Study Protocol and Statistical Analysis Plan

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Improving **B**lood **P**ressure Control in Diverse Populations by **M**easuring Accurately, **A**cting Rapidly, and **P**artnering with Patients: the BP MAP Study Protocol

I. EXECUTIVE SUMMARY

BP-MAP is a cluster randomized controlled trial (RCT) designed to compare the effectiveness of BP lowering from a clinic-based quality improvement program with Full Support (dedicated practice facilitation) vs. a Self-Guided version of the program. The American Medical Association (AMA) developed the framework for the interventions. The trial will be conducted within the National Patient-Centered Clinical Research Network (PCORnet) that enables distributed querying of electronic health record data in a common data model. The primary outcome will be change in clinic-level blood pressure (BP) control at 6 months. Secondary outcomes will include other blood pressure (BP) control metrics, other time points (12 and 18 months), and process measures such as BP measurement accuracy, medication intensification, and average systolic blood pressure (SBP) reduction after a medication intensification, and repeat visit within 4 weeks after a visit with elevated BP. We will also conduct non-randomized comparisons of BP control in the Full Support and Self-Guided intervention arms to BP control in healthcare organizations in PCORnet not participating in an intervention arm ("Usual Care organizations"). To gain insight into sustainability of the program (self-guided and full-support), we will perform a limited program evaluation to examine stakeholder satisfaction and assess barriers and facilitators to implementation as well as their willingness to continue program-related activities beyond the study period. We have obtained a certification of exemption from IRB oversight given that both arms will implement accepted guideline-based minimal risk quality improvement interventions.

II. BACKGROUND

Uncontrolled BP is the leading preventable cause of death in the US after smoking, causing nearly 400,000 deaths per year [1]. While effective medications are available to control BP, multiple rounds of medication adjustment and intensification are typically required, and BP control is often not achieved[2,3].

The usual configuration of healthcare delivery – periodic and relatively infrequent office visits with a physician – is not ideal for achieving BP control quickly and efficiently[4,5]. In-office measurement of BP is often performed using poor technique, while the patient is getting settled after arrival at the office[6]. Due to these reasons and the "white coat effect", it is often artificially elevated and may not be a reliable indicator of actual BP. Inaccurate BP measurement may result in missed opportunities for BP treatment intensification, which is common in the US, and a major cause of delay in attainment of BP control[4,7]. Patients' lack of adherence to BP medications is also a common cause of delay in control. While discontinuation of medications is sometimes due to medication side effects[8,9], it may also result from a lack of adequate time and attention paid to shared decision-making about the need for treatment intensification[10].

Some healthcare organizations have successfully reconfigured the way they deliver care for hypertension and manage their hypertensive patient population. Kaiser Permanente Northern California, for example, achieved BP control rates of 80% by using population management, frequent non-physician visits and evidence-based treatment protocols for optimal treatment intensification ([11]. Other programs utilize pharmacists and nurses as case managers to provide medication management between visits. Reconfiguring services with additional staff dedicated to medication and disease management programs[11-16], however, may not be feasible or sustainable in all settings, particularly in

resource-poor settings such as safety net clinics[17-19]. Deployment of sustainable programs may enhance clinic-based BP management.

The AMA developed a framework for clinic-based quality improvement that works within traditional office-based configuration of healthcare delivery (the "Measure Accurately, Act Rapidly, and Partner with Patients" (M.A.P.) Program, described below). The AMA is collaborating with AHA in the initiative, "Target:BP" to 1) recognize health care organizations achieving ≥ 70% BP control and 2) improve BP control by scaling the M.A.P. program to build a healthier nation. The initiative includes a set of tools, resources and detailed plans to support clinics interested in implementing the M.A.P framework as a structured intervention program.

Pilot implementation of this program led to dramatic improvements in BP control (from 63% to 90% in a single clinic and 64% to 74% in a group of 16 clinics). Although these results are promising, questions remain regarding how to optimize and efficiently scale the program in order to maximize sustained clinic-level involvement remain[20,21].

In this study, we will randomize 20-28 clinics to receive one of two types of support interventions: 1) a set of self-evaluation tools, improvement plans, and other resources that can be accessed by clinics and used independently ("Self-Guided"), and 2) a practice facilitation support program that helps clinics understand those tools/plans/resources and actually train people to implement the tools and plans ("Full Support"). We will then compare BP control between those arms, and against Usual Care control organizations. Additionally, we will perform a limited program evaluation to examine stakeholder satisfaction and assess barriers and facilitators to implementation as well as their willingness to continue program-related activities beyond the study period.

III. METHODS

Aim

To compare effectiveness of the M.A.P. program with "Full Support" (dedicated practice facilitation) versus a "Self-Guided" version (online access to M.A.P. materials and orientation webinar only). A secondary aim is to compare these active interventions to usual care.

Hypothesis

We hypothesize clinics randomized to the Full Support version will achieve a larger increase from baseline in the proportion of their hypertensive patients with controlled BP at 6 months as compared to clinics randomized to the Self-Guided version, and also as compared with usual care.

Study design

This is a pragmatic, cluster-randomized, comparative effectiveness trial designed to compare the effectiveness of the M.A.P. program with Full Support versus a Self-Guided version of the program, and versus usual care.

Study Population and Setting

We will recruit Active Clinics from REACHNet and ADVANCE, two of the 10 Clinical Data Research Networks (CDRNs) that comprise PCORnet. We chose these two CDRNs to focus clinic recruitment in safety net clinics and to boost numbers of underserved populations and enhance power to detect heterogeneity of treatment effects. We are targeting clinics that have varied racial/ethnic composition with substantial proportions of Hispanic and Black patients, and patients with lower socioeconomic status. Usual Care Clinics will come from other CDRNs within PCORnet.

