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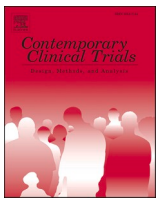

# Practice facilitation for scale up of clinical decision support for hypertension management: study protocol for a cluster randomized control trial

Saul Blecker [a,*], Matthew Gannon [b], Samantha De Leon [b], Donna Shelley [c], Winfred Y. Wu [d], Bahman Tabaei [b], Janice Magno [b], Hang Pham-Singer [b]

[a] NYU Grossman School of Medicine, New York, NY, United States of America
[b] New York City Department of Health and Mental Hygiene, New York, NY, United States of America
[c] NYU School of Global Public Health, New York, NY, United States of America
[d] University of Miami - Miller School of Medicine, Miami, FL, United States of America

A B S T R A C T

*Background:* Only half of patients with hypertension have adequately controlled blood pressure. Clinical decision support (CDS) has the potential to overcome barriers to delivering guideline-recommended care and improve hypertension management. However, optimal strategies for scaling CDS have not been well established, particularly in small, independent primary care practices which often lack the resources to effectively change practice routines. Practice facilitation is an implementation strategy that has been shown to support process changes. Our objective is to evaluate whether practice facilitation provided with hypertension-focused CDS can lead to improvements in blood pressure control for patients seen in small primary care practices.

*Methods/design:* We will conduct a cluster randomized control trial to compare the effect of hypertension-focused CDS plus practice facilitation on BP control, as compared to CDS alone. The practice facilitation intervention will include an initial training in the CDS and a review of current guidelines along with follow-up for coaching and integration support. We will randomize 46 small primary care practices in New York City who use the same electronic health record vendor to intervention or control. All patients with hypertension seen at these practices will be included in the evaluation. We will also assess implementation of CDS in all practices and practice facilitation in the intervention group.

*Discussion:* The results of this study will inform optimal implementation of CDS into small primary care practices, where much of care delivery occurs in the U.S. Additionally, our assessment of barriers and facilitators to implementation will support future scaling of the intervention.

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Hypertension (HTN) is the most prevalent modifiable risk factor for cardiovascular disease (CVD) among U.S. adults and a major cause of disability and premature death [1–3]. Furthermore, nationally there are significant racial and ethnic disparities in HTN prevalence and control [4], which may contribute to disparities in CVD outcomes [5–7].

Despite the availability of published guidelines for the treatment of HTN [1,8], half of U.S. adults diagnosed with HTN have poorly controlled blood pressure (BP), and more than half of non-Hispanic Black, non-Hispanic Asian, and Hispanic adults have poorly controlled BP [4]. In one study of small primary care practices, BP control was variable across practices but did not differ among racial and ethnic groups [9], while in another New York City-based study, non-Hispanic black patients and Hispanic patients had lower rates of BP control as compared to white patients [10]. Among other contributing factors to inadequate BP control, one reason is provider-related: there is inadequate provider uptake of evidence-based guidelines for HTN. This is due to a lack of knowledge on how to manage specific subgroups (e.g., the elderly), skepticism about guideline recommendations, and perceptions that patients are non-adherent to medications [11].

Electronic health record (EHR)-based clinical decision support (CDS) has the potential to overcome barriers to delivering guideline-recommended care and improve HTN management. CDS has been shown to improve HTN management, especially in the context of studies that restricted the population to those with other CVD-related diseases such as diabetes or heart failure [12–16]. In prior work, we found that a CDS for HTN management, implemented in Federally Qualified Health Centers (FQHCs) in New York City (NYC), was associated with a significant increase in BP control and improved process of care measures, such as scheduling follow-up visits [17]. Further, research has shown the potential of health information technology approaches to mitigate racial

* Corresponding author: NYU School of Medicine, 227 E. 30th St., Room 648, New York, NY 10016, United States of America.
*E-mail address:* saul.blecker@nyumc.org (S. Blecker).

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healthcare disparities [63].

