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Blood Pressure Visit Intensification Study in Treatment: Trial design

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Abstract

Background—There is a presumption that, for patients with uncontrolled blood pressure (BP), early follow-up, that is, within 4 weeks of an elevated reading, improves BP control. However, data are lacking regarding effective interventions for increasing clinician frequency of follow-up visits and whether such interventions improve BP control.

Methods/design—Blood Pressure Visit Intensification Study in Treatment involves a multimodal approach to improving intensity of follow-up in 12 community health centers using a stepped wedge study design.

Discussion—The study will inform effective interventions for increasing frequency of follow-up visits among patients with uncontrolled BP and determine whether increasing follow-up frequency is associated with better BP control.

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Competing interests

The authors declare that they have no competing interests with this research project.

Authors' contributions

K.A.F., J.N.T., and G.O. generated the idea. K.A.F. and J.N.T. obtained funding and orchestrated implementation of the protocol. H.H. contributed to the design and statistical analysis plan. J.C. contributed to design and implementation of the clinician training. C.K. and B.D. recruited practices. M.S. and A.C. managed the project. H.H. contributed to all aspects of design and analytic planning. All authors read and approved the final version of the manuscript.

Background

Hypertension is the most common medical diagnosis by physicians at office visits.^{1,2} Hypertension is also a major mutable risk factor for cardiovascular disease^{1,3} and the leading determinant of black-white disparities in cardiovascular morbidity and mortality.⁴ Despite long-standing national guidelines for the management of hypertension, blood pressure (BP) control remains suboptimal. Nationally, BP is controlled among only 64% of adults under treatment for hypertension.⁵ Black-white disparities in rates of BP control are seen nationally⁶ and also within federally qualified health centers.^{7,8}

National guidelines, including those from expert committees for the Joint National Committee (JNC VII and VIII) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, address when to initiate BP treatment, which medications to use, and the frequency of follow-up visits for patients not at target BP goal.³ The recommendation to schedule patients with uncontrolled BP for a follow-up visit within 4 weeks of the last office visit is largely based on observational data and expert opinion.^{9,10} Furthermore, many clinicians do not adhere to this recommendation—patients with uncontrolled BP are often seen less frequently than monthly.^{9,11–13} Interventions are needed to promote implementation of this increased visit frequency component of the guidelines into practice. More importantly, experimental data are needed to confirm observational data that increased office visit frequency improves BP control.

Study aims and hypotheses

The aim of this study, entitled Blood Pressure Visit Intensification Study in Treatment (BP-VISIT), is to determine whether a multimodal intervention designed to increase office visit frequency for patients with uncontrolled BP will lead to improvement in BP control rates. Using the theory of planned behavior as our conceptual model,¹⁴ our central hypothesis is that an intervention that targets clinician awareness, attitudes, norms, perceived control, and routines relevant to this recommendation will increase visit follow-up frequency on patients with uncontrolled BP. Our secondary hypothesis is that this intervention, by increasing visit frequency, will improve BP control. The specific aims and hypotheses of the BP-VISIT trial are shown in Table I.

Methods

Study design

The study design is a stepped wedge cluster-randomized trial (SWCRT). The target population is clinicians at 12 community health centers (CHCs), including federally qualified health centers that participate with Clinical Directors Network (CDN), a primary care practice-based research network (PBRN). When there is not perceived equipoise by practices, the stepped wedge design enables all practices to receive the intervention. This facilitates practice recruitment and retention into the study and permits study of a delayed treatment effect. The 12 CHCs are randomly assigned in blocks of 4, to when they receive the intervention, with early and delayed groups, and also the blocks separated by 6 months.

This results in 4 intervention periods, with 2 CHCs participating in first and last periods, 4 in the 2 middle periods, and follow-up periods of up to 30 months (Figure 1).