Active Clinics

For inclusion as an Active Clinic in this study, clinics may participate must be able to identify:

- A Site Champion who works at the clinic and who is willing to take primary responsibility for implementing the M.A.P. intervention
- A Physician Champion who works at the clinic and who is willing to advocate actively for the M.A.P. intervention
- A Practice Change Facilitator willing to attend a 1-day training and help guide implementation of the M.A.P intervention for Full Support sites, with the support of AMA staff (may be the Site Champion or Physician Champion, or a person with regional responsibilities who can support multiple sites)

Sites will be excluded if they:

- Have implemented any high blood pressure quality improvement component from the M.A.P. BP improvement program as part of Target: BP or from the AMA or Target: BP websites
- Are currently involved in an ongoing clinical trial or grant funded project related to high blood pressure or hypertension

Usual Care Clinics

We will include PCORnet Datamarts participating in BP TRACK, a concurrently-running BP Control Registry within PCORnet that will provide quarterly datamart-level estimates of BP control and other aggregate metrics relevant to BP control. All participating datamarts will be included, with the following exceptions:

- We will exclude datamarts with any Active Clinics participating in BP MAP
- We will exclude datamarts that obscure dates via date-shifting, as this will not allow for control of concurrent secular trends

Patients

Within clinics (Active or Usual Care), patients will be eligible (and identified from the electronic health record) if they meet National Quality Forum BP Control Metric (NQF 0018) criteria[22]:

- Age 18-85 on the date of analysis
- At least one outpatient encounter with a diagnosis of hypertension during the first six months of the measurement year (ending on the date of analysis)
- No diagnosis or evidence of end-stage renal disease on or prior to the end of the measurement year
- No pregnancy during the measurement year
- No admission to an inpatient setting during the measurement year

Interventions

This trial will compare two strategies for improving BP control at the clinic level and compare these two strategies to a group of non-randomized usual-care clinics. Both strategies rely on an extensive set of materials developed by the AMA to support clinic implementation of the M.A.P. Program. These materials have been tested, validated and include clinician and patient targeted resources. We will compare two different ways of helping clinics use these materials to implement the M.A.P. Program:

> **Arm 1: Self-Guided:** Active Clinics randomized to the Self-Guided Arm will receive access to an AHA/AMA web platform that includes the posted M.A.P. materials as described in the appendix and limited access to AMA Staff who are available to answer questions. We will facilitate access

to staff by hosting a kick-off webinar for program participants that will include an orientation to the materials on the website, general advice and practical tips about what works for implementation, and time for answering questions and discussion with the group.

Arm 2: Full Support: Active Clinics randomized to the Full Support Arm will receive online access to M.A.P. materials and orientation webinar, as described above, but also a Practice Facilitator (personnel trained to implement the M.A.P. BP Improvement Program) who will be supported by AMA staff, and will lead the health center clinical staff, site champions and physician leads at each clinic over the course of 6 months to support the implementation of the MAP Program. With support from an AMA "Improvement Advisor", the Practice Change Facilitators will perform a baseline assessment of current workflows and assess each domain of M.A.P. They will 1) identify gaps and plan for specific incremental modifications tailored to address specific clinic needs; 2) perform periodic evaluations with the AMA Improvement Advisor to monitor use of M.A.P assessment tools and checklists; and 3) support use of EHR-based reporting that displays clinic-level BP control and secondary outcome measures. The goal of the Full Support program is to help care teams develop skills and sustainable workflows that are effective at attaining and maintaining high levels of BP control.

Usual Care: Usual Care Clinics will receive no intervention.

Randomization

We will use a random number generator to randomize 10-14 Active Clinics to the Full Support Arm and 10-14 Active Clinics to the Self-Guided Arm. Randomization will be stratified (and balanced within strata) by CDRN and by participation (or not) in BP HOME, a concurrently running individual-level RCT that will provide home blood pressure monitoring devices to participating patients with a high blood pressure reading in clinic. As this is a real-world intervention that clinics will have to implement, they will not be blinded to the randomization.

Outcomes and measurements

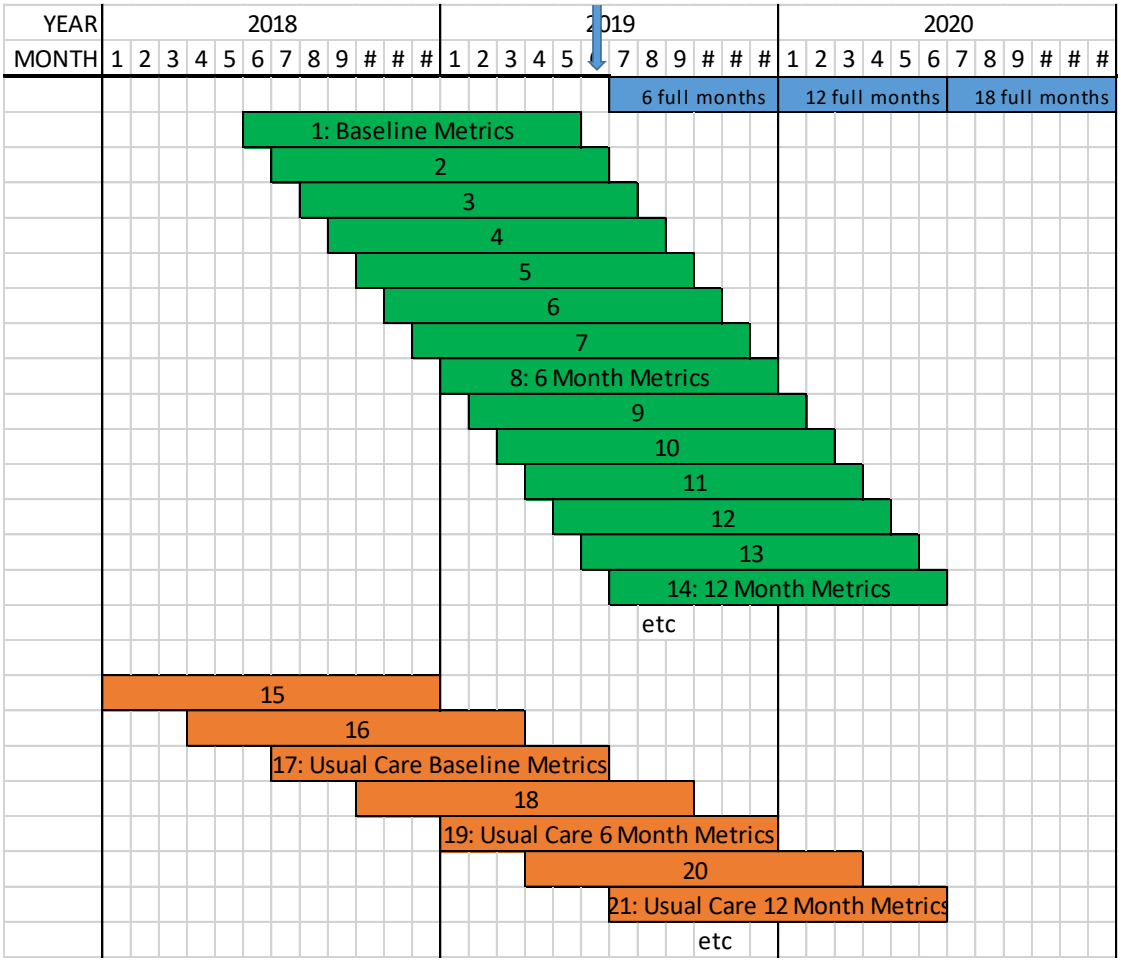
We will measure all outcomes by running a series of queries against EHR data maintained in the PCORnet Common Data Model. The outcomes will use individual patient-level data, reported in aggregate, for each participating clinic. Individual patients will not be followed over time across different repeat queries. Metrics are calculated for a specified 12-month measurement period, which allows time-dependent criteria, usually for including patients in the denominator (e.g., at least 1 visit during the measurement period, a diagnosis of hypertension at least 6 months ago, etc), and also "most recent" type criteria that can be used in metric definitions, usually for including patients in the numerator (e.g., BP is considered controlled depending on the most recent blood pressure measurement at an ambulatory visit within 6 months).