While the effectiveness of CDS has been demonstrated in large academic medical center settings [12,18–23], there is limited information regarding effective approaching to implementing and scaling of CDS in small independent primary care practices, where the majority of primary care office visits occur [24–26]. Small independent practices face challenges in redesigning their systems and care processes to meet regulatory requirements for practice transformation. Most small independent practices lack the resources and staff expertise needed to coordinate system changes without external assistance [27]. One implementation strategy that may effectively overcome such barriers is practice facilitation (PF).

Practice facilitation, typically delivered by trained staff (facilitators), provides external support and expertise to facilitate changes tailored to the workflow and context of each practice. A systematic review found that primary care practices are almost three times more likely to adopt evidence-based guidelines through practice facilitation [28]. A key role for facilitators is to help practices implement evidence-based system changes, such as CDS, that promote the adoption of guideline-recommended care. Despite growing evidence on the effectiveness of practice facilitation, this implementation strategy remains largely untested in scaling up of CDS for small independent practices.

We describe the design and methods of a two-arm cluster randomized trial that will test the comparative effectiveness of scaling up CDS for hypertension management using practice facilitation versus CDS without facilitation alone in small, independent primary care practices. We hypothesize that practice facilitation plus CDS will improve BP control as compared to CDS alone. We will also assess the implementation process.

## 1. Methods

This is a two-arm cluster randomized control trial to compare the effect of CDS alone with CDS plus PF on BP control. The units of randomization are primary care practices located in New York City.

### 1.1. Conceptual models

Our intervention and its assessment are based on three conceptual frameworks: the Technology Acceptance Model (TAM) [29,30], the 5 Rights of CDS [31], and RE-AIM (reach, effectiveness, adoption, implementation, maintenance) [32]. Both TAM and the 5 Rights of CDS provide guidance on CDS development and identifying potential barriers to adoption and implementation. TAM asserts that perceptions of usefulness and ease of use by end users will directly influence the intention to use a new technology, leading in turn to its adoption [33]. The 5 Rights of CDS describes principles of CDS design – delivering the right information, to the right person, using the right format, in the right channel, at the right time during the workflow – that are critical to achieving both maximal perceived usefulness and perceived ease [31]. We hypothesize that the addition of PF will enhance perceived usability and usefulness and thus result in greater adoption of CDS-recommended care and improved patient outcomes. The RE-AIM framework includes outcome measures considered most relevant to the real-world implementation and translation of research findings into practice [32].

### 1.2. Setting and eligibility

The study is being conducted at small primary care practices that have an existing partnership with the New York City (NYC) Department of Health and Mental Hygiene (DOHMH) through DOHMH's NYC REACH, a free membership organization which provides member practices with programming for EHR optimization, practice facilitation, and quality improvement support [34,35]. We will specifically include sites that are using MDLand (MDLand International Group, Great Neck, NY) for its EHR vendor. Prior to the intervention, MDLand did not have an existing HTN-focused CDS.

Eligibility criteria for practices to participate include: 1) active signed membership agreement with DOHMH; 2) using the MDLand EHR for at least one year; 3) meet a minimum sample size requirement of 188 patients with diagnosed HTN; 4) have no plans to participate in another CVD-related QI initiative; 5) have no plans to change EHRs in the next 18 months; 6) willing to identify a staff member to collaborate on all aspects of the intervention; and 7) agree to the study terms, including randomization, data sharing, participation in PF, and the completion of surveys.

All patients meeting eligibility criteria will be included in the study analysis if they were seen at practices enrolled in the study for at least 12 months. Patient inclusion is based on standard inclusion for BP control measures: 1) an outpatient clinic visit with an HTN diagnosis based on the ICD-10 code in the prior 12 months; 2) age 18–85 years; 3) not pregnant; and 4) not have end-stage kidney disease as defined by an ICD-10 code for dialysis or transplantation [36]. In a prior study we conducted in a similar group of small primary care practices, the population had a race/ethnicity breakdown of: 28.1% Hispanic patients, 21.5% non-Hispanic black patients, 17.0% non-Hispanic white patients, and 17.5% Asian patients; 47.5% of these patients had Medicaid insurance [37].

