Does Reducing Physician Uncertainty Improve Hypertension Control?
Rationale and Methods

Valory N. Pavlik, PhD; Anthony J. Greisinger, PhD; James Pool, MD; Paul Haidet, MD, MPH; David J. Hyman, MD, MPH

Abstract—Hypertension affects nearly one third of the US population overall, and the prevalence rises sharply with age. In spite of public educational campaigns and professional education programs to encourage blood pressure measurement and control of both systolic and diastolic control to <140/90 mm Hg (or 130/80 mm Hg if diabetic), 43% of treated hypertensives do not achieve the recommended Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure target. Among blacks, 48% are uncontrolled on treatment. The majority of persons classified as poorly controlled hypertensives have mild systolic blood pressure elevation (in the range of 140 to 160 mm Hg). We hypothesized that physician uncertainty regarding the patient’s usual blood pressure, as well as uncertainty regarding the extent of medication nonadherence, represent an important barrier to further reductions in the proportion of uncontrolled hypertensives in the United States. Using cluster randomization, 10 primary care clinics (6 from a public health care system and 4 from a private clinic system) were randomized to either the uncertainty reduction intervention condition or to usual care. An average of 68 patients per clinic were recruited to serve as units of observation. Physicians in the 5 intervention clinics were provided with a specially designed study form that included a graph of recent blood pressure measurements in their study patients, a check box to indicate their assessment of the adequacy of the patient’s blood pressure control, and a menu of services they could order to aid in patient management. These menu options included 24-hour ambulatory blood pressure monitoring; electronic bottle cap assessment of medication adherence, followed by medication adherence counseling in patients found to be nonadherent; and lifestyle assessment and counseling followed by 24-hour ambulatory blood pressure monitoring. Physicians in the 5 usual practice clinics did not have access to these services but were informed of which patients had been enrolled in the study. Substudies carried out to further characterize the study population and interpret intervention results included ambulatory blood pressure monitoring and electronic bottle cap monitoring in a random subsample of patients at baseline, and audio recording of patient-physician encounters after intervention implementation. The primary study end point was defined as the proportion of patients with controlled blood pressure (<140/90 mm Hg or <130/80 mm Hg if diabetic). Secondary end points include actual measured clinic systolic and diastolic blood pressure, patient physician communication patterns, physician prescribing patient self-reported lifestyle and medication adherence, physician knowledge, attitude and beliefs regarding the utility of intervention tools to achieve blood pressure control, and the cost-effectiveness of the intervention. Six-hundred eighty patients have been randomized, and 675 remain in active follow-up after 1.5 years. Patient closeout will be complete in March 2009. Analyses of the baseline data are in progress. Office-based blood pressure measurement error and bias, as well as physician and patient beliefs about the need for treatment intensification, may be important factors that limit further progress in blood pressure control. This trial will provide data on the extent to which available technologies not widely used in primary care will change physician prescribing behavior and patient adherence to prescribed treatment. (Circ Cardiovasc Qual Outcomes. 2009;2:257-263.)

Key Words: hypertension ■ blacks ■ randomized controlled trial ■ blood pressure monitoring, ambulatory

When hypertension was first identified as a major public health problem in the late 1960’s, strategies to address this cardiovascular risk factor focused on increasing public awareness and screening, and on educating physicians regarding the need to diagnose and treat the condition. Periodic national health surveys have demonstrated the effects of these efforts in increasing awareness, treatment, and control of hypertension in the population. Despite improvements, ≈30% of the US population professes to be unaware of being hypertensive and as of 1999...
to 2004, only 57% of patients being treated for hypertension were controlled.\textsuperscript{3}