For the Intervention Clinics in Arms 1 and 2, all measurements will be obtained on a monthly basis for the purpose of guiding implementation of the intervention, with the 12-month measurement periods set to end at the end of each month. The primary outcome will compare the metrics obtained at baseline, defined as the measurement period that ends at the end of the month prior to initiation of the intervention, and at "6 months" (and at 12 and 18 months in secondary analyses) for each clinic, defined

as the measurement period that ends and fully includes the 6th full month (or 12th/18th month) after initiation of the intervention. So, for example, if the intervention launches on June 15, 2019, the baseline measurement period would be June 1, 2018 – May 31, 2019, and the 6-month measurement period used for the difference in differences calculation of the primary outcome would be Jan 1, 2019-Dec 31, 2019 (note that this is 7 months offset from the baseline measurement period).

For the Usual Care clinics, all measurements will be obtained on a quarterly basis through the BP Track surveillance project (a companion study), with measurement periods set to end at the end of each calendar quarter (Mar 31, June 30, Sept 30, Dec 31). The primary outcome will compare the metrics obtained at baseline, defined as the measurement period ending June 30, 2019 for all Usual Care sites, and at 6 months, defined as the measurement period ending Dec 31, 2019, for all Usual Care sites. These fixed dates were set under the assumption that the BP MAP intervention clinics will all launch their interventions within the window of May 15, 2019-August 31, 2019, and that this is therefore the most appropriate single 6-month comparison period, acknowledging that it will not correspond precisely to the same calendar time period as all of the intervention clinics (which will launch at different times), and that the measurement periods will be offset by 6 months vs. 7 months for the intervention clinics due to practical constraints.

For added clarity, these measurement periods are illustrated in the Figure below, with an arrow indicating an example launch date of June 15, 2019 for an Intervention Clinic.



Below we list the outcome measures of interest. Additional technical details for how the queries were constructed for each measure are provided in the supplemental materials.

1) Change in % BP Control at 6 months (primary outcome). Our primary outcome will be clinic-level change in the proportion of patients with controlled BP from baseline to 6 months after the start of the intervention. We define BP control according to NQF 0018 as the percent of eligible patients (defined above) with SBP <140 mmHg and DBP < 90 mmHg, based on measurements obtained at the most recent ambulatory clinical encounter at baseline (using the lowest measures of SBP and DBP at that encounter) and similarly at the 6-month time point after initiation of the intervention.

Secondary outcomes will include nine additional EHR-derived clinic-level metrics relevant to BP control. These metrics include alternate measures and BP control and improvement, as well as process and proxy measures aligned to the domains of the M.A.P. program including: indicators of BP measurement accuracy, medication intensification, average SBP reduction after medication intensification, and repeat visit within 4 weeks after a visit with uncontrolled HTN. Each metric below (and the primary outcome) will be measured as a change from baseline to 6 months (our primary time point), and change from baseline to 12 and 18 months. We will assess each metric overall (in all eligible patients) and within subgroups defined in Table 3.

2) BP Control to 2017 Guideline Goal, %. This alternative overall measure of BP control is identical to Metric 1, except that attainment of BP Control is defined by lower thresholds for blood pressure (SBP < 130 mmHg and DBP < 80 mmHg), as per the goal stated in the 2017 ACC/AHA Hypertension Guideline[4].
3) Improvement in blood Pressure, %. This overall measure of BP improvement defines BP improvement as either a reduction of 10 mmHg in SBP or achievement of SBP that is "adequately controlled" (SBP < 140 mmHg) over a period of 3 months, among hypertensive patients not previously controlled.[23]
4) Confirmatory repeated blood pressure measurement, %. This process measure is designed to capture the practice of repeating a blood pressure measurement in the same visit when the first measurement done in clinic is high (SBP>140 mmHg or DBP>90 mmHg).
5) Medication intensification, %. This process measure captures the proportion of visits where BP is uncontrolled where a medication is ordered that is of a different class of medications than had previously been used. Note that this explicitly does not give credit for ordering a simple refill or medication dose increase, or use of a different medication in the same class.
6) Repeat visit in 4 weeks after uncontrolled HTN, %. This process measure captures the proportion of persons who had uncontrolled HTN who made a subsequent outpatient visit within the following 4 weeks.
7) Average SBP reduction after medication intensification, mmHg defined as the change in SBP observed between a visit with a medication intensification to the subsequent visit.
8) Terminal digit = zero, %. Inappropriate rounding of blood pressure measurements (usually to zero) leads to measurement error and worse treatment decisions. This metric is designed to catch this

behavior, which would lead to a terminal digit of zero of greater than 10% (if using an automated BP monitor is used) or greater than 20% (if a manual BP monitor is used with recommended rounding to even digits).