### 1.3. CDS intervention

All sites enrolled in the trial will receive a HTN-focused CDS within the MDLand EHR. The CDS is based on our prior work developing a CDS within another EHR that had been associated with improvements in BP control in a group of federally qualified health centers [17,38]. The CDS will include the key functions developed in the prior study [17], including passive alerts, order sets, documentation templates, a medication adherence questionnaire, and monthly reports. The CDS will also include a clinical reminder related to medication adherence that was not present in the earlier CDS. Adherence will be measured using the proportion of days covered (PDC), made available through EHR-pharmacy linkage via Surescripts (Surescripts, LLC) [39]. The complete set of features is listed in Table 1.

#### 1.3.1. Pre-implementation CDS refinement

Prior to the intervention, we used several approaches to maximize the usefulness and usability of the intervention. First, the study team worked closely with MDLand to develop an initial prototype of the CDS. Second, we presented the prototype to our Provider Advisory Council (PAC), consisting of primary care providers at affiliated practices. We elicited feedback on specific components of the CDS and included questions on content, appropriateness, and usability. We then integrated this feedback into CDS development. Third, we recruited providers from two sites not involved in the trial for usability testing. Usability testing was performed at the provider sites using the EHR testing environment. Providers were given a clinical scenario in which they were asked to use the EHR, including the CDS features, during a hypothetical clinic visit for a patient with HTN, to simulate clinical practice. Providers were asked to "think aloud" to verbalize their impressions of the tool and offer feedback while interacting with the CDS in order to identify usability issues [40,41]. After the testing, providers were surveyed on satisfaction with its navigation, interface, and perceived usability. This feedback was then used to finalize the CDS for the trial [42].

### 1.4. Practice facilitation intervention

Intervention sites will receive the practice facilitation intervention to support the use of CDS (Table 2). Each site will be assigned a practice facilitator who will conduct one-on-one on-site tailored visits combined with remote support (i.e., phone call, WebEx, email) to deliver the intervention over a 12-month period. Each intervention practice will have 12 encounters (including on-site and remote visits) with their

**Table 1**
Clinical decision support (CDS) features.

| CDS Feature | Description |
|---|---|
| Alerts | Passive alerts will be related to elevated BP or low medication adherence. BP measurements greater than or equal to 140/90 will be colored in red (based on the National Quality Forum [NQF] quality metric) [36]. In addition to the color-coding of BP values, two passive alerts will be used in the patient summary. One passive alert, the "HTN Alert," appears in the patient header for any patient who has a diagnosis of HTN. The alert is color-coded based on last BP value; if the last BP measurement is ≥140 systolic or ≥ 90 diastolic, the alert turns red. Otherwise, the alert is white. Clicking on this alert will display the patient's most recent BP and most recent PDC score. The second passive alert, the "Med Adherence Alert" shows for patients who have not completed a medication adherence questionnaire (see below) within the past six months. If the patient also has not completed a medication adherence questionnaire (see below) within the past six months, an additional red alert is added to the header, indicating the patient is due for the questionnaire. Passive alert notification occurs when PDC data is available for a patient's HTN medications; over 80% PDC shows a green alert, 50–79% a yellow alert, and < 50% a red alert. |
| Order Sets | Order sets will be based on guideline-based management and include: recommended medication regimens, common test orders associated with HTN management (e.g., blood chemistry panel orders), orders for follow-up appointments, and patient education materials that can be used to facilitate patient engagement, decision-making, and treatment adherence. |
| Documentation Template | A preconfigured template to record counseling provided to patients on diet, physical activity, smoking cessation, and home self-monitoring; as well as to record patient self-management plans, including goals and action plans. |
| Medication Adherence Tools | Standardized medication adherence questionnaires designed to identify potential non-adherence for staff to perform and document in the EHR. The questionnaire will be an adapted version of the Morisky Green Levine scale, which was utilized in the AHRQ EvidenceNOW study. |
| HTN Panel Summaries | EHR-accessed reports with the distribution of BP control among patients with HTN who were seen by a given provider in the prior months. Reports include information on the percentage of patients in each category with a follow-up visit in the next three months, PDC scores of HTN patients, and patients in need of follow-up to ensure prescriptions are refilled. Reports can be filtered based on patient BP control status. |