Funding support and ethics approval

This trial is funded by the National Heart, Lung and Blood Institute (NHLBI). Ethical approval was obtained from the University of Rochester, CDN, and New York University institutional review boards. We obtained waivers of consent and for Health Insurance and Portability Accountability Act restrictions for patient participants. Such waivers are relevant for conduct of pragmatic studies where there is minimal risk to patient participants, the practice is the unit of intervention, and the study could not be feasibly implemented if individual informed consent was required.^{15,16} The study is registered at www.ClinicalTrials.gov (NCT 02164331).

Data safety and monitoring board

An external data safety and monitoring board was established before enrollment. The 3 members include a biostatistician and 2 physicians with extensive experience in clinical trials for BP control, one who serves as the board's chair. The first data safety and monitoring board meeting included review and discussion of BP-VISIT's Charter, overview of study activities, protocol review, and recommendations, determining the frequency of meetings and interim analyses and discussion of trial monitoring and early stopping rules.

Power and sample size

We estimated sample size using the method described by Hussey and Hughes for SWCRTs.¹⁷ A total of 12 CHCs will be randomly assigned to implement the intervention at 1 of 4 phase-in periods of 6 months and postintervention follow-up of up to 30 months (Figure 1). With an estimated minimum of 200 patients satisfying eligibility criteria in each CHC, the study is sufficiently powered to test the study hypotheses including moderation effects. We used the SE and intraclass correlation (ICC) information from a prior NHLBI-funded cluster randomized controlled trial conducted by the authors (J.T. and G.O.).¹⁸

For the primary outcome in aim 1, the study has 80% power to detect a 0.35 difference in number of visits based on a 2-sided test with $\alpha = .05$, with the assumption of an average number of 3 visits (SE 0.38) for the preintervention within 6 months and an ICC of 0.05. For the secondary outcomes in aim 2, assuming that the systolic BP (SBP) and diastolic BP (DBP) are 150.7 (SE 16.7) and 91.0 (SE 10.6), respectively, the study has 80% power to detect a 1.5 mm Hg difference in SBP and 1.0 mm Hg difference in DBP, again based on a 2-sided test with $\alpha = .05$ and ICC of 0.05. Although this power exceeds clinically relevant BP reductions, it facilitates assessment of moderation effects including clinically relevant reductions in subgroups, particularly self-pay patients where an increased number of visits could be a financial burden. For this 10% of the cohort, we will have 80% power to detect a clinical relevant 4.6-mm difference in SBP.

Recruitment and eligibility

Practices are recruited through the CDN (www.CDNetwork.org), a primary care PBRN recognized by the National Institutes of Health as a best-practice Clinical Research Network

and selected by the Agency for Healthcare Research and Quality as a Center of Excellence for Practice-based Research and Learning. Table II shows practice, clinician, and patient eligibility criteria. Based on CDN's experience, we anticipate >90% participation by clinicians.

Randomization and blinding

An offsite study statistician at the University of Rochester will conduct randomization using computer-generated randomization of the practiced based on CHC study identification number. Analysis will be conducted with blinding of when the intervention occurred.

Intervention

The intervention consists of 5 main components: clinician training; clinician electronic health record (EHR) point-of-care prompts using templates and order sets; reports to clinicians regarding their performance, that is, frequency of visits and rates of BP control when compared to their CHC peers; and designation of a practice champion; and telephone outreach to patients not at goal who have not had a visit within 3 months.

Clinician training—We will offer onsite and Web-based CME-accredited training involving 3 monthly sessions to the CHC teams, including clinicians and nursing and clinical support staff at the time the CHC is randomized to the intervention. Clinician training is designed to target clinician perceived norms, attitudes, and perceived behavioral control.¹⁴ Trainings will also be recorded via webcast to facilitate (1) reviews by staff, (2) training for those who are not able to attend and for new staff, and (3) wider dissemination through a sustainable training resource for CHCs after the project is completed.

The first session opens with a brief overview of the study rates of control, need to improve, and rationale for engaging patients not at goal through monthly visits. This is followed by the 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults from the panel appointed to JNC VIII.¹⁹ We share available published observational evidence and simulation models supporting the recommendation for 1-month follow-up.^{9,10,20,21} We also introduce a simple algorithm for stepped care used by Kaiser.²² We encourage sound clinical judgment to minimize harm from overtreatment and encourage assessment of potential adverse effects, for example, dizziness and falls.