9) Use of fixed dose combination medications among patients taking 2 or more classes of medications, %. Use of fixed dose combination medications helps with adherence, promotes rational combinations of medications, and increases likelihood of achieving BP control.
10) Use of a CCB or thiazide-type diuretic among African-American patients on one medication %. Calcium channel blockers (CCB) and thiazide-type diuretics are medication classes recommended to treat black or African American patients as first line monotherapy due to increased efficacy.

Analysis Plan

Overview: We will use an unadjusted difference-in-differences analytic approach to testing comparative effectiveness hypotheses, weighting for differences in cluster size. Despite expected between-clinic differences in baseline characteristics and BP control (especially in the non-randomized comparison with Usual Care control organizations), the difference-in-differences approach provides some protection against confounding because the outcome being compared is a within-clinic change score, as described below. We will first conduct 3 pairwise primary hypothesis tests (adjusting for multiple comparisons), as described below. We will then conduct a series of exploratory analyses of secondary outcomes, sensitivity analyses adjusting for baseline clinic-level characteristics, subgroup analyses to examine heterogeneity of effect, and exploratory mediation analyses to understand the mechanisms by which the full-support intervention might provide greater effectiveness.

Differences-in-differences analytic approach: We will calculate difference-in-differences through the following steps:

1. Use clinic-level metrics (e.g., % BP control) at baseline for each clinic before the intervention starts (t_0) and then including the 6th full month of the intervention ("t_6", noting that the period will actually be 7 months offset for the Intervention Clinics and 6 months for the Usual Care Clinics; see Outcomes and Measurements, above)
2. Calculate the clinic-level pre-post difference in the metric ($t_6 - t_0$)
3. Calculate the mean pre-post difference in each treatment group, the between-group difference of differences, both with 95% confidence intervals, and compare the 20-28 pre-post differences by arm using weighted linear regression; observations will be weighted by the inverse of the site-specific variances of the change scores, which will be approximated using the site-specific sample size and level of the time-specific metrics, and the average correlation of the pre- and post-metrics across clinics. Weights will be normalized to sum to the total number of clinics in the Arm 1 vs. Arm 2 comparisons (and to the number of included clinics plus the number of participating PCORnet datamarts for the comparisons of each Arm with Usual Care).

Primary hypothesis tests, with adjustment for multiple comparisons

Our primary hypothesis tests will be 3 pairwise comparisons:

- Test 1: Arm 1 vs Arm 2
- Test 2: Arm 1 vs. Usual Care
- Test 3: Arm 2 vs. Usual Care

In order to maintain an overall type 1 error rate of 5%, we will set our critical p-value threshold for Test 1 at p=0.04, and then at p=0.005 for Test 2 and Test 3 since they will benefit from the very large sample size expected in the Usual Care groups. No other adjustments for multiple comparisons are planned for secondary outcomes or other exploratory analyses described below.

Descriptive analyses comparing clinic-level baseline characteristics: *Descriptive statistics* will be used to compare clinic-level characteristics between the two intervention arms at baseline. We will include descriptions of clinic-level patient population characteristics (age groups, gender, race/ethnicity, type of insurance, mean number of current antihypertensive medication classes prescribed, and prevalence of comorbid conditions such as diabetes, chronic kidney disease, or heart failure), workforce composition (i.e. proportion of nurse practitioners, physician assistants, physicians, and physician specialty - internal vs family medicine), clinic size and staffing level (total number of patients, nurses, and medical assistants), level of access (availability of same-day appointments, mean time to third next available appointment), and possibly other characteristics depending on availability.

Sensitivity analyses: In a sensitivity analysis, we will perform multivariable linear regression analyses to compare clinic-level pre-post differences in our primary and secondary outcomes. The regression models will adjust for health system as well as for whether the clinic was engaged in BP HOME, a concurrently running individual-level randomized trial that will provide home blood pressure monitoring devices to participating patients with a high blood pressure reading in clinic. We will also consider linear mixed models (LMMs) for repeated changes in the summary outcome measures, adjusting for age, sex and race-ethnicity. In particular, for each clinic we will calculate monthly values of the metric ($t_i - t_0$), for follow-up month i = 1, …, 6, within strata jointly defined by age, sex, and race-ethnicity, as well as corresponding within-stratum weights as described above, then estimate the effect of treatment adjusted for stratum, using an LMM that includes treatment assignment, month as categorical, the interaction of these two factors, and stratum. With a view towards model simplification, likelihood ratio testing will be used to determine whether age, sex, and race/ethnicity as additive factors adequately capture the stratification effects. We will: (1) present month-specific treatment effects with 95% confidence intervals (CIs); (2) test for heterogeneity in the monthly treatment effects across months; (3) summarize the treatment effect by the average of the month-specific effects also with a 95% CI, if the test for heterogeneity is not statistically significant (P>0.05); and (4) otherwise, use orthogonal contrasts to check for linear and quadratic trends in the monthly effects.

Subgroup analysis to test for heterogeneity of treatment effects (HTE): We will produce clinic-level subgroup-specific analyses limited to subgroups defined by the characteristics listed in Table 3 (with imputation as described above), and test for interactions by intervention group (as well as with Usual Care) and subgroup categories. We hypothesize that the BP Control effect from the Full-Support intervention relative to Self-Guided and Usual Care groups will be smaller in patients who are younger, male, and Black given published BP control difficulties in these patients. We will also specifically test for an interaction between treatment group and enrolling CDRN, given health IT infrastructures may differ by CDRN in ways that can interact with the effectiveness of the interventions. All subgroup analyses will be reported.