**Table 2**
Details of practice facilitation intervention.

| Intervention | CDS | CDS + PF |
|---|---|---|
| "Kickoff" Meeting | 60-min "kickoff" meetings at individual sites in the first month to establish aims and provide training on how to use the CDS. | 60-min "kickoff" meetings at individual sites in the first month to establish aims, define roles and responsibilities, and assess site workflow. Practice facilitators will assess workflow using a standardized tool and findings will be used to tailor the intervention. Assessment will include determining the routine process for acting on information. |
| Initial Meeting | Not provided. | On-site PF meeting in the second month lasting 60 min to provide training on how to use the CDS and review current guidelines for managing HTN. |
| Monthly On-site Meetings | Not provided. | On-site or virtual monthly PF meetings (based on practice preference) in months 3 to 6 lasting 60 min to support CDS integration into clinical workflow. Will include: training a site to track performance (including the use of a dashboard function to facilitate audit and feedback), establishing goals, training one improvement using PDSA (Plan-Do-Study-Act) cycles, providing coaching, and providing CDS technical assistance. |
| Phone and Email Exchanges | Phone and email exchanges as needed in the first 3 months. | Phone and email exchanges as needed in the first 6 months. |
| Remote "Check-in" | Not provided. | Remote "check-in" phone or virtual meetings in months 7 to 12 to assess sustainability and provide coaching as needed. |

assigned PF. Practice Facilitators will be guided by a custom practice facilitator guide, developed for this program; this guide leverages best practices and resources included in the DOHMH's HTN Action Kit [43]. Our PF strategy is grounded in the concept of tailoring quality improvement to maximize a practice's existing resources and builds upon commonly accepted practice staff roles, responsibilities, and activities [28,44–49]. For each encounter, the PF will document facilitation activities performed, a utilization assessment of the CDS, and a narrative summary of each visit. PFs will not collect information on baseline medication intensification and or other HTN management strategies.

Practice facilitators will have a minimum of a master's degree, prior clinical and managerial experience, and a minimum of one year of experience as a facilitator. Facilitators attended a one-day training on MDLand functionality and operations and completed a 92-h practice facilitator certification program led by a university, with a classroom component and field practicum component. We supplement this prior training with information related to the intervention, including information related to evidence-based treatment for HTN and CDS functionality. Each practice facilitator reports to a manager who provides managerial oversight for multiple concurrent practice facilitation programs including this one. Because of concurrent oversight responsibilities, each manager assumes a maximum of two facilitators for this specific project. Managers meet each week with their team to review the weekly schedule, anticipated challenges, and determine if additional expertise or assistance from information technology or other project staff is needed. These meetings will provide opportunities for problem-solving and will help facilitators develop and maintain relationships, gain content knowledge, and monitor practices' progress by reviewing structured weekly activity reports and narrative reports.

### 1.5. Control sites

All sites in the control arm will receive the CDS intervention. In addition, control sites will receive an initial kickoff meeting to provide initial training on the CDS. Practice Facilitators will also be available to respond to questions electronically for the first three months of the intervention.

### 1.6. Recruitment and randomization

Eligible practices were sent recruitment emails from DOHMH. Additionally, DOHMH staff who have existing relationships with these practices followed up after the initial recruitment materials were distributed. Prior to randomization, a sampling frame of eligible practices that agreed to participate was developed, which included basic information such as practices' patient population size (small, medium, large), and proportion of patients with HTN (low vs. high – using 50th percentile as cut point). These two factors were used as strata. We then conducted a block cluster randomization with balanced allocation to

randomized practices within each stratum by using random digit generation to either intervention or control group.

### 1.7. Measures

#### 1.7.1. Primary outcome

The primary outcome is the change in the percentage of patients who have achieved BP control in the post-intervention versus pre-intervention study periods. BP control is defined as BP <140/90 [36,50] in the mean of the last two EHR-recorded measurements on different days in each study period; for patients with multiple readings on the same day, we will use the average of those measurements. We will use the last two recorded measures to balance increased reliability with multiple BP measurements [51] with study timeline limitations. Due to variability in uptake, we will not utilize home BP readings. Patients without BP measurements in the post-intervention period will be considered lost to follow-up.

