly tool kits included: automatic BP monitoring equipment, portable furniture and a privacy screen for setting up a BP clinic in the pharmacy waiting area, and tools for more rapid adherence monitoring and intervention with patients and physicians. These tools included: a 2-page Brief Medication Questionnaire (BMQ) for screening patient adherence and barriers to adherence; a 4-page Health and Lifestyle Questionnaire (HLQ) for assessing patient risk factors, BP awareness, lifestyle, and patient goals; adherence counseling tips with an algorithm for "tailored intervention" using the BMQ and HLQ; a 1-page Team Action Plan (TAP) for documenting the patient’s BP, adherence and lifestyle issues, interventions, and plans; a 1-page BP Goal Check (BGC) for brief monitoring at follow-up visits; a 1-page TEAM Log for brief charting of BP and progress notes; a tool
and guidelines for informing and referring patients with severely elevated BP; and appointment tools (appointment cards, reminders, scheduling book). The clinical tools also included an innovative check list called the Request for Medication Review (RMR). The RMR enabled pharmacists to provide systematic and rapid feedback to physicians and included space for BP readings, adherence and lifestyle issues, and recommendations for change in the drug regimen, if appropriate. The RMR also included space and instructions for the physician to fax a response to the pharmacy if appropriate. Pharmacists were encouraged to send specific recommendations to physicians based on JNC 7 guidelines if appropriate.

### Patient Tool Kits (TC Sites)

The third intervention step involved the distribution of patient tool kits to intervention staff. These user-friendly tools included adherence aides and colorful leaflets that we designed specifically for our pharmacy-based BP clinics. The content was based on JNC 7 recommendations, established behavioral interventions, and the Health Collaboration Model. They included a pill organizer, BP tracker, pedometer, and easy-to-read leaflets or tips sheets for increasing patient awareness of BP goals, patient use of pharmacists and other strategies for managing medications, and tips for making lifestyle changes (Table 1).

### Pharmacy Clinic and TEAM Care Program

The fourth intervention step involved the establishment of BP clinic hours and implementation of a 6-month TEAM Care Program at each TC site. Intervention staff selected BP clinic hours based on available staffing; however, all TC sites aimed for 1 monthly visit with each enrolled patient over a 6-month period. Table 2 lists the components of the TEAM Care program and roles performed by intervention staff and patients. In preparation for all visits, the pharmacy technician made and confirmed appointments, printed patient profiles, and set up the BP equipment and furniture. During Visit 1, the pharmacy technician welcomed the patient, took BP readings, and introduced the BMQ and HLQ forms to be completed by patients. The pharmacist met with the patient to assess BP, made and confirmed appointments, printed patient profiles, and introduced the BP equipment and furniture. During Visit 1, the pharmacy technician welcomed the patient, took BP readings, and introduced the BMQ and HLQ forms to be completed by patients. The pharmacist met with the patient to assess BP, adherence and lifestyle issues, and patient goals for the next 6 months. The pharmacist also offered BP counseling, tailored intervention, and the patient tool kit. During Visits 2 to

### Table 1. Interventions in TEAM Trial

| Module 1: Measuring and Managing BP in blacks: Tools and Guidelines |
| Module 2: Improving Patient Adherence and Involvement in Care: Tools and Guidelines |
| Module 3: Improving Patient Follow-Up and Physician Collaboration: Tools, Guidelines, Barriers |
| B. Provide clinical tool kits |
| B1: Microlife Model 3AA1–2 |
| B2: BP measurement check list |
| B3: Pharmacy furniture |
| B4: JNC 7 Reference Card |
| B5: Brief Medication Questionnaire (BMQ) |
| B6: Health and Lifestyle Questionnaire (HLQ) |
| B7: Counseling Tips: BMQ and HLQ |
| B8: Team Action Plan (TAP) |
| B9: BP Goal Check (BGC) |
| B10: Request for Medication Review (RMR) |
| B11: Team Log |
| B12: Appointment tools |
| B13: Instructions for severely elevated BP |
| C. Provide patient tool kits |
| C1: Know Your Numbers |
| C2: My BP Tracker |
| C3: Manage Your Medications |
| C4: 7-Day Pill Organizer |
| C5: Add Steps to Your Day |
| C6: Pedometer |
| C7: Shake Your Salt Habit |
| C8: Try the DASH Eating Plan |
| D. Implement pharmacy clinic and TEAM Care program (components in Table 2) |
Table 2. Components of TEAM Care Program

Pharmacy Visit 1: Initial Consultation

- Pharmacy technician makes/confirms BP clinic appointments, sets up furniture, prints profile, welcomes/orients patient, measures BP, asks patient to fill out forms
- Patient fills out BMQ and HLO, giving feedback regarding adherence, barriers to adherence, BP awareness, lifestyle, and patient goals
- Pharmacist assesses BP, awareness, adherence, barriers, regimen, lifestyle, goals
- Pharmacist gives BP counseling, tailored intervention, and tool kit
- Pharmacist documents problems, interventions, and plans using TAP and log
- Pharmacist sends recommendations to physician using RMR, as needed
- Pharmacist or pharmacy technician makes appointment for visit 2, gives card

Pharmacy Visits 2 through 6: Brief Monitoring Follow-Up

- Pharmacy technician confirms appointment, sets up furniture, prints profile, welcomes patient, measures BP, asks patient to fill out part of BGC
- Patient fills out BGC, giving feedback regarding adherence, barriers, lifestyle
- Pharmacist re-assesses/documents BP, adherence, barriers, lifestyle, and regimen
- Pharmacist reinforces patient adherence and efforts; reviews options, as needed
- Pharmacist sends feedback/recommendations to physician using RMR, as needed
- Pharmacist or pharmacy technician makes appointments for visits 3 through 5, gives card

6, the pharmacy technician welcomed the patient, took BP readings, and showed the patient how to complete parts of the BGC form for assessing patient progress and concerns at follow-up visits. The pharmacist met with the patient to monitor progress, reinforce adherence, and support change efforts. Pharmacists also faxed written feedback with recommendations for change to the physician as needed. These follow-up visits were designed to be brief and coincide with the patient’s regular visits to the pharmacy for picking up refills, if possible.

