Hypertension affects 1 of every 4 adults, including two thirds of those over 60 years of age in the United States.\textsuperscript{1,2} Despite improvements in hypertension awareness and access to care, rates of blood pressure (BP) control remain below 50\% in most population studies.\textsuperscript{1,3–5} The Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) in Houston, Texas, is one of the largest regional health centers within the national VA system, handling more than 900,000 outpatient visits in 2006, including 50,000 patients enrolled in primary care. MEDVAMC serves as the main referral center for specialized care for veterans in Southeast Texas and Louisiana. From October 1, 2004, to May 31, 2005, 21,794 patients were treated for chronic hypertension within primary care at the MEDVAMC. Rates of control were 54\% in 2005 for all hypertensive patients without diabetes receiving primary care at the MEDVAMC and 30\% among patients with comorbid diabetes.\textsuperscript{6}

Under the guidance of the primary care clinic director (J.K.) and nurse manager (D.T.), selected clinicians and staff of the primary care clinic initiated a quality improvement (QI) program to specifically address the quality issues related to the care of patients with persistent, uncontrolled hypertension despite regular follow-up and treatment. The persistence of uncontrolled hypertension among patients with access to health insurance and treatment from a regular provider has been well characterized.\textsuperscript{7} The cause of treated but uncontrolled hypertension is often attributed to clinical inertia, the failure to initiate or intensify therapy.\textsuperscript{8,9} Clinical inertia in hypertension care may reflect uncertainty about whether the BP measurement merits intensification (clinical uncertainty) and/or preoccupation with the patient’s other problems (competing demands).\textsuperscript{10,11} The primary care providers (PCPs) at the MEDVAMC adapted a model of frequent, shared medical appointments (group clinics) to rapidly induce hypertension control by simultaneously addressing the issues of clinical uncertainty and competing demands. Randomized clinical trials using group clinics have demonstrated effectiveness in improving hypertension control among comorbid patients.\textsuperscript{12,13}

The current report describes the process and clinical outcomes of a QI initiative using group clinics and identifies patient and process-of-care characteristics associated with hypertension control.

Local Challenges to Implementation
In designing the QI program, primary care clinic personnel worked within the existing structure and strengths of their setting. PCPs, mostly board-certified internists along with nurse practitioners and physician’s assistants, provide direct patient care in a team structure. Clinical pharmacists are available to assist with complex medication management, and an integrated pharmacy system dispenses medications on site. PCPs share nursing support and administrative personnel, who assist with patient check-in and follow-up reminders. An electronic medical record system integrates patient administrative records, medical progress notes, laboratory and radiology results, medication status and refills, and all order entry. The electronic medical record system allows patient records to be available to all authorized personnel, facilitating implementation of clinical-services innovations.

The initiative had to address several operational challenges. Target panel sizes usually range from 1000 to 1600 patients per provider, and whatever innovation was attempted would need to efficiently use resources and personnel without adding to the existing work load. Another important stipulation of the QI initiative was that it could not require additional personnel or resources beyond what was already appropriated for the primary care clinic. Therefore, the clinic director and staff chose to ground the QI initiative within a group clinic model in which multiple patients could be cared for in a relatively short period of time (10 patients in a 90-minute span), with specific tasks that would be limited in time and scope using existing clinic staff. Furthermore, group sessions would occur frequently in a compressed time period (up to 3 visits within 6 weeks).

Barriers to frequent visits by patients include limitations in terms of transportation and financial resources because most...
patients live in rural or distant locations from the MEDVAMC, and many are on fixed-incomes. This challenge is difficult to ameliorate without significant additional resources, for example, financial incentives or reimbursements for travel. To overcome these limitations, clinicians devised the compressed 6-week schedule of the group clinics, without long-term group clinic follow-up, and an exclusive focus on rapid induction of hypertension control during the 6-week period. For veterans who qualified for travel voucher support, reimbursement for travel was made possible for each clinic visit. Participation of a clinical pharmacist provided quicker consultations and refill of medications helping to reduce the time spent during each clinic visit.