Table 3. Subgroups for HTE analysis
Age: 18-44 vs. 45-64 vs. 65+

Race/ethnicity: NH White vs. NH Black vs. NH Asian vs. Hispanic (any race) vs. Other
Sex: Male vs. Female
Enrolling CDRN
HTE – Heterogeneity of treatment effects NH – Non-Hispanic

Exploratory Mediation analysis: As many of our secondary outcomes are presumably process measures in the causal pathway to achieving BP control, we will perform a mediation analysis to understand the degree to which the potential added benefit of the Full Support intervention on BP control is explained by changes in the process measures. We will perform a mediation analysis using nested linear regression models for the effect of randomization assignment (i.e. Full Support vs. Self-Guided) on clinic level pre-post differences in percent control, first omitting, then adding each of our proposed mediators to the base model. The hypothesized process mediators will include pre-post changes in BP measurement accuracy, medication intensification, and average SBP reduction after medication intensification, and repeat visit in 4 weeks after uncontrolled HTN. These analyses will be implemented using the Paramed module in Stata statistical software [24] to calculate natural direct effect (NDE) of full-support on BP control and the natural indirect effect (NIE) through each mediator. The total causal effect (TCE) is the sum of the NDE and NIE. Dividing each NIE by the TCE will calculate the proportion of the causal effect explained by each mediator.[25]

Additional exploratory analyses**:** We will explore temporal patterns in the effect of randomization assignment using linear mixed models for repeated clinic-level changes since baseline in primary and secondary outcomes assessed at 6, 12, and 18 months. These models will include random effects for clinic, as well as fixed effects for treatment assignment (as a categorical variable), and their interaction. Heterogeneity of treatment effects across time will be tested using a 2 degree-of-freedom chi-square test; in addition, a chi-square test for linear trend will be obtained by comparing the fitted treatment assignment effects at 6 and 18 months.

Data source, collection, management, and safety: Consistent with principles of pragmatic clinical trials, we will use EHR data for patient identification and assessment of intervention implementation and outcomes. Both interventions (and usual care) are consistent with standard of care. Therefore, both the interventions and data collection in this study carry minimal risk to patients. We will leverage the data infrastructure and resources in the PCORnet Common Data Model to collect de-identified, clinic-level aggregate data needed for analysis. Additional details on the PCORnet Common Data Model procedures for data collection and linkage, and data management and safety are described elsewhere.

Sample size and power: Preliminary data from "Wave 2" implementation of the M.A.P. Program by AMA in 16 clinics shows average pre-post improvements (without a control group) in BP control of 6.8% (65.6%-->72.4% overall) +/- 4.4% (standard deviation of change in control rate). Assuming negligible change in the Self-Guided arm, standard sample size calculations show that we will have 83% power to detect a difference in differences of 6% in the BP control rate (or 92% power for 7% difference) between Self-Guided and Full-Support arms with 10 clinics randomized to each arm of the study; these results were confirmed using simulations. Power will be higher for comparisons of the Self-Guided and Full-Support groups with the large Usual Care comparison group in PCORnet under similar effect-size

assumptions. For the HTE analysis comparing the difference in differences between the 10 clinics in CDRN 1 (5:5 in each arm) and the 10 clinics in CDRN 2 (5:5 in each arm), we expect to have 80% power to detect an interaction effect (i.e., the difference in the difference in differences) of 12% in the BP control rate. Corresponding minimum detectable interaction effects would be 15%, 13%, and 12% for demographic subgroups comprising 20%, 30%, and 40% of the overall population.

Limited program evaluation

Objective: To gain insight into sustainability of the MAP BP program, we will perform a limited program evaluation to examine stakeholder satisfaction with and usability of the online digital guide, and assess barriers and facilitators to implementation and willingness to continue implementation of MAP BP beyond the study period.

Study procedures: The limited program evaluation will capture data through two mechanisms: an online survey and a web-based exit interview. Stakeholders will be asked to complete a 10-minute online survey prior to their scheduled exit interview session. For stakeholders who were unable to complete the online survey ahead of time, they will be asked to complete it at the beginning of the virtual interview. Following survey completion, investigators from the University of California San Francisco and the American Heart Association, along with study staff, will conduct 60-minute virtual, web-based exit interview sessions with investigators at each participating site. Each virtual session will include 1:1 semi-structured interviews with individual local stakeholders (i.e. practice change facilitators, site champions, and physician leads) in both study arms. Interviews will be audio-recorded via the web-based platform and transcribed.

Interview guide: We will use the COM-B framework and the Technology Acceptance Model (TAM) to inform an interview guide examining the feasibility of continued implementation of both versions of the MAP BP program (self-guided and full-support), barriers and facilitators to implementation, and the usability of the online digital guide component from the perspective of local stakeholders. The capability, opportunity, motivation and behavior (COM-B) model specifies Capability (physical and psychological), Opportunity (social and physical), and Motivation (reflective and automatic) as the drivers of behavior. It has been widely used as a theoretical framework for development and evaluation of health services interventions. TAM is a widely used information systems theory that models how users come to accept and use a technology. Using COM-B, the interview guide will explore perceived barriers and facilitators that could influence stakeholders' willingness to continue implementation beyond the study period. (See *Attachment A* below for the proposed interview guide; note this is subject to modifications at the discretion of the research team as it is put into use).

Satisfaction and usability: Through the semi-structured interview, we will determine the Net Promoter Score (NPS) as a quantitative measure of user satisfaction and willingness to use. The NPS is based on a single question: *How likely is it that you would recommend our service to a friend or colleague?* This score is increasingly used in health services research as a summary of consumer satisfaction[26].

Since implementation of the program includes use of an online digital guide, we will use the TAM framework to examine the usability of the digital guide and report the TAM score (overall and for each theoretical variable) as a quantitative measure of usability. The theoretical variables comprising the TAM

score include Perceived Usefulness (PU), Perceived Ease of Use (PEU), perceived facilitators, and intention to use.

Survey analysis: We will use summary statistics to describe the Net Promoter Score and TAM score (overall and for each variable) by study arm (full-support vs self-guided) and by type of stakeholder (site champion vs practice change facilitators vs physician lead).