The second session trains clinicians in use of the 5As (ask-advise-agree-assist-arrange) for engaging patients in collaborative partnerships for improving BP control by addressing medication adherence barriers and incorporation of lifestyle changes (sodium reduction, Dietary Approaches to Stop Hypertension diet and physical activity, smoking cessation by referral to NYS Quit Line, and prescribing nicotine replacement therapy, both of which are available for free) (see Figure 2). The 5As have been widely used for health behavior promotion counseling.^{23,24} We offer brief online “homework” before the second training session. This adjunctive training involves videos featuring each of the 5As in the context of hypertension counseling. Elements from the 5As are incorporated into templates and order sets.

The third session trains clinicians to use a simplified treatment algorithm from the panel members appointed to the JNC VIII. This approach improved office BPs in our previous studies.²⁵ We train clinicians to use EHR templates and order sets that reinforce use of the algorithm and scheduling of monthly follow-up visits. The session addresses barriers to monthly visits and reviews potential solutions, for example, scheduling adaptations, comanagement with nurse practitioners, and nurse visits.

Staff training in BP measurement—To improve BP data quality and validity,^{26,27} we host onsite training sessions in procedures for correct BP measurement and repeat measurement for nursing staff at each CHC.

Electronic health record hypertension template/order set—The template and order sets are designed to facilitate implementation of guidelines, algorithms, and collaborative goal setting. The core elements of the guidelines are adapted to different EHR systems. The template serves as a type of checklist or prompt for clinicians.²⁸ The order set automates ordering of JNC-recommended medications using an algorithm, laboratory testing, and patient education materials. Most importantly, the EHR template/order sets include a 1-month follow-up visit as a default option for the visit close-out for patients not at goal.

Clinician audit and feedback—Using data from the practice EHR, we will provide clinicians with monthly feedback regarding (1) their visit frequency for patients with uncontrolled BP and (2) percentage of patients with BP controlled. The reports will be based on each clinician's mean follow-up time (weeks) for patients with uncontrolled BP by month (ie, based on patient seen during the past month) and by cumulative performance (beginning with the intervention). Clinicians may exempt patients from the study and from reports, for example, those with limited life expectancy, by notifying the project champion. The reports will compare each clinician's actual performance with (1) their own past performance and (2) the average for other participating clinicians. Demonstrating a gap between expected/desired performance and actual performance is a strategy that has been demonstrated to enhance motivation.²⁹ Reports will include suggestions for improvement, for example, increase visit frequency; intensifying treatment; assigning staff to call patients with uncontrolled BP not seen >90 days; and obtaining hypertension specialist consultation.

Designation of a project champion—Each CHC designates a clinician champion who will serve as a liaison and whom we will train. Her/his specific roles include providing practice legitimacy for the intervention; energizing and facilitating clinicians; assisting with clinician training, customization of local adaptations to EHR template/order set; problem solving; consultation regarding resistant hypertension; ensuring outreach to patients with uncontrolled BP not seen in >90 days; and coordinating feedback to clinicians, including featuring successful adopters.³⁰ We will train project champions in facilitation using 2 CME-accredited webinars that include Agency for Healthcare Research and Quality best practices for practice facilitation.³¹ New project champions join BP-VISIT when their practice begins phase-in. Investigators on the study team with training in hypertension (G.O. and S.W.) provide expert consultation to project champions on management challenges.

Usual care

During the period before randomization, the CHCs will continue with their usual management of patients with uncontrolled hypertension, with visit frequency set locally.

Study outcomes, measurements, and data collection

Consistent with principles of pragmatic clinical trials, we will use EHR data for patient identification and assessment of intervention implementation and outcomes (Table III). Patient age, sex, race, ethnicity, and language are required for Health Resources and Services Administration reporting and are consistently recorded by registration staff based on patient report. Review of preliminary data show <5% of these data are missing. We anticipate that practices will use 4 to 6 different EHR systems.