Design of the Initiative

Given the inherent challenges faced by clinic staff (increasing case loads for PCPs/staff and patient limitations regarding transportation and finances), clinicians conducted a literature review and decided that a group clinic format would provide logistical advantages (as described above) for the QI initiative. In addition, the group clinic model offers several novel conceptual advantages for monitoring and intensifying antihypertensive therapy in primary care. Group clinics engage multiple patients simultaneously, and various clinicians can direct them, with effective results.12–14 Their structure permits clinicians to focus on a single clinical outcome (avoiding competing demands) and reduces uncertainty by using trained nurses to conduct frequent, standardized BP measurements.14

In a group clinic, various providers (nurses, PCPs, and pharmacists) can perform their particular roles in a focused manner for several patients simultaneously, allowing efficient delivery of care and not requiring additional expense or personnel. The group structure allows individual-level patient-clinician communication of BP goals to be reinforced by group norms. In addition, all clinic providers are reinforcing the same BP goals for each patient, with the ability to contrast these with the actual BP measurements taken at each visit.13,15

Achieving hypertension control is more likely within a collaborative goal-setting paradigm when (1) BP measurements are taken frequently and in a standardized fashion, (2) patients and clinicians have concordant and specific BP goals, and (3) treatments are automatically escalated if current measurements do not reach the goal BP.16 The QI initiative was structured to incorporate each of these principles. A rapid induction format was used as the basis for the initiative, whereby patients were asked to return to the group every 2 weeks over a 6-week period for treatment monitoring and intensification. If patients attained hypertension control at the first or second visit, they did not have to attend subsequent visits, thus reducing the transportation burden and financial expense.

The protocol currently in place at MEDVAMC for measuring and recording BPs into the electronic medical record was used to ensure standardization of BP measurement and recording by all clinicians. Nurses were trained to select the appropriately sized cuff, place the cuff in a standardized manner, and sequentially take 2 BP measurements with a fixed interval between measurements. BP measurements were performed at the beginning of each session using a Vital Check 4400 series noninvasive blood pressure monitoring device (Alaris Medical, San Diego, Calif) and the lower value was recorded per hospital protocol. Nurses took and recorded BP measurements for all participants before the arrival of the PCP. PCPs sequentially reviewed the BP measurements of all group clinic patients. Whenever PCPs noted BP measurements that were above goal, they were instructed to escalate antihypertensive therapy unless a patient reported an adverse event. Standardized protocols for medication selection and titration were not in use during the study, mirroring routine care. PCPs, therefore, had latitude in choosing antihypertensive agents, based on patient characteristics or prior adverse effects.

Individual patient-provider discussions regarding BP goals and current measurements occurred within the group clinic setting. This format allowed some individualized discussion of medication adherence, side effects, and lifestyle modification, in addition to informal peer-to-peer conversation among patients. An educational video on hypertension control and antihypertensive treatments was shown to patients after measurement and recording of BPs, while they waited for their individual time with the PCP. The clinic pharmacist provided new prescriptions the same day, if PCPs recommended them. Periodically they discussed medication adherence and side effects. The clinic nurse or pharmacist would review medication changes with the patient at the end of the group clinic. After achieving hypertension control and/or completing the 6-week group clinic sessions, patients returned to their normal primary care visit schedules with their PCP.

Implementation of the Initiative

Seven (23%) PCPs from the primary care clinic at MEDVAMC along with their associated staff nurses and pharmacists participated in the implementation of the QI initiative. Eligible patients for this QI initiative report included those who received chronic hypertension care but had persistently elevated measurements despite ongoing treatment on all recorded BP measurements for a 90-day period before referral. There were no explicit exclusion criteria. Referring providers informed patients that participation required adherence to a strict group clinic protocol that included attendance for three consecutive clinic visits every 2 weeks for 1 to 2 hours until hypertension control was achieved. Hypertension control was defined as a systolic BP (SBP) of <140 mm Hg and a diastolic BP (DBP) of <90 mm Hg, or SBP <130 mm Hg and DBP <80 mm Hg for patients with diabetes mellitus. Clinic staff scheduled appointments for patients who agreed to participate in the QI initiative during the period of observation from March 2005 to June 2006. For the first session, patients could choose any date on which a group clinic was scheduled to be held with their PCP. Thereafter, they were automatically scheduled to attend a session occurring 2 weeks after the prior session, but patients did have flexibility to change dates. Attendance at subsequent sessions was not linked to other patient-participants (ie, peer group membership was not constant for all 3 sessions). Among the 683 patients who attended a group clinic, 179 were excluded from this report because of missing baseline BP values during the
90-day baseline period (5.8%), controlled hypertension during the baseline period (6.8%), or no BP measurements during the follow-up period (13.4%). The remaining 504 (73.4%) reflect the analytic sample for this report. The MEDVAMC Research and Development Committee and Institutional Review Board of Baylor College of Medicine gave retrospective approval for analysis and publication of data.