Qualitative analysis: Qualitative analysis of interview transcripts will examine barriers and facilitators to implementation of MAP BP from the perspective of local stakeholders. Transcripts will be coded using an integrated inductive-deductive qualitative data analysis approach.[35] In particular, we will use the constant comparison method, an inductive qualitative data analysis approach in which data are broken down, compared for similarities and differences, and grouped together under similar conceptual themes to uncover a wide variety of themes from the data, while also employing predetermined conceptual codes drawn from COM-B and TAM. One study author, blinded to randomization assignments, will independently code the transcripts (TBD) to identify preliminary themes through initial readings of the transcripts. Iterative discussions among all the study investigators will refine thematic categories and lead to a final set of salient themes identified across all the interviewees.

Table 1. Using the capability, opportunity, motivation and behavior (COM-B) framework to assess barriers and facilitators to implementation of bother versions of the MAP BP program (self-guided and full-support)

COM-B domains	Definitions	Proposed interview/survey question areas
1. Capability - Psychological (Knowledge, memory, cognitive and interpersonal skills, decision-making skills, behavioral regulation, etc.) - Physical	Stakeholders' perceived ability to use the MAP BP program and its tools to successfully affect practice change in their clinic to improve BP control Capacity of clinic(s) personnel (medical assistants, nurse, primary care providers) to implement best practices recommended in MAP BP – e.g., use of treatment algorithm, BP measurement protocol.	1. Do you believe the MAPBP training and tools have enabled you and your team to favorably affect practice for HTN management at your clinic(s)? Why/why not? Barriers/Facilitators? 2. How much do you agree that the MAP BP program improved the capacity of your clinical staff to better measure, treat, and manage hypertension? Please explain.
2. Opportunity a. Physical: environmental context and resources b. Social: social influences	Factors (organizational, technology, or cultural infrastructure) at the clinic or health system that makes adoption/implementation of MAP BP easy or difficult Capacity of the clinic(s) to implement best practices recommended in MAP BP – e.g. frequent patient encounters, use of treatment algorithm, BP measurement protocol.	1. What were your most significant challenges in implementing MAP BP in your clinical environment? 2. How supportive were your clinic(s) leaders, doctors, nurses, and staff of the program? (E.g. BP measurement protocol, treatment intensification algorithm, etc.) 3. Describe aspects of your clinical environment (personnel, resources, and technology) that made it easier or harder to implement MAP BP?
3. Motivation a. Automatic: Emotion b. Reflective: Intentions, beliefs about capabilities, beliefs about consequences	Stakeholders' reported level of value placed on management of hypertension Stakeholders' reported likelihood they will continue to use MAP BP tools and continue to lead practice change for hypertension management	1. Considering all the priorities that comes with your role, how important is improving your clinic(s)' BP control? 2. How much do you agree that your clinic now sees patients with uncontrolled BP more frequently and providers treat uncontrolled BP more aggressively? Please explain. 3. Will you continue to use MAP BP tools and training going forward? Why/why not? How?
4. Behavior	Stakeholder choices in implementing the MAP program, changes made in the clinical environment, and steps taken to ensure fidelity to various components of the intervention.	1. Did your clinic(s) choose a hypertension treatment algorithm? Which one? 2. Did your clinic(s) train providers on the algorithm? If so, how? 3. How did your clinic(s) choose to disseminate the algorithm? (e.g. posters, pocket cards, pdf attachment in EHR, electronic decision support tool)

Table 2. Usability measures informed by the Technology Acceptance Model (TAM) and corresponding COM-B domains to assess usability of the online digital guide for the MAP program.

TAM usability Measures	Definitions	COM-B
1. Perceived usefulness and satisfaction	Level of agreement that they were satisfied with the digital guide and that it added value to their work or was helpful in enhancing their ability to implement the three components of the MAP program	Reflective motivation
2. Ease of use	Level of agreement that the digital guide is easy to use and is useful, for facilitating practice change in hypertension management.	Psychological capability
3. Adoption and intention to use	Level of agreement they will continue to use and/or would recommend colleagues to use it to implement systems changes for hypertension management	Behavior and Motivation

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Attachment A: Proposed Interview Guides

Participant Name: _____ Study Site:_____

Interview Date:_____ Interview Time: _____

BP: MAP Site Champion Interview Guide
Full Facilitation Arm

Hello [*INSERT NAME*], thank you for taking the time to talk with me today. My name is [*provide name and title*] and I am a program evaluator from the Centers for Health Metrics and Evaluation at the American Heart Association. Our team is supporting the evaluation efforts for the BP MAP program. I am interested in talking with you today to get your thoughts and perspective about how well the BP MAP program was implemented and ways you think the team can improve the program.

To capture the information you share with me, I will use an interview format. During this interview, I will ask you several open-ended questions that are designed to encourage you to freely share your thoughts. There are no right or wrong answers. Please feel welcome to express yourself freely and openly during the discussion.

Some practical issues: Our discussion today will last for about one hour. I will be audio recording our conversation today to help with our note taking process. All information collected on the recording will be kept confidential and anything you say today will not be shared in any way that will identify you. So, you can feel free to share with me any information you feel will be helpful for the staff to hear so they can make any needed improvements to the program.

We are performing several interviews with staff from other participating sites. Once the interviews are completed, a final report will be prepared for BP MAP study team. Lastly, right after this call I will be sending you an Amazon gift card in the amount of $_____ in appreciation for sharing your experiences with us today.

Before we begin, do you have any questions?

a. What clinics did you support for the BP MAP Study?

B. Barriers and Facilitators to Implementing BP MAP

1. Let's start by talking about your **EXPERIENCES** using the BP MAP **DIGITAL GUIDE**.

    a. What aspects of the **DIGITAL GUIDE** were **HELPFUL** to you and your clinical teams when implementing BP MAP? **(Probe**: How were they helpful? Can you explain?)

i. *[After each response]:* What else about the **DIGITAL GUIDE** did you find helpful?

b. In what ways do you think the BP MAP **DIGITAL GUIDE** could be **IMPROVED** to help you and your clinical teams implement BP MAP? **(Probe**: Is there something about the **DIGITAL GUIDE** that could be added or made better to help you and your clinical teams implement BP MAP best practices?)
   i. *[After each response]:* What else about the **DIGITAL GUIDE** do you think could be improved?