Primary and secondary outcome measures will be obtained through export of data from the EHR through contract with DARTNet.³² DARTNet has developed and refined data extraction, transformation, and loading processes that allow aggregation of standardized data from different EHRs into a limited database. It has also developed algorithms for converting *International Classification of Diseases, Ninth Revision (ICD-9)*, to *International Statistical Classification of Diseases, 10th Revision (ICD-10)*.

Data for mediating and moderating factors will be collected through practice and clinician surveys at baseline and follow-up using e-mail with Web links to surveys using RedCap.³³ Follow-up surveys will include an unstructured section where clinicians will report their successes and challenges, including any distracting effects of the project.

Planned analysis

All statistical tests are 2 sided with $P < .05$. Descriptive statistics (counts and proportions for categorical variables and means and SDs for continuous outcomes) will be used to depict the characteristics of both the patient participants (eg, age, sex, race, ethnicity, insurance types, number of hypertensive visits in the year before study, antihypertensive medications prescribed, clinical comorbidity).³⁴ We will describe clinician participants by age, sex, race/ethnicity, clinician type, and experience working in CHCs. We will also compare baseline practice characteristics, such as practice size, and patient characteristics between practices that implement the intervention earlier to those that implement the intervention later using t tests, χ^2 tests, and Fisher exact tests (Table III). We will also examine associations between the outcome variables and patient characteristics. We will treat as covariates those characteristics that are significantly associated with outcomes when constructing regression models. For the time-varying covariates such as insurance, antihypertensive medications (types and number of medications prescribed), and comorbidity, we will compare their pre-post treatment distributions. If significant differences are found, we will include them in the model to account for potential confounding effects.

We will use both weighted generalized estimating equations (WGEE) and linear mixed-effects model approach (LMM)^{35–38} to assess treatment differences while accounting for clustering effect of patients within clinicians and clinicians within practices. If findings differ between the 2 approaches (or a large variation occurs in the actual sample size across

CHCs), we will rely on WGEE, as it provides a more robust inference.¹⁷ To account for the dynamic treatment assignment of the SWCRT design, we will include a time-varying treatment indicator (ie, phase-in of the intervention) as the main predictor in the LMM/WGEE models, controlling for the practice, clinician, and patient covariates identified in the preliminary analysis.

The primary outcome is the number of primary care visits (regardless of visit codes) among patients with a diagnosis of hypertension (*ICD-9* codes 401x–405x and *ICD-10* I10x) per 6 months after the baseline. Each patient from the inception cohort with at least 1 visit during that period will be assessed at 1 of 6 phase-in periods including the 6-month intervention period. The secondary outcomes are the average of the SBP and DBP among the visits per 6 months as well as the BP control (SBP <140 and DBP <90) at the most recent visit before the end of the phase-in for the inception cohort. We will apply WGEE/LMM models to the outcomes with the time-varying treatment indicator as the main predictor. To examine moderation, we will include the moderators along with their interaction with the treatment indicator in the models. To take into account the time effect, we will include the time and the interaction between the time and treatment in all the LMM/WGEE models. We will restrict visits to those with any hypertension diagnosis coded during the visit. We also assess a cohort that includes all hypertensives and examine the median duration of follow-up when BP is not at goal during the preceding visit during 6-month periods. In addition, we will assess adoption of JNC VIII guidelines and examine the proportion of patients age ≥60 years with SBP <150.¹⁹ In the secondary analysis of the outcomes, we will assess for lagged treatment effects by modeling the lagged outcomes assessed at the next period with the current treatment assignment as the main predictor to examine the possibility that the treatment effects occur after the intervention. Similar longitudinal methods described above will also be applied to this secondary analysis.

To examine the mediation hypotheses, we will use structural equations models.^{37,39} We will use a lagged time approach to relate treatment conditions to the potential mediators and to the outcomes and test for mediation of treatment effects.^{35,40} We will assess goodness of fit using the χ^2 test, the comparative fit index, the index of Tucker and Lewis, and root mean square error of approximation.^{41,42}

Discussion

This project evaluates a feasible, multimodal approach to promote monthly office visits among patients with uncontrolled hypertension receiving primary care at NY metropolitan area CHCs. Findings will inform practical strategies for improving population management of hypertension.