Statistical Analysis
Evaluation of the success of the initiative relies on statistical analyses comparing participants with controlled versus uncontrolled hypertension during a follow-up period occurring 45 to 365 days after the first group clinic visit. This time period was selected as the follow-up time frame because return visits to participants’ PCPs were highly variable, and this broader time frame ensured adequate capture of repeated outpatient BP measurements. Hypertension control status during this follow-up period was determined from the mean systolic and diastolic values calculated from all BP measurements (mean of 2.67, standard deviation of 1.92, range of 1 to 8) obtained during usual PCP visits within this 10-month follow-up period after the last group clinic visit. Baseline BP values represented the mean of the recorded systolic and diastolic measurements obtained during primary care visits in the 90 days before the first group clinic; however, the vast majority had only 1 measurement during this baseline period.

Patients who had mean BPs in the controlled range during the study follow-up period (controlled group), based on the criteria defined above, were compared with those who had mean BPs in the uncontrolled range during the follow-up period (uncontrolled group). BP measurements at the last attended group clinic visit and individual changes from baseline to follow-up periods were also calculated and stratified by hypertension control status during the follow-up period. Descriptive statistics were used to calculate significant differences in baseline variables between these follow-up groups. Patient adherence to the QI initiative protocol is hereafter referred to as protocol adherence and represents a key analytic variable. Protocol adherence is defined as attendance by a patient to 3 consecutive group clinic visits every 2 weeks. Patients could be deemed protocol-adherent with attendance at less than 3 group clinic visits if BP measurements were in the controlled range during their last group clinic visit.

Logistic regression models with 95% confidence intervals (CIs) were constructed to identify baseline and study variables associated with attainment of hypertension control during the follow-up period. Baseline characteristics found to be significant in the descriptive analyses were included in bivariate and multivariate regression with hypertension control. Furthermore, adjusted odds ratios (ORs) were also calculated to identify the association of hypertension control and the protocol-adherent variable, stratified by diabetes comorbidity.

Assessing Implementation and Adoption of the Initiative
After the conclusion of the QI initiative follow-up period, interviews of key clinic staff were conducted to identify barriers and facilitators to implementation of the QI initiative within the MEDVAMC and to elicit suggestions for dissemination to other sites. Interview responses were transcribed and coded using a deductive approach that focused on the adoption of the QI initiative and particular barriers and facilitators to adoption. Evaluation of the implementation of the QI initiative was also based on the “reach” (external validity) of potential clinical improvements in hypertension control across all patient subgroups and clinical characteristics.

Four key informant interviews were conducted with clinic staff and providers including a primary care physician, 2 registered nurses, and a primary care clinic coordinator at MEDVAMC. Interviews generated consensus regarding barriers and facilitators to QI initiative implementation within the primary care clinic and suggestions regarding sustainabil- ity and dissemination. Interview respondents all reported that one problem was the lack of restrictions to patient recruitment, which respondents attributed to lower adherence rates with the clinic protocol. Respondents correlated adherence to patients’ level of interest in controlling hypertension, impatience with having to wait for individual attention with the PCP, copayment charges for some patients, and transportation difficulties with frequent trips to the clinic. Nurse respondents stated that developing a standardized procedure for taking and recording vitals on all patients was an important added benefit of the QI initiative that was now in use across the primary care clinic.

Interview respondents also identified various suggestions to facilitate implementation for future interventions. Interview respondents reported that conducting telephone reminders with patients early in the QI process helped to make minor adjustments in scheduling. They suggested that having clinic staff involved from the beginning with the development of a recruitment protocol could ensure consistency in recruitment, improve staff engagement in QI, and perhaps reduce the administrative burden. Furthermore, they suggested that a more formal recruitment process, mirroring a clinical trial run-in period, might improve adherence to the clinic protocol. Respondents all reported ongoing interest in the hypertension group clinic format and consistent participation beyond the time frame of this report.