Hypertension is a major contributor to disparities in mortality between blacks and non-Hispanic whites. Epidemiological data indicate an earlier age of onset and higher age-specific prevalence of hypertension among blacks. Control of diagnosed hypertension for blacks was comparable to that of whites in the third National Health and Nutrition Examination Survey (1988–1994), but at an unacceptably low level (27% of all hypertensives, 47% of treated hypertensives).\textsuperscript{2} Since that time, control levels for whites have outpaced those for blacks.\textsuperscript{3} Although health care access and patient adherence represent important barriers to population-level hypertension control, a large and growing literature on the subject shows that the majority of uncontrolled hypertensives, including blacks, are under medical care, and that physicians frequently do not act in the clinical encounter to achieve the recommended treatment goals.\textsuperscript{4–10} This “clinical inertia,” in which physicians do not act to achieve evidence-based goals, is a major barrier to hypertension control. There is considerable evidence that physicians simply have higher thresholds for action than recommendations made by evidence-based guidelines, such as the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7).\textsuperscript{11}

Based on discussions with practicing physicians and our work in evaluating blood pressure (BP) control in primary care settings, we found that issues related to BP measurement and variability are an underappreciated barrier to achieving JNC 7 goals. Most of the “uncontrolled” BP measurements seen in practice are in the 140 to 160 mm Hg systolic pressure range.\textsuperscript{8,12} The intrapatient standard deviation in studies with careful BP measurement protocols is \( \approx 10 \) mm Hg.\textsuperscript{13,14} Therefore, a substantial proportion of clinic measurements in persons with an average SBP >140 mm Hg will be below 140 mm Hg. This represents a source of uncertainty for both patients and physicians about the need to intensify treatment.

We hypothesized that barriers to adequate BP control arise from an interaction between physician uncertainty about the patient’s usual BP and their adherence to treatment, and patients’ own perceptions about the need to intensify treatment. In recent years, several published reports have supported the hypothesis that physician uncertainty regarding usual BP level and compliance are major factors in the lack of control. Studies that have examined reasons why physicians do not titrate in the face of elevated BP at clinic visits report physician beliefs that the observed BP is atypical and uncertainty over current adherence are the principal reasons for failure to intensify treatment.\textsuperscript{15,16} Differences in adherence to treatment, prevalence of side effects, and perceptions of the health risks associated with hypertension have been reported in blacks compared to other racial groups.\textsuperscript{16,17} Thus, it is possible that factors underlying uncertainty regarding the need to titrate medications may differ for black patients.

In this article, we describe a cluster-randomized clinical trial to determine whether eliminating uncertainty regarding the need for treatment intensification in primary care settings will result in hypertension control to JNC 7 recommended goals. We planned the study to include 2 years of follow-up in a sample of at least 60% of black patients whose hypertension was uncontrolled at the beginning of the study. The rationale for the overrepresentation of blacks is to ensure that the study results can be generalized to this high-risk group.