#### 1.7.2. Secondary clinical outcomes

Secondary outcomes will include change in systolic and diastolic BP between the pre- and post-intervention period [8]. We will also measure adherence to HTN medications using Surescripts data, which is linked to the MDLand EHR data and contains a record of pharmacy fills [52]. These data are updated on a near continuous basis in the EHR. We will obtain patient-level fill data at the end of the study period and use them to calculate PDC; we expect to have data available for ≥80% of patients [39]. Adherence will be defined as PDC of at least 80% [53,54].

#### 1.7.3. Implementation outcomes

Implementation Outcomes are described in Table 3. Reach will be assessed by calculating the proportion of patients with elevated BP for whom the CDS was triggered (i.e., the sensitivity or recall of the CDS). We will assess the adoption of guideline recommendations by calculating the proportion of encounters with elevated BP in which there was an intensification (change in dose or frequency) or change of BP medication and the proportion in which a follow-up appointment was scheduled within one month [8]. These will be calculated using de-identified patient-level data received from MDLand, specifically through automated analysis of EHR data. Assessment of implementation will include fidelity and acceptability. Fidelity will be measured using EHR data assessing whether providers use various components of the CDS as intended and using practice facilitator documentation and reports to assess their activities. Acceptability will focus on perceived usefulness and usability of the CDS [29]. To assess maintenance, at 15 months, we will ask providers about plans and barriers to continued use of CDS, and will also assess outcomes data.

### 1.8. Statistical analysis

Practice and individual characteristics at baseline will be compared between the study arms to assess the comparability of the two study groups. Descriptive statistics will include frequency distributions, means, standard deviations, and standardized differences between groups.

We will apply a multilevel mixed-effects modeling framework to examine the impact of the CDS interventions on BP control and measurements. For the primary outcome, changes in BP control from pre-intervention to post-intervention will be assessed by the study arm and compared using a multilevel generalized linear mixed model with a binary distribution for residual errors and a logit link function. We will develop a model that includes BP control (1 = yes, 0 = no) as outcome of interest, one between-group fixed effect factor (study arm: 1 = CDS plus PF compared to 0 = CDS only), one within-group fixed effect factor (time: 1 = post-intervention compared to 0 = pre-intervention), and a two-way group-by-time fixed effect interaction term (study arm x time) to estimate odds ratios and 95% confidence intervals to predict BP

**Table 3**
Description of outcome measures, organized according to the RE-AIM framework.

| RE-AIM Domain | Level of Assessment | Measure | Data Source |
|---|---|---|---|
| Reach | Patient | • Characteristics of patients in practice panel | EHR database query |
| | Setting/ Organization | • Proportion of recruited practices that express interest in participating<br>• Practice and provider characteristics | Practice recruitment tracking logs |
| Effectiveness | Patient | Primary outcome:<br>• Proportion of patients with HTN who achieve BP < 140/90<br>Secondary outcomes:<br>• Proportion of patients with HTN who achieve BP < 130/80<br>• Mean systolic BP and diastolic BP<br>• Patients with medication adherence ≥80%<br>• Clinic visits with elevated BP with medication started or increased | EHR database query<br>Surescripts database via EHR database query |
| Adoption | Patient/ Encounter | • Proportion of patients who received follow-up appointment scheduled following encounter when elevated BP observed | EHR database query |
| | Provider | • Behavioral intention and use<br>• Barriers to adoption | 12-month survey; semi-structured interview |
| | Patient/ Encounter | • Number of encounters in which HTN order sets were used<br>• Number of encounters in which HTN note templates were used<br>• Proportion of encounters of patients with PDC < 80% who had documented utilization of medication adherence scale | EHR database query |
| Implementation | Practice Facilitation | • Proportion of visits completed, both overall and at the individual site level<br>• Fidelity to the practice facilitation protocol<br>• Acceptability of CDS (i.e., perceived usefulness and ease of use) | PF review logs |
| | Provider | • Proportion of providers who generated monthly HTN panel summaries<br>• Assessment of utilization of available CDS features, including medication adherence questionnaire and order sets | Semi-structured interview; 12-month survey |
| Maintenance | Provider | • Self-reported plans to continue usage of CDS beyond study<br>• Continued use of system at 15 months | Semi-structured interview; EHR data |

control within and between the two study arms. The model will also incorporate random effects to account for non-independence and correlation of BP control within patients (level 1) and the hierarchical clustering of patients within practice sites (level 2). In addition to the random effects, the model also accounts for any potential temporal trend by including and assessing time as a fixed effect for each time point. To account for any baseline imbalance between arms, the model will include any baseline characteristics that have standardized differences between groups of 10% or greater; such characteristics will include patient demographics, visit diagnosis, practice-specific characteristics such as the number of providers, and the availability of Surescripts data.