Success of the Initiative
Primary Clinical Outcome: Hypertension Control During the Follow-Up Period
In this population of chronically treated but persistently uncontrolled hypertensive patients, more than half (53.8%) of the 504 previously uncontrolled participants of this QI initiative were able to achieve and maintain controlled BP during the follow-up period. The moderate rate of hypertension control was appropriate, given the emphasis on rapid induction of a difficult-to-control population, including diabetics, without longitudinal follow-up beyond usual care. However, closer scrutiny of this primary clinical outcome demonstrates significant variation in the rate of hypertension control, based on adherence to the QI initiative protocol by patients and a
few baseline clinical characteristics, with rates of control as high as 81% among some subgroups of participants.

BP changes over the course of the QI initiative differed significantly by follow-up status (ie, controlled versus uncontrolled hypertension). The Figure illustrates the change in SBP measurements from the baseline period to the last group clinic measurement to the follow-up period, with separate lines for controlled hypertension during follow-up (line with diamonds) and uncontrolled hypertension during follow-up (line with squares) categories. Patients categorized as having controlled hypertension at follow-up had significantly lower mean systolic (130.1 ± 11.5 versus 145.5 ± 18.7, \( P < 0.0001 \)) and mean diastolic (70.6 ± 10.9 versus 78.6 ± 10.9, \( P < 0.0001 \)) BP measurements during the follow-up period compared with those categorized as having uncontrolled hypertension at follow-up. These differences were already apparent by the time of the last group clinic BP measurements. Those in the controlled group had significantly lower systolic (134.7 ± 7.5 versus 148.8 ± 17.3, \( P < 0.0001 \)) and diastolic (71.2 ± 10.7 versus 79.6 ± 13.0, \( P < 0.0001 \)) measurements compared with those in the uncontrolled group at the time of these last group clinic measurements. Mean BP reductions from baseline to follow-up periods were also calculated on an individual basis and represented as mean individual reductions in systolic (29.1 ± 15.3 versus 11.4 ± 16.3, \( P < 0.0001 \)) and diastolic (13.4 ± 11.4 versus 4.5 ± 10.6, \( P < 0.0001 \)) BPs. Despite having lower SBPs at baseline, patients in the controlled group had significantly greater mean reductions from baseline to follow-up periods that far exceeded the quantitative differences at baseline.

**Secondary Outcomes: Predictors of Hypertension Control at Follow-Up**

Table 1 compares baseline characteristics of the QI initiative patients, based on hypertension control status achieved during the follow-up period. Patients in the controlled group had lower body mass index and fewer comorbidities, took fewer antihypertensive medications, and were more likely to self-report compliance with medications. Patients in the controlled hypertension group also had lower SBP and serum creatinine levels at baseline (see Table 1).

Table 2 describes the association of baseline and clinical variables with controlled hypertension during follow-up. Participant self-report of medication compliance and protocol adherence were significantly associated with hypertension control, whereas diabetes, higher baseline SBP, Deyo comorbidity score, body mass index, number of antihypertensives, serum creatinine, and African American race were all inversely associated with hypertension control in bivariate analyses. In multivariate analyses, protocol adherence remained significantly associated with hypertension control (OR, 8.90; 95% CI, 5.36 to 14.8), whereas a diagnosis of diabetes remained inversely associated with hypertension control (OR, 0.25; 95% CI, 0.13 to 0.45).

Table 3 provides a more detailed assessment of the differential contributions of baseline diabetes diagnosis and group clinic protocol adherence. Among patients without diabetes, over 60% were adherent to the group clinic protocol. In this group, protocol adherence was strongly associated with hypertension control, even after adjustment for baseline SBP, comorbidity index, body mass index, serum creatinine, race, number of medications, and medication compliance (OR, 21.13; 95% CI, 9.84 to 45.4). Only 48% of patients with
diabetes were adherent to the group clinic protocol, but adherence remained a significant predictor of hypertension control for participants with diabetes (OR, 4.65; 95% CI, 2.09 to 10.3) as well. Furthermore, 81% of patients without diabetes and 74% of patients with diabetes who achieved hypertension control during the follow-up period were protocol-adherent.

To identify predictors of protocol adherence when recruiting potential participants, an ad hoc multivariate analysis was performed to identify baseline patient characteristics associated with adherence to the group clinic protocol. Having a higher SBP at baseline was significantly predictive of not being adherent (OR, 0.97; 95% CI, 0.95 to 0.99; \( P = 0.02 \)). No other baseline variables were associated with adherence to the group clinic protocol.