2. Next let's talk about the **AMA Facilitator** that worked with you and your team to support implementation of BP MAP.

   a. What things did the **AMA Facilitator** do that you found **HELPFUL** when implementing BP MAP? **(Probe**: In what ways did the AMA make it **EASIER** for you to implement BP MAP?)
      i. *[After each response]:* Is there anything else that the **AMA FACILITATOR** did that you found **HELPFUL** or **USEFUL** when implementing BP MAP?

   b. What could the **AMA** do **MORE OF** or **DO DIFFERENTLY** to help you implement BP MAP? **(Probe**: Is there something you think could be added to the role of the **AMA** to help you implement the BP MAP program?)
      i. *[After each response]:* Is there anything else that the **AMA FACILITATOR** could do **MORE OF** or **DO DIFFERENTLY** to help you implement BP MAP?

   c. Was there anything that the **AMA FACILITATOR** did during your interactions that was **NOT HELPFUL**? **(Probe**: Is there anything that the **AMA FACILITATOR** did that you think should be avoided?)

C. Changes Made in the Clinical Environment

1. Let's change topics. Now I would like to talk to you about the changes made in the processes and procedures at your clinic as a result of implementing BP MAP.

   a. Tell me about any changes that were made at your clinic(s) related to how staff **MEASURE BLOOD PRESSURE**. **(Probe**: Did your clinics change anything about the type of equipment used or the process used to prepare or position the patient when measuring their blood pressure? Any other changes such as adding a chair for patients to sit on, or moving the BP wall device to eye level?)
      i. *[After each response]:* Describe for me how do you think [insert response] has led to improved blood pressure control in the patients at your clinic(s)?
      ii. *[After each response]:* What other changes were made at your clinic(s) regarding how your team measures blood pressure?

b. What changes were made at your clinic(s) regarding the way clinicians **CHANGE THE DOSE OR TYPE OF MEDICATION** prescribed for patients with hypertension to help improve their blood pressure control. **(Probe**: Did your clinics implement any best practices change anything about how they decide when to intensity or change medications for patients with high blood pressure?)
    i. *[After each response]:* Describe for me how do you think [insert response] has led to improved blood pressure control in the patients at your clinic?
    ii. *[After each response]:* Do you know of anything else done differently when deciding when to change medications for patients with hypertension?

c. Talk to me about any **CHANGES** that were made at your clinics in the way you use **DATA** to better understand and improve blood pressure control rates in your patients. **(Probe**: Did your clinics implement any BP MAP components focused on using data in new ways?)
    i. *[After each response]:* Describe for me how do you think [insert response] has led to improved blood pressure control in the patients at your clinic?
    ii. *[After each response]:* Is there anything else that you now do differently with data to help staff in your clinic improve hypertension control rates?

d. Describe for me any changes that were made at your clinics regarding the way your clinics **WORK WITH PATIENTS** to help support managing their high blood pressure. **(Probe**: Did your clinics implement any BP MAP resources related to partnering with patients to help them better manage their high blood pressure?)
    i. *[After each response]:* Describe for me how do you think [insert response] has led to improved blood pressure control in the patients at your clinic?
    ii. *[After each response]:* Can you think of any other BP MAP best practices that were done differently at your clinics regarding working directly with patients to help them control their blood pressure?

D. Overall Barriers/Facilitators to Program Implementation

Next, I am interested in hearing about ways you think your clinical environments made it easier or more difficult to implement BP MAP best practices.

a. Let's start with EASY. Tell me about something in your clinical environments that made it **EASIER TO IMPLEMENT** BP MAP. **(Probe**: Was there someone or something that helped you implement BP MAP at some clinics?)
    iii. *[After each response]:* Was there anything or anyone else that made it easier to implement BP MAP?

b. Now let's switch to things that made it more **DIFFICULT**. Tell me about something in your clinical environments that made it **MORE DIFFICULT TO IMPLEMENT** BP

MAP. **(Probe**: Was there someone or something that made it **HARDER** or **MORE CHALLENGING** for you as you tried to implement BP MAP?)

i. *[After each response]:* Was there anything else that made it more difficult to implement BP MAP?

c. Were there any other **CHALLENGES** you experienced **IMPLEMENTING THE BP MAP PROGRAM** that we have not yet discussed in the previous questions? (**Probe**: Was there anything else that you found difficult or challenging about the BP Map Program that we have not yet talked about?)

i. *[After each response]:* Was there anything else about BP MAP that you found challenging? (Probe: How do you think it could be improved?)

E. Overall Thoughts and Moving Forward

We are almost finished, I just have one last question for you. As we finish up, I'd like for you to think back on all that your clinic changed as a result of implementing BP MAP. Think about the practices and procedures

a. What do you feel were the **MOST SIGNIFICANT CHANGES** that occurred in your clinics that resulted from implementing BP MAP? (**Probe**: What were the most impactful changes in the clinical workflows or practices that enhanced the way clinics manage hypertension?)

We sincerely appreciate your time today. Your input has been so valuable for the BP Map Program.

Are you interested in receiving the Amazon Gift Card for your time today? _____Yes _____No

Please provide me with the email you would like it to be sent to:

INTERNAL USE ONLY:

Date Gift Card Was Sent: _____

Order Number: _____

Person Sending Gift Card: _____

Participant Name: _____ Study Site:_____

Interview Date:_____ Interview Time: _____

BP: MAP Site Champion Interview Guide
Self-Guided Arm

Hello [*INSERT NAME*], thank you for taking the time to talk with me today. My name is [*provide name and title*] and I am a program evaluator from the Centers for Health Metrics and Evaluation at the American Heart Association. Our team is supporting the evaluation efforts for the BP MAP program. I am interested in talking with you today to get your thoughts and perspective about how well the BP MAP program was implemented and ways you think the team can improve the program.

To capture the information you share with me, I will use an interview format. During this interview, I will ask you several open-ended questions that are designed to encourage you to freely share your thoughts. There are no right or wrong answers. Please feel welcome to express yourself freely and openly during the discussion.

Some practical issues: Our discussion today will last for about one hour. I will be audio recording our conversation today to help with our note taking process. All information collected on the recording will be kept confidential and anything you say today will not be shared in any way that will identify you. So, you can feel free to share with me any information you feel will be helpful for the staff to hear so they can make any needed improvements to the program.