**Conceptual Framework**

In the theoretical framework of Everett Rogers’ “Diffusion of Innovations” model, adoption of new ideas or technologies goes through a predictable series of phases, from acquisition of knowledge about the innovation, persuasion that the innovation should be adopted, the decision to adopt, implementation, and confirmation.\textsuperscript{18} As mentioned previously, the term “clinical inertia” was introduced to describe physician failure to act to achieve a recommended treatment target. O’Connor has written, “Strong evidence now indicates that therapy for hypertension, dyslipidemia, and diabetes can prevent or delay complications . . . . Despite such advances, health care providers often do not initiate or intensify therapy appropriately during visits of patients with these problems. We define such behavior as clinical inertia—recognition of the problem, but failure to act.”\textsuperscript{19} According to the diffusion of innovations model, once knowledge of the innovation has been disseminated, the characteristics of the innovation can alter its rate of adoption. These characteristics are (1) its perceived relative advantage over other strategies; (2) its compatibility with existing norms and beliefs; (3) the degree of complexity involved in adopting the innovation; (4) the trialability of the innovation— ie, the extent to which it can be used on a probationary basis and its effects observed; and (5) the observability of the results of adoption. The studies of physician practice cited earlier\textsuperscript{15,16} suggest that delay in adoption of the JNC-7 treatment guidelines is primarily attributable to problems with perceived relative advantage, trialability, and observability. The relative advantage of a treatment intensification may be questionable if the physician doubts the patient is taking the currently prescribed drugs. Trialability may be perceived as limited by the possibility of side effects or the inconvenience of altering a treatment regimen with which the patient is satisfied. Only if the physician and patient are convinced of the need to intensify treatment, does the treatment intensification seem worth attempting. Observability may be limited in the short-term by errors in measurement of BP, because office BP’s have a high variance and access to more valid and reliable measurements is restricted. The components of the intervention to be evaluated in our study are designed to address each of these aspects of blood pressure management, as outlined in Table 1. Twenty-four-hour ambulatory blood pressure monitoring (ABPM) provides the gold standard measurement of usual blood pressure, and can answer directly the question as to whether the patient’s office blood pressure is atypical.\textsuperscript{19–21} Medication adherence monitoring with electronic bottle caps is likewise the most valid measurement of the patient’s adherence.\textsuperscript{22,23} The provision of lifestyle assessment and counseling followed by 24-hour ABPM addresses the question of relative advantage of a drug titration. As long as the provider and the patient believe that the patient should make additional efforts to control blood pressure through lifestyle, drug treatment intensification can be postponed indefinitely.
When we designed the study, there was no experimental evidence to indicate whether these interventions can be effective in achieving improvement in blood pressure control. However, a study of electronic bottle cap monitoring of hypertensive patients in Switzerland, published in 2008, provides support for the validity of objective medication adherence feedback to primary care providers as a way to improve control.24

The recent studies on physician uncertainty cited above15,16 were carried out in systems with electronic medical records systems designed to prompt appropriate treatment intensification. These studies suggest that even when health systems have implemented sophisticated mechanisms to support achievement of blood pressure control targets, patient and physician factors within systems still account for significant variations in treatment outcomes. Although the diffusion of innovations model was useful in guiding the selection of intervention elements, it should be noted that the inclusion of clinics from 2 different health care systems will permit exploratory analysis of the contribution of additional systems factors in the observed outcomes.

### Study Methods

#### Design

We will test the hypothesis that physician uncertainty reduction will improve blood pressure control in a cluster randomized trial with 5 intervention clinics and 5 control clinics (see Figure 1). The clinic serves as the unit of randomization, physicians as the unit of intervention, and a sample of eligible patients within each clinic as the unit of observation. We are comparing the physician uncertainty reduction (PUR) intervention to usual practice (UP), which consists of physicians providing care without access to the uncertainty reduction tools. Our primary end point is expressed as the proportion of patients with average clinic blood pressure \$/text{H11021}/text{H140}/text{H90} \text{ mm Hg} \text{ in the previous 2 visits} \text{ (130}/text{H80} \text{ mm Hg if the patient also has diabetes)}. Secondary end points are actual measured clinic systolic and diastolic blood pressure, patient-physician communication patterns, patient adherence to medication and healthy lifestyle (measured with self-report and electronic bottle cap monitoring in a subsample), physician knowledge, attitude and beliefs about JNC 7 goals and barriers to achievement of the treatment goals, and the cost necessary to achieve the study goals. We expect that temporal trends and physician awareness that their patients are being monitored will lead to blood pressure control in 20% to 30% of patients initially uncontrolled in the UP clinics, and have powered the study for an effect size of 50% of patients controlled in the PUR condition versus 30% in UP. The requisite sample size to detect this effect with $\alpha=0.05$ (2-sided) and power of 0.90, an intraclass correlation of 0.008 (to account for the cluster design) is 160 per group. The intraclass correlation was calculated in a sample of patients with serial blood pressure measurements from the clinics in which the study is being implemented. We inflated this number to 340 per group (680 total) at initial randomization to allow for an expected 20% attrition over 2 years of follow-up and to allow for 40% of the sample to consist of nonblacks. In summary, the study is