This study is highly pragmatic. It is conducted in the real-world health care settings of CHCs who deliver comprehensive primary care to >22 million low-income, minority, and other medically underserved populations. It relies on pragmatic measures using data extracted from EHRs. It uses a SWCRT design where the unit of intervention is the practice. Similarly, randomization is done at the practice level to minimize intrapractice contamination.

The components of the intervention including training in communication skills, use of EHR templates and order sets, and clinician audit and feedback are grounded in theory of clinician behavior change.⁴³ An experimental study that documents that the increases in visit frequency are associated with improvement in BP control would represent some of the strongest evidence to date in support of more intensive visit follow-up for patients with hypertension whose BP is not at goal.

Most notably, our study design suggests a model for pragmatic, quality improvement research that will prove vital to learning health care systems.⁴⁴ Several features warrant comment. First, we obtain waivers of informed consent for patient participants. Such waivers are appropriate when there is minimal risk, for example, promotion of existing guidelines and when the project could not be feasibly implemented without such waivers. Because the entire practice is the unit of intervention, it is not feasible to obtain consent from every patient in the practice affected by the intervention. In addition, the intervention involves training clinicians to support patient autonomy in decision. Thus, although clinicians are trained to advise patients to return within a month for management of their uncontrolled BP, clinicians are also trained as part of the 5As to actively engage patients in this decision and support patient autonomy. Last, we combine a randomized design with use of EHR data to assess both primary and secondary end points.

There are both limitations and challenges associated with this protocol. The first limitation pertains to use of clustered randomized design. There is a risk that because the practice is the unit of analysis, any differences in practices' capacity for improvement could confound results. Such confounding would involve a spurious association between temporal effects and changes in visit frequency for patients with uncontrolled BP and/or changes in BP control. In other words, temporal changes in payment or practice redesign might be confounded with time of randomization into the intervention group. We will assess this possibility using practice surveys conducted at baseline and follow-up.

The primary implementation challenge involves extracting data from different electronic health record systems. Practices have varying levels of IT expertise and different data extraction software. We minimize this challenge by extracting only data from structured fields, contracting with DARTNet, and conducting validity checks. Nonetheless, this represents both an important technical challenge and a significant mechanism to enhance spread and sustainability of the intervention both within and across CHCs. Blood pressure data from EHRs may be less reliably measured than those derived from trained research study staff, but BP data represent the target for clinician's action. We will improve reliability and validity through clinical staff training in BP measurement. The study will contribute to our understanding of guideline dissemination and implementation, strategies to enhance team-based care, utilization of EHRs for patient identification, intervention delivery, and outcome assessment, as well as contributing to novel models for quality improvement research, all conducted within real-world settings serving large numbers of minority, female, and medically underserved population. Furthermore, the staff from the 12 CHCs and the Web-based intervention materials will provide the basis for future dissemination activities that can be targeted to reach the 1,200 grantees and 9,000 CHC delivery sites funded by the Health Resources and Services Administration.

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Figure 1.
Timing of stepped wedges (the intervention) for BP VISIT

Figure 2.
The 5As: Engaging patients in collaborative partnerships for improving BP control.

Table I**Aims and study hypotheses**

Aim 1: To implement the JNC recommendation for monthly visits for hypertensive patients with uncontrolled BP using a theoretically informed, empirically grounded, multimodal quality improvement intervention.

Hypothesis 1.1: The intervention will improve hypertension visit frequency among patients with uncontrolled BP.

Aim 2: To improve BP control and reduce disparity in BP through implementation of monthly visits.

Hypothesis 2.1: The intervention will improve BP control among patients with uncontrolled BP.

Hypothesis 2.2: The intervention will decrease black-white disparity in BP control.

Aim 3: To assess potential mediators and moderators of the intervention.

Hypothesis 3.1: Changes in clinician perceptions will mediate effects on visit frequency.