We are performing several interviews with staff from other participating sites. Once the interviews are completed, a final report will be prepared for BP MAP study team. Lastly, right after this call I will be sending you an Amazon gift card in the amount of $_____ in appreciation for sharing your experiences with us today.

Before we begin, do you have any questions?

F. Barriers and Facilitators to Implementing BP MAP

3. Let's start by talking about your **EXPERIENCES** using the BP MAP **DIGITAL GUIDE**.

    a. What parts of the **DIGITAL GUIDE** were **HELPFUL** to you and your clinical teams when implementing BP MAP? **(Probe**: How was that helpful? Can you explain?)
        i. *[After each response]:* What else about the **DIGITAL GUIDE** did you find helpful with implementing BP MAP?

    b. In what ways do you think the **DIGITAL GUIDE** could be **IMPROVED** to help you and your clinical teams implement BP MAP? **(Probe**: Is there something about

the **DIGITAL GUIDE** that could be added or enhanced to help you and your clinical teams implement BP MAP?)

i. *[After each response]:* What else about the **DIGITAL GUIDE** do you think could be improved?

4. Next let's talk about the **KICK-OFF WEBINAR** that was held after your site was randomized to the self-guided arm. I am specifically referring to the webinar aimed at guiding teams through how to use and navigate the **DIGITAL GUIDE**.

   a. What about the **KICK-OFF WEBINAR** did you find most **HELPFUL** to helping you use and navigate the **DIGITAL GUIDE**? (**Probe**: In what ways did the **KICK-OFF WEBINAR** make it easier to use the **DIGITAL GUIDE** to implement BP MAP?)

   b. What aspects of the **KICK-OFF WEBINAR** could have been done **DIFFERENTLY** to help you and your clinical teams use the **DIGITAL GUIDE**? **(Probe**: Was there information or instruction about the DIGITAL GUIDE that you needed but was not provided in the WEBINAR?)

G. Changes Made in the Clinical Environment

2. Let's change topics again. Now I would like to talk to you about the changes made in the processes and procedures at your clinic as a result of implementing BP MAP.

   a. Tell me about any changes that were made at your clinic related to how staff **MEASURE BLOOD PRESSURE**. **(Probe**: Did your team change anything about the type of equipment used or the process used to prepare or position the patient when measuring their blood pressure?)

      i. *[After each response]:* Describe for me how do you think [insert response] has led to improved blood pressure control in the patients at your clinic?

      ii. *[After each response]:* What other changes were made at your clinic regarding how your team measures blood pressure?

   b. What changes were made at your clinic regarding the way clinicians **CHANGE THE DOSE OR TYPE OF MEDICATION** prescribed for patients with hypertension to help improve their blood pressure control. **(Probe**: Did your team implement any best practices change anything about how they decide when to intensity or change medications for patients with high blood pressure?)

      iii. *[After each response]:* Describe for me how do you think [insert response] has led to improved blood pressure control in the patients at your clinic?

      iv. *[After each response]:* Do you know of anything else done differently when deciding when to change medications for patients with hypertension?

   c. Talk to me about any **CHANGES** that were made at your clinic in the way you use **DATA** to better understand and improve blood pressure control rates in your

patients. **(Probe**: Did your team implement any BP MAP components focused on using data in new ways?)

v. *[After each response]:* Describe for me how do you think [insert response] has led to improved blood pressure control in the patients at your clinic?
vi. *[After each response]:* Is there anything else that you now do differently with data to help staff in your clinic improve hypertension control rates?

d. Describe for me any changes that were made at your clinic regarding the way your teams **WORK DIRECTLY WITH PATIENTS** to help support them manage their high blood pressure. **(Probe**: Did your team implement any BP MAP resources related to partnering with patients to help them better manage their high blood pressure?)

vii. *[After each response]:* Describe for me how do you think [insert response] has led to improved blood pressure control in the patients at your clinic?
viii. *[After each response]:* Can you think of any other BP MAP best practices that were done differently at your clinic regarding working directly with patients to help them control their blood pressure?

H. Overall Barriers/Facilitators to Program Implementation

Next, I am interested in hearing about ways you think your specific clinical environment made it easier or more difficult to implement BP MAP best practices.

d. Let's start with what made things EASIER. Tell me about something in your clinical environment that made it **EASIER TO IMPLEMENT** BP MAP. **(Probe**: Was there someone or something that helped you implement BP MAP?)

ix. *[After each response]:* Was there anything or anyone else that made it easier to implement BP MAP?

e. Now let's switch to things that made it more **DIFFICULT**. Tell me about something in your clinical environment that made it **MORE DIFFICULT TO IMPLEMENT** BP MAP. **(Probe**: Was there someone or something that made it **HARDER** or **MORE CHALLENGING** for you and your team as you tried to implement BP MAP?)

ii. *[After each response]:* Was there anything else that made it more difficult to implement BP MAP?

f. Where there any other **CHALLENGES** you experienced **IMPLEMENTING BP MAP** that we have not yet discussed in the previous questions? (**Probe**: Was there anything else that you found difficult or challenging about implementing BP MAP?)

i. *[After each response]:* How do you think it could be improved? (Probe: Can you think of a way BP MAP could be changed to make the program more helpful at helping your teams better measure blood pressure or manage patients with hypertension?)

I. Overall Thoughts and Moving Forward

We are almost finished, I just have one last question for you. As we finish up, I'd like for you to think back on all that your clinic changed as a result of implementing BP MAP. Think about the practices and procedures

a. What do you feel were the **MOST SIGNIFICANT CHANGES** that occurred in your clinic practices that resulted from implementing BP MAP that influenced your team's ability to improve hypertension management? (**Probe**: What were the most impactful changes in your clinical workflow or practices that enhanced the way your team manages hypertension?)

We are almost finished. We have talked about your experiences with many aspects of the BP MAP program.

We sincerely appreciate your time today. Your input has been so valuable for the BP Map Program.

Are you interested in receiving an Amazon Gift Card for your time today? _____Yes _____No

Please provide me with the email you would like it to be sent to:

INTERNAL USE ONLY:

Date Gift Card Was Sent: _____

Order Number: _____

Person Sending Gift Card: _____