### Table 1. Relationship of Intervention Methods to Diffusion of Innovation Model

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Knowledge</td>
<td>HTN indicates hypertension.</td>
</tr>
<tr>
<td>II. Persuasion</td>
<td>Follows adult learning theory principles</td>
</tr>
<tr>
<td>III. Decision</td>
<td>Emphasizes importance of HTN control in blacks</td>
</tr>
<tr>
<td>IV. Implementation</td>
<td>Provide medication and lifestyle adherence counseling as needed (relative advantage, trialability)</td>
</tr>
<tr>
<td>V. Confirmation</td>
<td>Special intervention in 5 clinics to increase rate of adoption among physicians.</td>
</tr>
<tr>
<td>Future studies</td>
<td>Special intervention in 5 clinics to increase rate of adoption among physicians.</td>
</tr>
</tbody>
</table>

HTN indicates hypertension.
powered to permit an analysis of the primary end point in black participants. No a priori hypotheses were specified for nonblacks, but we considered the inclusion of other racial/ethnic groups seen in the study clinics essential for ethical reasons and acceptability of the study to the community representatives charged with reviewing and approving proposed research projects in these health care systems. However, we do plan to conduct exploratory analyses to determine whether the intervention effects are similar in nonblacks.

Study Sites
Our study is being conducted in 10 primary care clinics that represent a public health care delivery system and a private practice network in a large urban area. The clinics are geographically dispersed throughout Houston, Texas. The public health care system, the Harris County Hospital District (HCHD), is a tax-supported county authority charged with providing comprehensive health care to uninsured or underinsured residents of the county. It consists of 2 general hospitals, 1 specialty hospital, and 11 community health centers that offer a full range of primary care services. The HCHD has affiliation agreements with 2 medical schools for physician staffing, and residency and medical student teaching. The system generates more than 1 000 000 outpatient visits annually. The private clinics are part of the Kelsey-Seybold Clinic system, a large multi-specialty group practice with 300 physicians and 18 clinic locations serving the greater Houston area. Over 400 000 patients are served annually. The Kelsey-Seybold Clinic system participates in clinical research through the Kelsey Research Foundation, which provides infrastructure and research study coordination expertise. The 6 HCHD clinics and 4 Kelsey-Seybold System clinics were selected for the study based on availability of a sufficiently large black population to meet sample size requirements. To prevent imbalances in the number of private and public clinics included in each study arm, we randomly assigned them to intervention or control conditions within strata.

Patient Inclusion and Exclusion Criteria
Potentially eligible patients are being identified through a combination of medical records review and screening interviews with study research coordinators. The inclusion criteria include: (1) age greater than 21 years; (2) at least 1 visit to a participating primary care physician in a study clinic in the past 12 months; (3) a chart diagnosis of hypertension; and (4) 2 most recent consecutive blood pressure readings greater than 140 mm Hg systolic or 90 mm Hg diastolic (or 130/80 if diabetes was present).

Patients are excluded if they have a chart diagnosis or laboratory evidence of chronic renal disease, have a diagnosis of cancer (other than nonmelanoma skin cancer) in the past 5 years, other serious conditions such as HIV/AIDS, have dementia or are dependent on a caregiver for activities of daily living, are pregnant, are planning to move to another city within the next 2 years, or cannot be contacted by telephone.

Description of Interventions
Physician Education Regarding JNC 7 Guidelines (Dissemination Phase and UC Condition)
During the first year of the project, all physicians in the study received a comprehensive educational program regarding the JNC 7 guidelines, appropriate medication choices, effective patient-physician communication strategies, and special considerations for treating blacks with hypertension. Before the educational session, the physicians were asked to complete a knowledge, attitudes, and beliefs questionnaire; this questionnaire will be used to evaluate the effectiveness of the intervention, and will be administered again after 18 months and at the end of the study period.