### Summary of the Experience and Future Directions

The QI initiative enrolled a diverse population of patients with chronic, uncontrolled hypertension without using strict recruitment criteria common to many clinical trials. Primary care clinic staff and providers recruited and scheduled patients as well as conducted the clinic visits without research personnel. Overall, more than half of all previously uncontrolled patients were able to rapidly lower their BPs to controlled levels within 6 weeks and maintain control into the follow-up period. Furthermore, two thirds of patients without diabetes achieved hypertension control, including more than 80% of those who adhered to the group clinic protocol. Among protocol-adherent patients, rates of hypertension control for diabetics and non-diabetics were significantly higher when compared with similar groups drawn from the overall primary care clinic during this same time period, as previously described.6 Adherence to the QI initiative protocol was the most powerful predictor of hypertension control for all patients during the follow-up period, including those with diabetes. Higher SBP at baseline was negatively associated with protocol adherence. Interviews with clinic staff suggested that insurance copayments and transportation barriers may have also affected protocol adherence.

The components of the QI protocol are similar to those recently advocated by Phillips and Twombly19 to reduce clinical inertia in hypertension care. In this QI initiative, patients with consistently high BP levels were asked to attend a series of visits dedicated to BP control. Clinic measurements were compared against BP goals, and intensification of therapy was triggered by every uncontrolled measurement after accounting for significant adverse events.19 Conceptually, this paradigm parallels rapid induction strategies used by oncologists to treat many cancers. Induction therapies use chemotherapy regimens given over a short period to eliminate cancer cells and place the patient in complete remission. Rapid induction is a useful metaphor to describe the protocol and results of this QI initiative. The epidemiological impact of cardiovascular events warrants an urgency and approach to hypertension control matching that of cancer control.

To continue with this metaphor, ongoing chemotherapy is needed to maintain cancer remission in some cases. Similarly, about 24% (67 of 282) of patients who were adherent to the QI protocol did not have controlled BP measurements during
the follow-up period. These patients may have benefited from periodic maintenance visits to the group clinic. For example, interventions for diabetes prevention and control have demonstrated that prolonged patient engagement in behavior change may be more effective than medication adherence alone. Using maintenance group clinic sessions after the 6-week induction period may further enhance the effectiveness of this QI initiative for patients with diabetes.

This QI initiative, implemented at a large primary care practice within a single regional VA medical center, used existing personnel and resources without restrictive eligibility rules to encourage recruitment and retention. The integrated health care and pharmacy services of the VA, as well as the largely male veteran population, may limit the external validity of this QI initiative. Participation in the QI initiative was voluntary for both patients and clinicians, which presents an additional limitation to the external validity of this initiative. In addition, the key informant interviews used to identify barriers to implementation included only 4 participants, none of whom were patients. Important barriers to patient follow-up after the QI initiative may not, therefore, be reflected in this report. Furthermore, the results of the QI initiative described in this report do not reflect the outcomes of excluded patients, specifically those who did not have baseline or follow-up measurements. These results were not compared with patients in a concurrent, usual care group.

However, rates of hypertension control in primary care at the MEDVAMC during the same time period of the QI initiative have been previously published. Finally, all included patients had uncontrolled hypertension within 3 months before the QI initiative, and BP measurements were recorded for up to 10 months after completing the QI protocol, allowing for robust pre-post comparisons. Despite the potential limitations and challenges to implementation, the hypertension group clinics have been continuously used since 2006 at the MEDVAMC. They represent an important feature of routine hypertension care and have contributed to ongoing improvements in the rates of hypertension control, now above the 75% benchmark for the typical primary care clinic panel at MEDVAMC (personal communication with hospital epidemiologist Charles Wright, PhD).

The results of this report suggest that a rapid-induction, group clinic approach following a structured yet succinct protocol can be implemented into a primary care practice and produce results similar to those described in clinical trials. For most patients who followed the clinic protocol, hypertension control was achieved within 6 weeks and maintained over a broad follow-up period. Future dissemination of a rapid induction protocol should consider targeting recruitment to patients who are able and willing to attend frequent clinic visits over a short time. Implementation of this initiative requires engagement by clinicians willing to devote 2 hours weekly to measurement and titration of BP treatments and adequate resources, including clinic staff responsible for repeated reminder calls and scheduling of group clinics during the rapid induction phase. Future research should include assessments of the cost-effectiveness of the group clinic model in non-VA settings. As Medicare and private insurers move to pay-for-performance reimbursement systems, the rapid-induction group clinic may be an effective method of improving the quality of routine hypertension care.

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Disclosures

None.
References


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