The change in BP control from pre-intervention to post-intervention will be directly measured by the group x time interaction term within each intervention group and then compared between the two intervention groups. As the result, baseline BP control will be included as one of the repeated outcomes measures and both the pre-intervention and post-intervention outcome measurements are response variables, assuming that (1) the two study arms are not different systematically at baseline since they represent two random samples from the same population; (2) any potential baseline differences can be attributed to random chance; and (3) there are no problems with the randomization process and no significant measurement error issues. To ensure however, that our assumptions regarding the equality of pre-intervention BP values are correct, before building the final model we will conduct explanatory data analysis to check whether there is a statistically significant differences in the pre-intervention BP values between the two study arms. If we detect a potential difference in the pre-intervention BP, we will then run two sensitivity analyses by developing additional conditional multi-level mixed-effects models. In the first sensitivity analysis, we will develop a conditional mixed-effects baseline constrained model. This model is an extension of our original multilevel generalized linear mixed model adjusting for the pre-intervention BP values by omitting the differences at pre-intervention period. We will also conduct a second sensitivity analysis by developing a mixed-effect longitudinal covariance model, in which we adjust for the pre-intervention BP control value as an independent variable.

### *1.9. Sample size consideration*

We estimated our sample size by adjusting for a pre- to post-intervention cluster design effect at the practice level [55,56]. We used a previously published intra-cluster correlation coefficient (ICC) = 0.015 for BP control among those with hypertensive medication use [57]. Additionally, we assumed a baseline BP control rate of 73%, based on BP control achieved among similar practices in our prior work [17]; and 30% attrition to account for the potentially high number of individuals who are missing a follow-up BP measurement. Using this method, given a pre-specified number of 40 practices (20 practices per study arm) using a two-sided test, alpha = 0.05, and 85% power, we needed a minimum number of 188 individuals per practice per cluster, to detect a 5% change in proportion of individuals with BP control between study groups. We chose 5% for our effect size as one systematic review found the use of practice facilitation increased odds that primary care practices would adopt evidence-based practice by 2.8 [28], while another systematic review found that practice facilitation improved rates of cardiovascular disease outcomes, including BP control, by 10% [58]. Given the possibility of practice dropout, we recruited 6 additional practices, for a total of 46 practices into our study.

### *1.10. Qualitative analysis*

We will conduct qualitative interviews to obtain a more in-depth understanding of potential barriers to CDS adoption, implementation, and maintenance. We will use purposeful sampling to identify providers from various practices and continue to interview providers until saturation is reached. Questions will be guided by our conceptual frameworks and will include facilitators and barriers to adoption, perceived value of the CDS, experience with using the CDS, how the CDS fits into workflow and workload, perceived efficiency and effectiveness in enhancing patient care and adherence, and long-term sustainability. Interviews will be audio-recorded and transcribed verbatim by an outside vendor. Qualitative data will be analyzed using a constant comparative analytic method in which we begin with open codes and progressively group and refine codes into categories [59]. Initially, two coders will review a selection of interviews and develop codes to describe the content of interviews for the development of an initial code list. Emergent themes will be informed by TAM and the Five Rights of CDS framework. The codebook will be updated and revised throughout the review process. Once all interviews are coded, the investigative team will meet to discuss and identify code clusters, relationships between codes, and common themes.