Uncertainty Reduction Interventions
The special intervention is designed to reduce physician uncertainty regarding the need to take actions to reach the recommended treatment goals and the results of those actions.
After exposure to the educational program emphasizing the elements of the JNC 7 guidelines and the benefits of achieving recommended blood pressure targets, physicians in the intervention clinics are being provided with a specially designed study form that includes a graph of recent blood pressure measurements in their study patients, a check box to indicate their assessment of the adequacy of the patient’s blood pressure control, and a menu of services that they can order to aid in patient management. These menu options include (1) 24-hour ambulatory blood pressure monitoring (ABPM); (2) electronic bottle cap assessment of medication adherence followed by medication adherence counseling in nonadherent patients; and (3) lifestyle assessment and counseling followed by 24-hour ABPM. The intervention tools are not currently available in routine practice in the 2 participating health systems. Physicians can order these tests in any combination or sequence they wish.

In response to a faxed physician order for a special intervention procedure, a study research assistant contacts the patient to arrange for ABPM or electronic bottle cap monitoring. The ABPM is done with Oscar2 U manufactured by Suntec, and electronic bottle cap monitoring is carried out with the Aardex system caps and software. Up to 3 antihypertensive medications can be monitored for a 30-day interval. This interval is long enough to provide an accurate estimate of the patient’s behavior, but short enough to be practical for clinical decision-making purposes. Reports of the 24-hour ABPM and electronic bottle-cap monitoring results are placed in the patient’s clinic record, and the physician is notified by email that the report has been sent.

When lifestyle adherence assessment and counseling is ordered, the patient’s questionnaire responses on the Block Fruit and Fiber and Fat Intake screeners, the International Physical Activity Questionnaire, and smoking questionnaire25–27 to determine which areas need to be addressed by a counselor. Two trained counselors use a motivational interviewing method based on Prochaska and DiClemente’s stages of change model to encourage patients to follow a low-sodium low-fat diet (DASH), increase their physical activity, or stop smoking if they are current smokers.28

Printed instructional materials in English or Spanish, suitable for low-literacy audiences, are mailed to the patient a week before counseling begins. The protocol used by the lifestyle counselors to stage patients, and determine their individual counseling needs is listed in Table 2. If a patient needs counseling on at least 1 behavior, he/she receives 3 counseling phone calls. After counseling is complete, a 24-hour ABPM is carried out to document the participant’s control level.

The telephone counseling algorithms were adapted from those developed for a multiple behavior change intervention targeting smoking, increased physical activity, and reduced dietary sodium.20 A new module was on medication adherence was developed specifically for the present study.

**Study Outcomes**

The medical records of participating patients are being reviewed every 6 months to abstract clinic blood pressure measurements and physicians’ medication orders.
A trained research assistant is meeting with participating patients approximately every 6 months in the study clinic to collect the following measurements: blood pressure, medication history, standardized diet and physical activity measures, smoking status, quality of life, and the Croog hypertension symptoms check list. The encounter with the research assistant is timed to coincide with the patient’s regular clinic appointment whenever possible. If the patient is not able to complete all the questionnaires during the clinic visit, the data are collected by telephone or mail. The clinic blood pressure measurements recorded by the nurse in the patient’s chart are being used to calculate the primary end point. This is the BP measurement that is most consistently available. We will also document whether or not the primary care provider made additional measurements, but these will not be included in the primary end point. The standardized research study measurements will be considered as secondary end points. History of hospitalizations and emergency room visits is collected from the patients every 6 months. The study measurement schedule is summarized in Table 3.

### Analysis of Outcomes

Generalized linear models with logit link will be used to compare the proportion of patients with blood pressure controlled to goal in the intervention clinics and the usual care clinics. This approach will allow for adjustment of potential imbalances in patient characteristics across clinics that were not evenly distributed in spite of the randomization of clinics within public and private system strata due to the cluster randomized design. In the mixed effects models, random effects will be blood pressure changes over time, individual clinic variability, and treatment allocation of the clinic. Similar mixed effects linear regression models will be used to test the intervention effect on the secondary end point of blood pressure treated as a continuous variable.