Hypothesis 3.2: Clinician use of template/order set will mediate effects on visit frequency.

Hypothesis 3.3: Visit frequency and medication intensification will mediate effects on BP.

Hypothesis 3.4: Patient insurance, comorbidity, resistant hypertension, and high baseline values will moderate effects on visit frequency.

Table II

Eligibility criteria

Inclusion criteria	Exclusion criteria
CHC	
Membership in CDN PBRN	Practices planning to change EHR systems or merge with a nonparticipating organization during the study period
Leadership commitment to full participation	
Designation of practice champion	
Use of the electronic health record for at least 6 months before beginning the study	
Ability to successfully generate and export patient-level data from the EHR	
Clinicians	
Provision of primary care (both full and part time) to adult patients within a CDN participating CHC*	Clinicians who plan to leave the practice within 6 months of the study starting
Patients	
Age 18 years and older	
Any hypertension diagnosis based on (<i>ICD-9</i> codes 401x–405x and <i>ICD-10</i> I10x) from either billing codes or from the patient problem list in the EHR	
Uncontrolled BP at last visit before start of study. <i>Uncontrolled BP</i> is defined as SBP ≥ 140 mm Hg or DBP ≥ 90 mm Hg. If 2 SBP readings appear for the same visit, the mean will be used.	
CHC visit with participating primary care clinician within 12 months before date of study enrollment	

* Primary care clinicians include family medicine physicians, internal medicine physicians, pediatric physicians, geriatricians, gynecologists, nurse practitioners, and physician assistants.

Table III

Study measures, purpose, and operationalization

Variable	Purpose	Operationalization of measure	Data source
Practice characteristics	Comparability of groups	Size, location, percent uninsured, percent African American; family medicine vs internal medicine/multispecialty organization, length of medical director tenure	Survey
Clinician characteristics	Comparability of groups	Age, sex, race, ethnicity, specialty, years in practice	Survey
No. of BP visits	Primary outcome (H 1.1 and H 3.3)	Count of number of primary care visits, ie, those with a primary care clinician, among eligible patients	EHR data
Patient characteristics	Comparability of groups (H 2.2)	Age, sex, race, ethnicity, insurance, language, number visits in year before study for BP (based on ICD-9 401x–405x codes for the visits)	EHR data
SBP	Secondary outcome (H 2.1)	SBP values recorded in the BP in the medical record among eligible patients during study period. Secondary analyses will examine rates of BP control	EHR data
Physician perceptions	Mediator (H 3.1)	Clinician attitudes (perceived behavioral control and norms regarding monthly visits for patients with uncontrolled BP based on a 7-point Likert scale measured pre/post knowledge and behavioral intention questions)	Survey
Clinician use of templates	Mediator (H 3.2)	Indication that a template/order set has been used	EHR data
Medication intensification	Mediator (H 3.3)	Count of antihypertensives during observation period divided by visit number	EHR data
Stage II hypertension	Moderator (H 3.4)	SBP 160 mm Hg at start of intervention	EHR
Resistant hypertension	Moderator (H 3.4)	Patient taking 3 antihypertensives at baseline	EHR data
Comorbidity	Moderator (H 3.4)	Scheeweiss/Pace comorbidity index based on problem list, ICD-9/ICD-10 codes, and laboratory data. CHD, renal disease, diabetes, and stroke will also be coded separated as dummy variables ³⁴	EHR data
Insurance	Moderator (H 3.4)	Presence or absence of insurance and/or visit copayment	EHR data

Definitions

The intervention period: This is the 6-month period starting with the date of the intervention.

Inception cohort: This includes all patients meeting eligibility criteria with uncontrolled BP at the last 2 consecutive visits before the start of the study.

Uncontrolled BP: This is defined as an SBP >139 or DBP >89. In secondary analyses, we will apply the definition from the panel of JNC VIII that applies the above definition to persons 18 to 59 years old, but for patients >60 years, *uncontrolled BP* is defined as SBP >149 or DBP >89.

Abbreviation: CHD, Coronary heart disease.