## 2. Discussion

HTN is a major cause of morbidity and mortality, but patient outcomes can be improved through guideline-targeted BP control. CDS can lead to greater adherence to HTN management guidelines and to mitigation of racial disparities of care [63], but most studies have been conducted in large health care systems and have not considered optimal implementation of CDS across many practices with separate ownership, staff, and unique existing processes [18,27]. This study will specifically target small, independent primary care practices, where much of primary care is delivered and where support in implementing effective system changes like CDS may be needed [24–26,60]. We propose testing the effectiveness of practice facilitation for CDS on BP control in such practices. The CDS is adapted from a tool which was found to be effective in federally qualified health centers, and applied for this project to small, independent, urban practices [17]. This study will provide much-needed guidance on how to optimize implementation and adoption of an evidence-based CDS in the small practice primary care setting. Results can guide future work by technical assistance organizations, Independent Practice Associations (IPAs), Accountable Care Organizations (ACOs), and Local Health Departments (LHDs) seeking to implement CDS or similar interventions across groups of providers.

To fill this knowledge gap, we will be conducting a prospective, randomized trial to test the comparative effectiveness of two implementation strategies for CDS implementation: practice facilitation versus usual vendor support (e.g., brief information shared via user training documents). Few prospective studies have tested the comparative effectiveness of implementation strategies for CDS, which may limit our understanding of the factors influencing success [61]. Although a number of meta-regression analyses have evaluated implementation factors associated with CDS success, such studies are limited by their observational nature [22,62–64]. This study will add to our knowledge of optimal implementation strategies for CDS.

Practice facilitation is an ideal strategy to implement CDS, as practice facilitation has been shown to improve the adoption of evidence-based guidelines [28]. Practice facilitation is associated with sustained improvements in guideline adherence even after the intervention has ended [45,65,66]. However, the use of practice facilitation in the implementation of CDS remains largely untested, particularly in small independent practices. Our proposed trial will create a new evidence base to guide the implementation of CDS in the small practice setting by a technical assistance provider across a group of multiple unrelated practices, considering providers' perspectives and feedback on the technology and the implementation process to improve usability and sustainability of the CDS.

There are a number of potential limitations in our study design. First, our study is focused on practices in New York City, which may limit generalizability. Nonetheless, we believe many small independent practices face similar challenges related to the adoption of evidence-based guidelines, including limited practice resources, staffing, and

diverse patient populations, regardless of their location. Second, there is potential for variation in PF implementation across sites. For this reason, we are collecting implementation data to understand variation and its impact on success. Third, our measure of adherence is based on pharmacy fills available through Surescripts, which may miss medication fills if purchased without insurance or at certain pharmacies that are not linked with Surescripts. Nonetheless, Surescripts should include such data for the majority of patients in our population [52]. Further, we will limit our analysis of adherence to patients with Surescripts data and statistically account for any differences between groups in the availability of Surescripts data. Fourth, patients may also regularly fill a prescription but not take the medication, resulting in a high PDC but low adherence. To address this, practice facilitators will inform providers of the limitations of the PDC and underscore the importance of performing a more thorough adherence screening beyond review of the PDC alone. Fifth, while our proposal is limited to one new EHR vendor, the core components of the CDS are based on existing functionality available in most certified systems, the guidelines from which this CDS is built are publicly available, and the design of the PDC calculation algorithm is publicly available; therefore, we believe this effort will provide the blueprint for other EHR systems to implement a similar CDS. Sixth, as we do not have a control group, we will not be able to evaluate the effectiveness of the CDS itself. Seventh, given the high baseline rate of BP control observed in baseline data, there may be a ceiling effect for opportunity in improvement. This may limit our ability to find a difference in effect between groups. Eighth, the study will not capture any direct patient input about their hypertension management or health behaviors.

Upon completion, this trial will answer the question of whether using practice facilitation to support implementation of a hypertension focused CDS can improve BP control as compared to CDS without practice facilitation. The study will also determine if practice facilitation leads to improvements in important process measures including guideline-concordant patient follow-up and medication adherence. Concurrently, we will measure barriers and facilitators to implementation of the intervention, which will allow for future scaling of the intervention if shown to be successful. If the intervention is not associated with improved outcomes, the assessment of implementation will inform our understanding of limitations to success. The study is strengthened by grounding in conceptual frameworks, focus on small independent practices, and incorporation of pharmacy fill data to detect medication adherence at the point of care through CDS.

## Declaration of Competing Interest

The authors have no conflict of interest to declare.

## Data availability

No data was used for the research described in the article.

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