Measurement and Analysis

Based on past studies with a similar protocol and >30% blacks, we estimated an intervention effect size ranging from 0.40 to 0.55. Because of the hierarchical nature of the data (patients within pharmacies), we projected varying pharmacy dependencies in patient responding ($\rho = 0.02$ to 0.08). We used the OPDES (Optimal Design Version 0.19) computer program\textsuperscript{11} to estimate the optimal sample size to maintain statistical power at 0.80, with $\alpha = 0.05$ (2-tailed). A study of power based on various size configurations of pharmacies, patients, and pharmacy dependencies indicated that a configuration of 28 pharmacies would require approximately 18 patients per site or 504 patients overall to maintain statistical power with an effect size of 0.40 and a pharmacy dependency of $\rho = 0.08$. We oversampled patients (25 patients per site) to allow for attrition. The final sample included 597 patients.

The follow-up evaluations were performed by the University of Wisconsin Survey Center, a nationally recognized center that uses experienced interviewers and experts in locating and tracking subjects in longitudinal studies. As a result, we retained 566 patients (approximately 20 patients per site), yielding a preliminary response rate of 94.8%. This means we should have sufficient power.

Table 3 lists the measures and data collected. The primary outcomes (BP control and reductions in BP) were measured 6 and 12 months after enrollment by data collectors blinded to the patient’s assigned group and trained to obtain accurate BP readings using appropriately sized cuffs, an adjustable table, and a monitor validated by the British Hypertension Society (Microlife Model 3AA1-2). After measuring the patient’s BP, data collectors asked patients to complete 2 questionnaires: a BMQ\textsuperscript{30} for assessing adherence and barriers to adherence, and a questionnaire for measuring patient background characteristics and other outcome measures.

In addition to self-reported patient adherence, we are measuring changes in refill adherence using pharmacy prescription profiles. Changes in adherence monitoring and intervention will be examined using program records, staff surveys, and patient survey items. Changes in prescribing will be measured using prescription records to determine whether the prescriber intensified drug therapy, whether the regimen was consistent with JNC 7 prescribing guidelines, and how prescribers responded to any pharmacist recommendations. Cost-effectiveness will be analyzed for TC versus UC patients using program records, prescription profiles, and patient-reported use of health services. Costs to deliver the intervention include primarily pharmacist and pharmacy technician time. We also anticipate changes in antihypertensive medication use and changes in the use of other health care services in the short run. We will apply the societal and provider perspectives although we will only include short-run elements.

We plan to construct 2-level hierarchical regression models in our analysis of intervention effects. Our plan includes identifying and controlling any preexisting patient differences that can impact patient involvement and response (eg, patient age, gender, education, income, comorbidities, payment source, drug regimen). We also will analyze variations in “intervention fidelity” or the extent to which intervention staff actually use the TEAM tools and adhere to TEAM guidelines for adherence monitoring and intervention with patients and physicians. It is hypothesized that greater intervention fidelity will be associated with greater reductions in the “core” barriers to adherence, prescribing changes, patient adherence, and BP control (Figure 1). Finally, we will examine whether any baseline pharmacy and staff characteristics are linked to changes in adherence monitoring, intervention, and intervention fidelity. This analysis will help identify barriers to change in pharmacy practices. For example, higher workloads may reduce the extent to which intervention staff is willing or able to fully implement the TEAM protocol and tools for adherence monitoring and intervention.
Challenges and Lessons Learned To Date

We have experienced several challenges. The first challenge was to identify pharmacy corporations able to participate in a large controlled trial. We first identified a corporation that was willing to participate and gave access to pharmacies in 2 states. Unfortunately, the corporation experienced delays when installing a new information system and later notified us that they planned to sell their pharmacies before the program could be implemented. We then approached Walgreens and Aurora Pharmacy Inc. Fortunately, they were interested and provided exceptional support during the study. A key lesson in our partnership with Walgreens and Aurora Pharmacy Inc was the importance of regular communication with district supervisors who believed strongly in the need for improved pharmacy care in this area and provided valuable help in recruiting pharmacies, encouraging staff to participate, and addressing barriers to implementation.

Second, we anticipated the lack of private space in a busy pharmacy. Despite these challenges, data collectors and pharmacy staff were able to create semiprivate spaces using portable tables, chairs, and privacy screens in pharmacy waiting areas. Another set of challenges involved the review of protocols by multiple IRBs. The IRBs had limited experience with pharmacy trials and often had different concerns or points of view about consent procedures, whether and how to inform physicians, and other issues.

Another set of challenges related to the staff time, resources, and coordination required to recruit and orient pharmacy staff and patients at 28 pharmacies in 5 cities. Fortunately, many pharmacists and pharmacy technicians were eager to participate and provided valuable help in enrolling nearly 600 patients over an 8-month period. As in many trials, intervention staff later experienced difficulties relocating and contacting patients because of disconnected telephones and changes in home address and insurance. As a result, a number of patients never attended any pharmacy visits or had a low rate of attendance despite heroic outreach efforts by pharmacy staff. Whether patient attendance at a pharmacy-based clinic is associated with certain patient-related or pharmacy-related barriers to change will be examined along with sources of variation in staff adherence to the TEAM guidelines (“intervention fidelity”). These findings will help researchers identify the predictors of program success or failure across different patient populations, providers, and sites.

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None.

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