Assuming that we observe a significant intervention effect, a cost-effectiveness analysis will be performed to determine the monetary value of achieving a unit of blood pressure reduction (either percent of patients controlled or mm Hg of systolic and diastolic blood pressure reduction) in intervention group patients. The costs to be calculated include drug and equipment costs, personnel time, and health care use. Cost effectiveness (CE) ratios for each study arm will be calculated as the amount of BP reduction achieved (both percent of patients and mm Hg) divided by the cost of care in that arm. The incremental CE ratio will be calculated as the average reduction in BP in the intervention group minus the average reduction in BP in the control group divided by the average cost in the intervention group minus the average cost in the control group. We will calculate both the short-term costs of achieving control in a group of treated patients (<1 year), and we will project the cost-effectiveness over 5 years, discounting both costs and effects at 3% per annum. Because the costs of care in the 2 participating health systems may vary, we will run the analyses using both sets of costs.

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

Recruitment began in January 2006 and was completed in March 2007. A total of 706 patients were enrolled, and 680 remained in active follow-up as of September 2007. Approximately 80% of potentially eligible patients approached for the study agreed to participate. We expect to close out the last patient by March 2009.

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**Table 3. Study Measurement Schedule**

<table>
<thead>
<tr>
<th>Variable/Outcome</th>
<th>Source/Device</th>
<th>Follow-Up Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary blood pressure control outcome</td>
<td>Clinic reading recorded at patient visits*</td>
<td>X X X X X</td>
</tr>
<tr>
<td>Secondary outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research staff BP</td>
<td>Measured in clinic with validated automated device under standard conditions</td>
<td>X X X X X</td>
</tr>
<tr>
<td>Medications</td>
<td>Patient-reported medication history</td>
<td>X X X X X</td>
</tr>
<tr>
<td>Lifestyle</td>
<td>Stage of change for exercise adoption</td>
<td>X X X X X</td>
</tr>
<tr>
<td>Block fruit and vegetable and fat intake</td>
<td></td>
<td>X X X X X</td>
</tr>
<tr>
<td>Smoking prevalence and stage of change</td>
<td></td>
<td>X X X X X</td>
</tr>
<tr>
<td>International Physical Activity Questionnaire</td>
<td></td>
<td>X X X X X</td>
</tr>
<tr>
<td>Physician prescribing patterns</td>
<td>Visit monitoring form, medical records audit</td>
<td>X X X X X</td>
</tr>
<tr>
<td>Hypertension related quality of life</td>
<td>Croog hypertension symptoms checklist</td>
<td>X X X X X</td>
</tr>
<tr>
<td></td>
<td>EuroQol (overall health status)</td>
<td>X X X X X</td>
</tr>
<tr>
<td>Patient–physician communication patterns</td>
<td>Audio-taped recordings of patient-physician visits</td>
<td>X X (ss) (ss)</td>
</tr>
<tr>
<td>Physician attitudes/beliefs about hypertension control</td>
<td>Develop and pilot during first year</td>
<td>X X</td>
</tr>
<tr>
<td>Patient characteristics</td>
<td>Age, sex, education, employment status</td>
<td>X</td>
</tr>
</tbody>
</table>

ss indicates subsample.

*Either automated device or mercury sphygmomanometer.

As requested by primary care physician in special intervention group only.
Although study implementation has progressed generally as planned, we encountered several challenges. Although we assumed that patients would have follow-up appointments at regular 3- to 4-month intervals, this happened only rarely in the private clinic settings. Patients in the private clinics were more likely to miss appointments and to see their primary care providers after longer intervals. We assigned extra research assistants to monitor appointments in real time and increase the amount of data collected by telephone.

Another event that had a significant impact on the original intervention protocol was the gradual implementation of an electronic medical records (EMR) system in all of the participating clinics. This rollout began in the county clinics approximately 6 months after the intervention was initiated. As the new EMR system became established in each clinic, physicians relied less and less on the paper records, although they remained available as “read only” documents. In time, all the information contained in the intervention form can reside in the EMR, but in its early implementation phase these kinds of specific modifications were unavailable. We responded by having the research assistants make the paper records available to the clinic physicians at the time of a patient study visit.

These challenges underline the complexities of carrying out planned controlled experiments in multiple clinical settings and health systems.

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Disclosures
None.

References

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